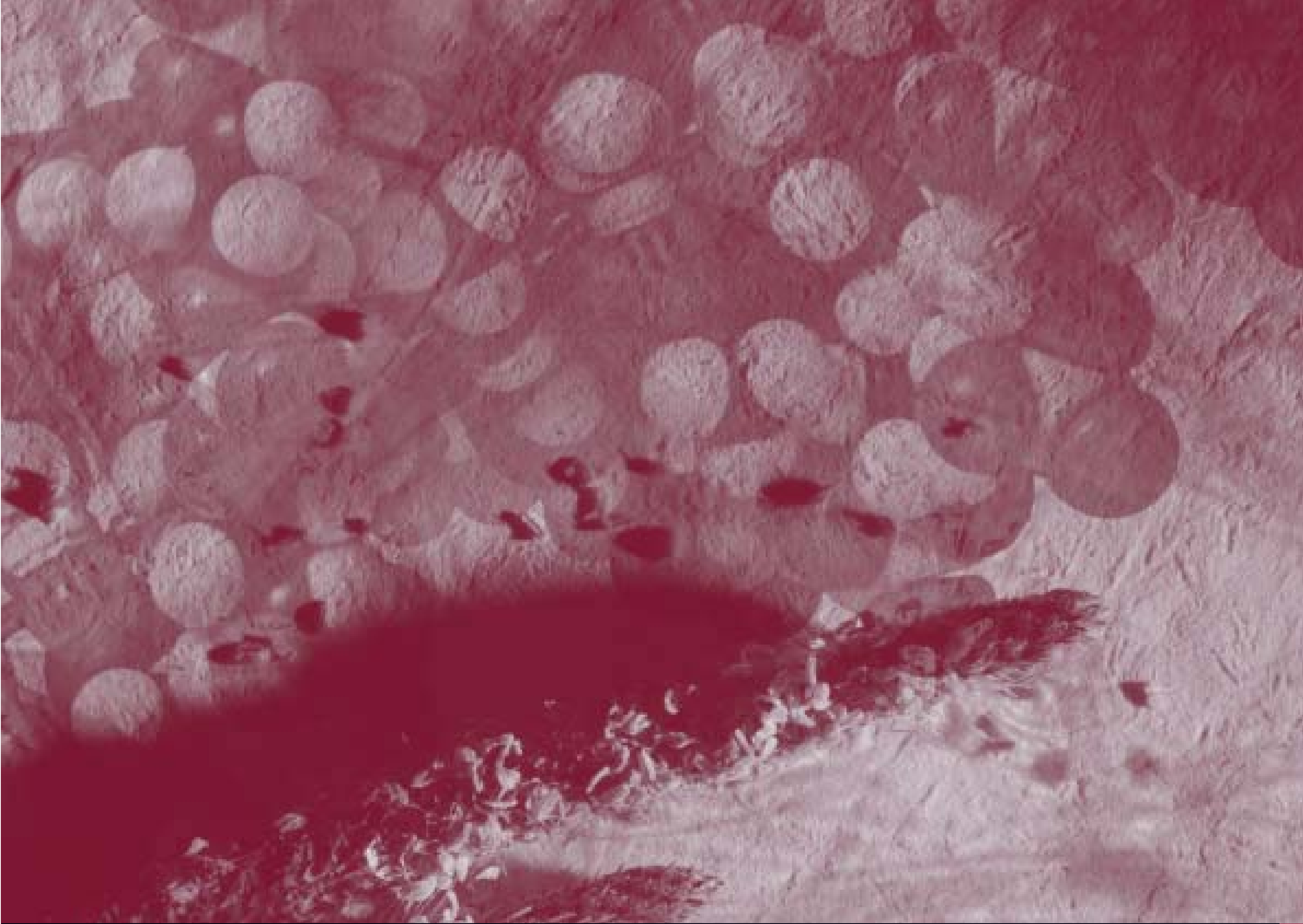


The Supply and Demand for Skills in the Biotechnology Sector

A study for the

Expert Group on
Future Skills Needs

To the Tánaiste, and Minister for Enterprise, Trade and Employment and the Minister for Education and Science

Forfás

The Supply and Demand for Skills in the Biotechnology Sector

A study for the

Expert Group on Future Skills Needs

by Peter Bacon & Associates

Economic Consultants

To the Tánaiste, and Minister for Enterprise, Trade and Employment and the Minister for Education and Science

September, 2003

Acknowledgements

A wide range of consultations were undertaken in the preparation of this report. These consultations formed the basis of the material in Chapter 3 of the report and provided key inputs to Chapters 4 and 6. A full list of consultations is included in Appendix 1. Key data were also provided by the Higher Education Authority (HEA) and the Department of Education and Science (DES). The contributions of Ms. Barbara Carr and Mr. Brian Dennehy of the HEA and Ms. Christine Dean of the DES are appreciated. The authors of the report also wish to acknowledge the input of the Steering Group and the contributions of participants in a workshop hosted by Forfás.

Foreword by Dr Daniel O'Hare, Chairman, Expert Group on Future Skills Needs

This report is submitted by the *Expert Group on Future Skills Needs* to Mary Harney, TD, Tánaiste, and Minister for Enterprise, Trade and Employment and to Noel Dempsey, TD, Minister for Education and Science. It was prepared as part of the ongoing work of the Expert Group in looking at the future skills needs of key sectors in the Irish economy.

Biotechnology is an emerging technology which has the potential to revolutionise many facets of our lives, from our food to medical therapies. Allied with these advances, will be great opportunities for economic growth in those countries that are proactive in promoting the associated industrial sector. Due to its high added-value and its reliance on intellectual capital, biotechnology is widely expected to become a keystone of the knowledge economy. The European Commission has estimated that the market for biotechnology products in Europe alone could be worth €100 billion by 2005 and that by 2010 the value of the global market for the broad life sciences sector, including biotechnology, could amount to €2,000 billion. Ireland already has achieved critical mass in two closely related industrial sectors, namely pharmachem and medical devices. Therefore, it is well positioned to lever this base, as well as its other advantages, notably its favourable corporate tax regime and the investment to date by Science Foundation Ireland in basic research in biotechnology, in order to stimulate the growth of this sector.

The principal objectives of the current study were to identify the potential growth of the biotechnology sector in Ireland, to quantify the levels of skills that would be required to realise this growth and to review the projected supply of these skills over the period 2004-2010. It is intended to inform the policies of stakeholders ranging from education providers, government departments and industrial development agencies.

The report outlines in detail the potential for Ireland in this fast emerging field. It contains an analysis of a number of successful biotechnology clusters from the US to Singapore and identifies the common factors underpinning their success. It identifies a number of challenges that must be addressed if Ireland is to achieve its full potential as a centre for biotechnology. The crux of the report is an analysis of the shortfall in science skills, at each level of education attainment, from sub-degree to PhD, in the light of current trends in the supply of these skills, and the ensuing requirement for increasing the output of these skills.

On behalf of the Expert Group on Future Skill Needs, I would like to thank the Steering Group who guided the work, Dr Catherine Kavanagh of Forfás, who chaired the Steering Group and without whose dedicated management of the project, this publication would not have been possible, and Dr Eamonn Cahill of Forfás for his efforts in finalising the report. Finally, I would urge the bodies that are the subject of recommendations in this report to act promptly on their implementation in order to ensure that Ireland reaps the maximum economic benefits from the dynamic and burgeoning field of biotechnology.

Dr Daniel O'Hare
Chairman

Expert Group on Future Skills Needs

Table of Contents

List of Tables

List of Figures

Executive Summary

Biotechnology and the Biotechnology Industry

Biotechnology is the application of biological knowledge relating to genes and cells in order to develop useful *products, processes* or *services* such as new medicines and therapies, cloning, genetically modified foods and enhanced crops. It encompasses an ever-growing range of laboratory techniques for the alteration and manipulation of molecules, genes and cells and often involves the harnessing or usurping of biological processes for a particular purpose such as the biological synthesis of pharmaceutical compounds. The biotechnology industry is based on the commercial exploitation of these techniques. The primary challenge for commercialisation is that of scaling up the extremely delicate laboratory procedures to an industrial scale.

This definition means that, unlike many other industries, it is defined not by the products it produces but by the technologies it employs. The structure of the industry reflects divisions in the underlying science and is reinforced by the nature of the business processes involved. The Pharma/Agricultural/Environmental division involves long initial developmental periods of, typically, 10–15 years to initial product release, while the trajectory to profitability of medical device companies resembles that of traditional engineering, with a relatively short period to product release and profitability.

Biotechnology is an 'enabling technology' and advances impact on numerous industries such as: Pharmaceutical and Healthcare, Medical Devices, Diagnostics, Agriculture, Food and Drink, Environment and Information Technology. The industry consists of firms which develop newly discovered knowledge and exploit it commercially. Many regions, which are establishing themselves as biotech clusters, frequently include supplier and service companies. This collection of industries is referred to variously as the biotech or life sciences sector.

Many jobs in the industry arise in areas such as R&D and within research centres. Development of the industry may have a major impact on employment in associated sectors, such as healthcare, where the new products of biotechnology may impact on the processes that take place. Also, there are significant employment possibilities in the production (bio-processing) of high value-added products resulting from underlying developments in the knowledge base. The opportunities may arise in areas such as healthcare, pharmaceuticals, chemicals and medical devices. Companies in these sectors can provide the core for an emerging biotechnology industry, in the sense of providing a labour pool with relevant experience.

Some firms in the biotechnology industry are beginning to redefine themselves as *bio-pharmaceuticals*. This development path is potentially important for Ireland, given the established critical mass of multinational pharmaceutical companies. As a result, bio-pharmaceuticals represent a significant opportunity for Ireland.

Ireland already has a number of strengths which could facilitate the exploitation of this opportunity, *viz.* our growing prominence in the global pharma/bio-pharma industry; the attendant reservoir of skills in pharma processing and engineering as well as specialisations such as quality control and regulatory affairs; the substantial investment to date in basic research in biotechnology by *Science Foundation Ireland;* and Ireland's highly competitive corporate tax regime.

A highly skilled workforce is essential for the development of biotechnology. However, in the absence of supporting policies and conditions this would not of itself be sufficient to stimulate the development of a high value-adding industry that fully utilises these skills. However, there are also important challenges that could undermine the ability or willingness of the private sector to provide the requisite investment. For example, risks and difficulties associated with protecting intellectual property (IP) have the capacity to undermine the commercialisation of new discoveries. Also, changing demographic trends entail fewer young people entering the job market or pursuing further education than previously. These circumstances pose a challenge and potential constraint on biotechnology development in Ireland.

Ireland's Competitiveness to Participate in Biotechnology Development

The evidence suggests that, although there are problems to be addressed, it is likely that the global biotechnology industry will grow rapidly into the medium-term. Ireland has put in place the foundations necessary for the development of a competitive biotech industry. A result is the decision by Wyeth to invest more than $1 billion to expand its production facilities in Ireland with the construction of a multi-product biopharmaceutical Campus at Grange Castle in Clondalkin. This new Campus will employ 1,300 people at full production, bringing the total Wyeth workforce in Ireland to 3,000 producing pharmaceuticals, infant formula products, and animal vaccines.

The analysis in this report indicates that Ireland is positioned to develop in biotechnology areas where bioprocessing and commercial applications are currently or soon to be available. However, in terms of manpower planning, a clearer view needs to be taken as to the breath of activity to be pursued. In particular, it needs to be determined if the objective is primarily to meet the needs of biotech production, or to additionally pursue the longer-term objective of creating a self sustaining biotechnology cluster. The commitment of resources needed for each development and the attendant risks are very different.

In developed clusters virtually all stages of a continuum – stretching from society's needs, the research to understand them, the development of products to satisfy them, clinical trials, production and marketing – are present. Where this is present, an internal dynamic is established.

Comprehensive Cluster or Niche Development

There are reasons for preferring the emergence of a dynamic cluster. However, it may be that comprehensive clusters will be the exception rather than the rule. At present about 200 separate regions worldwide are independently attempting to implement policy initiatives to develop this competency. This suggests that late-comers to the industry, unless they have identified some important competitive advantage, may be better advised to adopt a niche-based approach to development.

Industry models of growth suggest that the biotechnology industry broadly displays two distinct types of industry models:

- one specialising in knowledge-intensive clusters; and
- one developing its production base.

Each model requires different skill sets, with the former requiring intellectual assets, in particular, successful research scientists, key business leaders, and local talent whereas the latter by its nature requires a more diverse, but nonetheless still high-level, skill set. In knowledge-intensive clusters, well-recognised research institutes are important to attract the right mix of skills and organisations. Firms at the research end of the activity are highly dependent on top quality researchers. High skill levels remain important at development stages but the number of jobs at these stages is quite small in comparison with the level of investment that is required. A much different skill set is required at later stages and the regions that have been most successful in this regard have developed a range of education and training courses to supply these skills. For example, the University of California, San Diego, San Diego State University, the Scripps Research Institute and the Salk Institute are among several institutions that develop skills in bioscience at multiple levels. The output is designed to equip students with the skills to cater for the differing demands and needs of the industry in the region.

Analysis undertaken for this study shows the importance of a biotech community and a high standard of living in all the successful biotech areas. Networking organisations are also a very important feature of the localities and undertake a very broad range of activities including close collaboration with universities. These networks perform very important functions, the most important being to act in enhancing the perception of a community and providing assistance in commercialisation. Most biotech firms are deeply rooted in their areas and do not foresee future movement. However, this may change as production becomes a more important activity.

Policy initiatives have been very important in all successful areas. The core features of these initiatives are the early identification of the industry and its central requirements, and large-scale funding of basic research and scientific training.

Success of the industry depends not solely on one component or another, but on the alignment of many factors. In summary, successful biotechnology clusters derive their competitive advantage from the alignment of four key components:

- intellectual capital;
- a collaborative culture or formal networks that promote interaction between the business and research communities;
- access to finance; and
- government support.

Private venture capital (VC) firms are reluctant to invest in biotechnology start-ups due to the high-risk nature of the business and the long payback time for successful ventures. Therefore, Enterprise Ireland venture capital initiatives for the biotech sector should be expanded to fill this void. In addition, ways of stimulating greater interest by the private VC companies in the sector should be explored.

It is necessary that skills are seen to be in supply in sufficient quantities thereby providing Ireland with a competitive advantage in attracting large FDI[1] projects. In addition, the development of the industry in the US indicates that a key factor in promoting the growth of biotechnology was that sufficient personnel were available, particularly at PhD level to create competition for places, for example, in the universities. This provided an incentive for entrepreneurial activity at this level and a stimulus to engage in commercialisation of new research output.

In conclusion, a range of skills will be required. In the short-term, demand is likely to be driven by production activities, requiring a broad range of high-level skills. In the medium-term, with a horizon of perhaps twenty years, the sector offers opportunities for developing a comprehensive cluster, which can provide the highest value-added and offer the greatest prospects of dynamic growth. However, the manpower investment decisions in respect of this prospect need to be made now.

Current Pattern of Demand for Skills: Particular Shortages and General Requirements

To a very large extent, the biotechnology industry in the short-term, will be competing in a labour market that is common to many different industries for many of its skills needs. An example is regulatory affairs. Research in the US has identified this area as the greatest difficulty facing the biotechnology firms in terms of skill requirements. The provision of these skills is a clear prerequisite for the development of the industry in Ireland.

Another area where skill shortages exist internationally is process operators in terms of knowledge of bioprocessing operations including fermentation and separation technology. Validation is also a key area with deficiencies. Other areas identified in this report that require specialised skills include process equipment maintenance, process control, aseptic processing and measurement. In general, these do not require degree level qualifications but the availability of skills in these areas would be a key competitive advantage in attracting firms.

An area that is undergoing rapid growth and is experiencing a shortage is bioinformatics. To fill this growing need, redundancies from ICT[2] might be accessed but there is a considerable need to retrain. The shortage of bioinformatics graduates exists not only in the US but throughout the pharmaceutical industry. Niches such as this provide Ireland with an opportunity to gain a competitive edge if courses are provided to increase output considerably.

Eastern European countries such as Hungary have many excellent scientists, particularly in areas of weakness in the West. These tend to be mathematically orientated, although often with expertise in biological applications. The employment of immigrants from those countries, and from other areas such as India and China, is an opportunity to redress skills deficits.

1 Foreign Direct Investment
2 Information and Communications Technology

Two key conclusions emerge from the analysis:

1. Ireland, in the short-term, can stimulate the development of biotechnology by developing specialisations, while working to overcome the broader challenges over the longer term. These specialisations can be based on existing skills.
2. The skill sets for many of the jobs created by biotechnology do not fit neatly into existing training definitions and structures. However, the industry has identified the types of skills it requires. These are set out in considerable detail in the report (see Section 4.2.3, Table 4.3).

Current Trends in Supply of Skills

The Irish Council for Science, Technology and Innovation's (ICSTI) benchmarking study, *Benchmarking Science, Technology and Mathematics Education in Ireland against International Good Practice* (2000) highlighted various characteristics of secondary science education that were inhibiting Ireland's potential national competitiveness:

- falling proportions of students in physical sciences;
- skills shortages in sectors of Irish industry;
- above average proportions of lower grades in some science subjects;
- gender imbalance in the uptake of science subjects;
- the nature of student assessment; and
- provision of facilities at school.

Despite more than a 6-fold increase in the number of students in higher education since 1965 to almost 120,000 full-time students today[3], with Department of Education and Science (DES) projections showing a further rise to 127,000 by 2005/06, there is considerable concern that the number of students enrolling in Science (and Technology and Engineering) subjects is declining. The *Third Report of the Expert Group on Future Skills Needs* (2001) stressed the need for a continued supply of science graduates at certificate, diploma and degree levels in the disciplines of chemistry, biology and instrumentation physics.

The analyses of student participation rates and levels in science in Irish universities gives cause for concern. The falling numbers enrolled on Diploma and Certificate courses is also a cause for concern since these courses tend to be more targeted than university courses at the immediate and short-term needs of industry and provide opportunities for students with lower academic qualifications to enter science-based industries. This is particularly the case since the type of biotech industry that is likely to emerge in Ireland in the short to medium-term will require a mixture of skills at this level combined with large numbers with higher degrees.

Projections of Demand and Supply of Skills and Estimation of Skills Gap

Table A provides a summary of the estimated skills demand in the biotechnology sector on the basis of meeting the skills requirements of a successful biotechnology cluster. Demand is expressed as the average annual requirement over the seven years that it is assumed would be required for this nascent cluster to emerge. It should be noted that the analysis is primarily concerned with the impact of new developments on the demand and supply of skills rather than the absolute numbers involved.

The analysis is based on the following assumptions.

- Five new product development companies, are likely to emerge, each employing approximately 100 people, at different levels of qualification.
- FDI-related growth of a biotechnology cluster will generate 3,500 additional jobs while indigenous biotechnology firms will generate a further 1,400 jobs.

3 Higher Education Authority figure.

- Twenty research 'stars', i.e. research scientists who are internationally acknowledged leaders in their fields will establish research operations in Ireland. These stars, some of whom will come from abroad, will act as centres of nucleation for a full biotech cluster. These stars will generate a demand for an additional 100 PhDs and a further 100 skilled personnel, of whom 50 would be graduates.
- There will be a requirement for 30 PhDs in universities to support the increased teaching load as well as the greater research management responsibilities. In addition, Government departments and state agencies charged with oversight and regulator responsibilities will require 20 MSc graduates over this period.

Table A: Projected Skills Demand for a Nascent Biotechnology Cluster (2003-2009)

Average additional number required, per annum	
Skill Level	**Additional Numbers Required**
PhD	98
MSc	82
BSc	212
Diploma and Certificate	166
Other[4]	243

Table B provides an estimate of projected supply of science graduates, based on forecasting forward from 2002 and assuming a continuation of current trends. Each row of the table contains an estimate of the absolute numbers graduating at each level of qualification by year, as well as an indication of the change in output relative to 2001 (negative values imply a decline in numbers). The projected supply of skills, on current trends, is set to fall at undergraduate level while some growth is likely to occur at postgraduate level. Supply is shown relative to the numbers supplied in 2001 because the labour market in 2001 is assumed to be in equilibrium. Between 2003 and 2009, there will be a cumulative increase of 280 PhDs and 421 MScs whilst there will be a cumulative decrease of 1,351 BScs and 1,407 Diploma/Certificates.

Table B: Supply Trends (2003-2009)

Award	2003	2004	2005	2006	2007	2008	2009
PhD	245 (-8)	252 (-1)	276 (+23)	298 (+45)	316 (+63)	329 (+76)	335 (+82)
MSc	221 (+25)	239 (+43)	253 (+57)	263 (+67)	269 (+73)	274 (+78)	274 (+78)
BSc	2,481 (-98)	2,449 (-130)	2,417 (-162)	2,385 (-194)	2,354 (-225)	2,323 (-256)	2,293(-286)
Dip/Cert.	713 (-140)	692 (-161)	671 (-182)	651 (-202)	631 (-222)	612 (-241)	594 (-259)

Estimated output (supply), in absolute terms, at each qualification level by year. Changes relative to 2001 are shown in parentheses; negative values indicate a decline in output.

The tables highlight that in order to meet the growing needs of the biotech and life sciences industry, interventions need to be made to increase the numbers of science graduates and postgraduates, as the projected increase in supply will not be sufficient. If the demand for these skills remains at the 2001 level until 2009, then the additional number of qualified personnel to avail of the biotechnology opportunity would have to be supplied from some source. If this is to be supplied through the education system then the number that qualify with diplomas and certificates would have to rise by about 20% over the projected output for 2003, rising to almost 44% over projected output in 2009. The number of personnel required with degrees would need to increase by 4% in 2003 over the projected output to overcome this fall in supply. This rises to 12.5% in 2009.

4 "Other" includes non-science qualifications such as BA, BComm, ACCA, BL as well as operatives, etc.

Table C shows the projected skills gap which takes into account not only changes in supply trends but also the additional skills required for growth in biotechnology. The increased demand identified in Table A was based on requirements to allow for the growth of a biotech cluster. This requirement is added to the gap that emerges from the falling supply at sub-degree and degree level and is partially offset by projected increases in postgraduate output.

Table C: Projected Supply/Demand Skills Gaps (2003-2009)

Qualification	2003	2004	2005	2006	2007	2008	2009
PhD	-106	-99	-75	-39	-35	-22	-16
MSc	-57	-39	-25	-15	-9	-4	-4
BSc	-310	-342	-374	-406	-437	-468	-498
Dip/Cert.	-306	-327	-348	-368	-388	-407	-425
Total	**-779**	**-807**	**-822**	**-828**	**-869**	**-901**	**-943**

Based on an assumed labour market equilibrium in 2001. Negative values indicate a deficit.

The gaps in numerical terms are concentrated most heavily at the primary degree and diploma and certificate levels. However, there is also a consistent shortage of MSc and PhD awards estimated. While the numbers involved here are lower, in percentage terms, they are considerable. The conclusion emerging is that Ireland needs to increase substantially the number of people studying science at diploma, undergraduate and postgraduate levels in order to be in a competitive position to develop a biotechnology industry. In addition to greater numbers, there is a need to ensure that skill sets are well designed to meet the requirements of emerging firms in biotechnology sectors.

Recommendations on Skills Development

The key finding of this report is that there will be a considerable gap between the demand for skills that would be implied by the development of a biotechnology cluster in Ireland in the medium-term and the projected output of relevant skills over this period. If Ireland is to be successful in developing this industry then this deficiency must be overcome. The recommendations put forward to achieve this can be summarised under three broad themes.

1. Initiatives to increase interest in the study of science and in careers in science;
2. Measures to improve the capacity of the Irish economy to supply suitably skilled personnel; and
3. Supporting interventions, particularly in the development of Ireland's research competency.

These reflect the arguments that have been put forward: that intervention must increase the demand for training in science as well as the number of available places. In addition, the quality and structure of the skills that are produced must be appropriate.

In summary, the output of relevant skills by the education sector needs to be increased significantly if the biotechnology sector in Ireland is to realise its full potential over the period 2004-2010.

National Research and Government Funding

1. It is clear from international experience that the public provision of funds for research is a key prerequisite for the development of a dynamic and sustainable biotechnology industry. Good progress has been made by *Science Foundation Ireland* in attracting leading, international research scientists to Ireland. However, there is a real danger that these scientists will leave once their initial contracts have expired. It is therefore recommended that, **an unambiguous statement of long-term commitment to the public funding of science in general and biotechnology in particular, should be issued by the Government. This commitment should incorporate *quantified* targets for the level of support to be provided on a multi-annual basis.**

Such a policy statement would be particularly opportune at this juncture in view of the fact that Ireland is now over half-way through the *National Development Plan* (2000-2006) and that SFI is also half-way through its original remit. It would serve to dispel the growing uncertainty about the future funding of science in Ireland and to retain the confidence of key researchers and investors.

(Responsibility: Government)

2. **It is further recommended that capital funding under the HEA-operated *Programme for Research in Third Level Institutions* should be restored immediately.**

   (Responsibility: Government)

School System

3. The Biotechnology Sector, like other Science/Technology based sectors, requires a sustained commitment to improving the quality and relevance of the broad school programme. In particular, a strong emphasis on *Science and Mathematics* in school programmes is advocated. **The recommendations of the *Task Force on the Physical Sciences* are strongly endorsed and should be implemented *in full*, with immediate effect.**

   (Responsibility: Government)

4. The transition to the senior cycle merits particular attention. **It is recommended that a quantitative national target should be established in relation to the proportion of students undertaking science at Leaving Certificate.**

   (Responsibility: Government)

Transition Year Programmes

5. It has been observed that the activities undertaken by students during their transition year have a pronounced influence on their subsequent choices of subject at senior cycle. Therefore, it is recommended that:

   i. **the forthcoming pilot *awareness campaign* by the *Irish Pharmaceutical & Chemical Manufacturers Federation* (IPCMF), aimed at promoting science in transition year, be extended and expanded;**

   (Responsibility: IPCMF, Forfás)

   ii. **business should sponsor work placement programmes specifically for transition year students to provide them with realistic experience of applications of science and technology in industry; and**

   (Responsibility: IBEC)

   iii. **third level institutions should introduce outreach programmes centred around *active participation* by transition year students in science and technology projects.**

   (Responsibility: Governing Authorities)

Promotion of Science

6. The current efforts to promote Science and Technology based courses and careers should be intensified; business and industry should play a central role in this activity. **The diverse and rewarding career paths (including, in particular, biotechnology) opened up by an education in the sciences should be highlighted.**

   (Responsibility: IBEC, Forfás)

7. In the past, the coverage of Science and Technology on RTÉ has been poor, in terms of both news coverage and programming. RTÉ should address this shortcoming by the appointment of a science editor and a higher prioritisation of science and technology in its scheduling.

(Responsibility: RTÉ)

Technicians/Higher Technicians

8. A new emphasis should be put on the education and professional development of technicians and higher technicians relevant to biotech production by Institutes of Technology and Universities. Further **education/conversion courses should be provided to enable mature life-science technicians to upgrade their skills to incorporate the latest technology and techniques**. This could be done through existing full-time programmes and through a range of industry/Institute collaborative formats. It is imperative that such programmes should be delivered in a *flexible* manner in order to maximise the uptake. This entails part-time courses, weekend tuition, distance learning, in-service development, etc.

   Business and industry have a crucial role to play in this matter; they must adopt a more proactive role in promoting and facilitating training and professional development among their employees.

   (Responsibility: VECs, TLI[5])

Tertiary Education

9. Third level institutions should be more cognisant of, and responsive to, industry's needs; both parties should actively promote greater communication and closer collaboration in research and technology transfer.

   (Responsibility: Governing Authorities, Academic Councils, HEA, IBEC)

10. While acknowledging that courses are being continually updated in many third level institutions to reflect the rapid advances in this area and indeed that new courses such as MSc in *Bioinformatics* are being introduced, it is recommended that **all institutions should be encouraged to adopt a proactive approach to course development**:

    i. Curricula should be reviewed periodically, in conjunction with industry, to ensure their continued relevance;

    ii. Current trends towards inter-departmental teaching multi-disciplinary research should be accelerated.

    (Responsibility: Governing Authorities, Academic Councils, HEA, IBEC)

11. There should be a strong emphasis in undergraduate, postgraduate and part-time education on the nurturing of **business and enterprise skills** to augment the core scientific skills.

    i. Modules **encompassing non-traditional subjects such as *business, marketing, law and regulatory affairs*** should be included in science curricula. These courses should be tailored to the needs of the biotech sector with, for example, particular emphasis on intellectual property, technology transfer/commercialisation of research and securing venture capital;

    ii. **Third level institutions should encourage and facilitate postgraduate students to take courses taught at other institutions** in order to compensate for the relatively narrow focus of biotech expertise within individual institutions. This would also promote networking and foster collaboration between institutions.

    (Responsibility: Governing Authorities, Academic Councils)

5 Third Level Institutions

12. **The promotion of associated industries and technologies within the broader life sciences sector should be intensified by the relevant agencies.** Medical Diagnostics, for example, is an important application area for biotechnology. Enabling or supportive technologies such as Bio-informatics are also worthy of consideration, in view of Ireland's established strengths in computing, mathematics and physics at third level. The third-level institutions should support this initiative by promoting the appropriate skills in their curricula.

(Responsibility: Governing Authorities, Academic Councils, HEA, IBEC, IDA Ireland, Enterprise Ireland, SFI)

Overseas Talent

13. **It is recommended that national research programmes, in addition to attracting and promoting indigenous talent, should also endeavour to attract high calibre individuals from overseas to undergraduate and postgraduate programmes, post-doctoral and lead research positions, relevant to the Biotechnology Sector.** Ireland should actively promote itself as a desirable location for the pursuit of biotechnology-related study and research. In addition to raising the bar for postgraduate study and research, this would promote international networking by the Irish TLI.

(Responsibility: HEA)

Gender Balance

14. The gender profile at *entry-level* in the biotech sector is well balanced. However, it becomes progressively more imbalanced the further one looks down the career path. **Obstacles to long-term female participation in industry, ranging from child-care costs to structural issues, should be explored and addressed.**

(Responsibility: Government, social partners)

Levering the Research Base/Achieving Critical Mass

15. One of the shortcomings of the Irish research system has been the fragmented nature of research effort and the poor co-ordination of research activity among the various research and third level institutions. As a result, it has failed to date to achieve its full potential, where *the whole becomes greater than the sum of the parts*. The Government established a Commission under ICSTI in 2002 to develop proposals for an oversight and review mechanism for the science and technology system in Ireland and this report was submitted to the *Tánaiste* and *Minister for Enterprise, Trade and Employment* in December 2003. **It is recommended that the proposals of the ICSTI Commission be implemented to achieve greater cohesion in the science and technology system. The work of the Inter-Departmental Committee on Science and Technology to develop an Irish Action Plan to respond to the European *Research Area* initiative is also strongly endorsed in this regard.**

(Responsibility: Department of Enterprise, Trade and Employment)

1 Overview of the Industry and this Report

1.1 What is Biotechnology?

1.1.1 Science and Technology

Biotechnology is the application of biological knowledge relating to genes and cells in order to develop useful *products, processes* or *services* such as new medicines and therapies, cloning, genetically modified foods and enhanced crops. It encompasses an ever-growing arsenal of laboratory techniques for the alteration and manipulation of molecules, genes and cells and often involves the harnessing or usurping of biological processes for a particular purpose such as the biological synthesis of pharmaceutical compounds. The biotechnology industry is based on the commercial exploitation of these techniques. The primary challenge for commercialisation is that of scaling up the extremely delicate laboratory procedures to an industrial scale.

An agricultural engineer first used the term biotechnology in 1919. However, its applications stretch much further back in history to the first brewing of beer. Although plant and animal breeding techniques were refined over time, they remained confined to cross-breeding between individuals of the same species until the twentieth century when biotech moved forward rapidly through a series of fundamental discoveries. These discoveries included:

- the structure of DNA (Watson and Crick, 1953);
- the first synthetic antibiotic (1960);
- cracking the genetic code, i.e. how DNA works (Nirenburg & Ochoa, 1966);
- manipulation (cutting and pasting) of genes (Cohen & Boyer, 1973); and
- monoclonal antibodies (Kohler and Milstein, 1975).

These breakthroughs made it possible to overcome the species barrier and greatly enlarged the scope for the deliberate engineering of desired genetic changes. New techniques made it possible to introduce, delete, or enhance particular traits by inserting genes from an organism into another to alter its genetic make-up. In 1985 genetically engineered plants were field tested; in 1988 the first patent for a genetically modified animal, a transgenic mouse, was issued; Dolly, the first cloned sheep, appeared in 1997 and the human genome was sequenced in 2001. At the same time, legal decisions promoted commercial interest in these advances by opening the way for patent protection in new life and near-life creations.

The new sciences – pharmacogenetics (the correlation of the DNA sequence of genes to a drug response) and pharmacogenomics (the study of the pattern of expression of genes involved in a drug response in a defined environment) will revolutionise the ways in which drugs are researched, developed, marketed and prescribed. We are moving rapidly towards an era of personalised medicine (within 10 years) whereby drugs will incorporate bio-recognition technology and will be capable of being tailored to specific patient populations as well as being targeted at specific molecules and disease areas. The largest category of biotechnology applications is in health and medicine: diagnosing, treating, and in some cases preventing disease. In terms of resulting products, Standard and Poors has estimated that human diagnostics and therapeutics account for 95 percent of biotechnology revenues[6].

6 Standard and Poors (2000). *Biotechnology Industry Survey.* New York: Standard and Poors.

With each scientific development, knowledge has also been translated into new techniques and tools. For example, monoclonal antibodies revolutionised the diagnosis of diseases through the provision of highly specific antibodies – a new platform technology that has given rise to a large number of diagnostic reagents and technologies and holds the promise of new specific treatments for diseases such as cancer. Knowledge of how to manipulate genes (known as genetic engineering) has allowed development of transgenic plants and animals, i.e. species born with genes derived from another species or strain of their own species. Now, the production of antibody-based diagnostics, drugs and of transgenic animals for research are multi-million dollar industries.

With the knowledge of the components of biological systems at the molecular level now greatly enhanced by advances in genomics and proteomics, a parallel step is the modelling of these systems *in silico* i.e. electronically. Such models offering improved drug discovery and development will become an essential tool for evaluating hypotheses. The e-R&D environment will not stop here. It is predicted that the future will see the introduction of a virtual community for clinical trials including computer-aided trial design and simulation, electronic data capture and on-line analysis, reporting and review. This has clear implications for the process of drug discovery. Biotechnologies are also having an impact on the validation process through advances in pre-symptomatic diagnostics where outcomes cannot be easily determined through established methodologies.

1.1.2 Defining the Industry

The biotechnology industry is based on the commercial exploitation of cellular or molecular research on animal, plant, or microbial species. This definition means that, unlike many other industries, biotechnology is defined not by the products it produces but by the technologies it employs. The structure of the industry reflects divisions in the underlying science and is reinforced by the nature of the business processes involved. The Pharma/Agricultural/Environmental division involves long initial developmental periods of, typically, 10–15 years to initial product release, while the trajectory to profitability of medical device companies resembles that of traditional engineering, with a relatively short period to product release and profitability.

Biotechnology is an 'enabling technology' and advances impact on numerous industries: Pharmaceutical and Healthcare, Medical Devices, Diagnostics, Agriculture, Food and Drink, Environment and Information Technology. The biotechnology industry consists of firms established to develop the newly discovered knowledge and to exploit it commercially. Many regions which are establishing themselves as biotech clusters frequently include supplier and service companies. This collection of industries is referred to variously as the biotech or life sciences sector.

Defining the industry in terms of well-understood and internationally consistent sectors is not straightforward. Its relatively recent development means that biotechnology firms are not classified separately as such in the most widely used systems of classification, such as NACE, SICT or NAICS (the most recently devised North American Industry Classification System). The emerging practice is to assign biotechnology firms to broader industry categories encompassing research and development and drug manufacturing, for example, NAICS 54171 (Research and Development in the Physical, Engineering, and Life Sciences) or NAICS 3254 (Pharmaceutical and Medicine Manufacturing). This does not mean that operators in the industry and in support and associated sectors do not know the boundaries but it does raise some difficulties in providing comparative measures. A further discussion of definitions of the biotechnology industry is provided in Appendix 2.

There is a tendency to equate biotech firms as the emerging pharmaceutical companies (*pharmas*) of the future. This is because pharmaceuticals have been the first products that have come to market as a result of biotechnology. In addition, biotechnology firms have formed many alliances with existing pharmaceutical companies. However, while the pharmaceutical industry and the biotechnology industry have features in common that distinguish them from other industries, there are a number of important characteristics that distinguish them from each other.

Biotechnology research firms tend to be small and fairly recently established unlike pharmaceutical firms that tend to be much larger and older (see Appendix 3 for discussion of this gap in size). The typical pharmaceutical corporation is four decades older than the typical biotech research firm and has employment and sales a hundred times greater[7]. Amgen, the largest US biotech company, is smaller than any of the ten largest pharmaceutical firms, while the tenth-largest US pharmaceutical firm (Pharmacia & Upjohn) had sales in 1999 greater than the combined sales of the ten largest biotech firms ($7 billion)[8]. This difference in size is reflected in industry volatility. It has been estimated that half of the biotech firms formed since the 1970s have disappeared while pharmaceutical firms tend to be much more long-lived[9]. Profitability differs greatly also. While most biotech firms are losing money, pharmaceutical firms tend to be extremely profitable.

Biotech firms also devote most of their resources to research and development (R&D) while well-developed production and marketing operations are more characteristics of pharmaceutical firms. The skill sets required, not least in management, for these two types of firms suggest – and this is confirmed by the available evidence – that firms will tend not to move between the two industries. In other words, small biotechnology companies are unlikely to grow into large pharmaceutical firms. Instead, they tend to sell or license their technologies or firms to larger pharmaceutical firms, or to form joint ventures. There are also differences in the locations of pharmaceutical and biotech firms. The United States has, by far the largest concentration of biotech firms, but many of the largest pharmaceutical firms are located outside the US. Within the US, the largest pharmaceutical firms are concentrated in the New York-Philadelphia corridor, but none of the ten largest biotech firms are in that area.

However, there are similarities. There are widespread ties between firms both within these sectors and most noticeably between them. Biotechnology is recognised as a risky business and genetic knowledge has led to relatively few new products to date. Some pharmas have diversified and expanded their R&D portfolios to include elements of biotech. The ensuing products are referred to as biopharmaceuticals. The development of new biopharmaceutical products is uncertain, time consuming, and expensive. This makes large amounts of long-term capital an essential ingredient for success in biotechnology. The pharmaceutical industry understands this in a way that other new high-tech industries – and the venture capital sources that support them – generally do not appreciate. An important result is a shared understanding and culture that is very different from that which exists, for instance, in software, even among development firms. Cross-ownership, joint ventures, and licensing and research agreements are common, with pharmaceutical firms investing in promising biotech research[10]. Through this process, the biotechs obtain access to regulatory expertise and production and marketing capability. A second important similarity is the way in which both sectors are impacted upon by government policy. In both cases, performance is greatly dependent on factors such as the regulatory environment, the protection of intellectual property (IP), the provision of research funding and demand created by public health services.

While there is some difference of opinion in relation to its exact boundaries, there is an entity that can be described as the biotechnology industry. The industry is still in its infancy and its future structure remains very unclear. However, there are some important characteristics becoming clear and some indicators of its future structure are also emerging. This is discussed in much more depth in Chapters 3 and 4 where a model of the industry, as it is likely to develop in Ireland, is articulated. The next section provides an overview of the industry as it has developed to date and identifies issues related to the commercialisation of the technologies.

---

7 Dibner, M. (1999) *Biotechnology Guide USA* Research Triangle Park, N.C.: Institute for Biotechnology Information

8 Cortright, J. and H. Mayer (2002) *Signs of Life: the Growth of Biotechnology Centres in the US* Washington, D.C.: Brookings Institute

9 Dibner, *op. cit.*

10 Recombinant Capital, a US research firm specialising in the biotechnology industry, estimate that more than 10,000 industry alliances took place in this sector during the 1990s and the number is growing by about 20% per year. (**www.recap.com**)

1.2 The Commercial Development of Biotechnology

1.2.1 The Commercialisation Process

Modern biotech has been described as a

> 'foundation science defining the world's progress in treating and curing diseases; in providing enough food for a growing world population; in reducing reliance on non-renewable energy sources; in sustaining escalating industrial production without harming the environment; in cleaning up existing pollution and in saving endangered species'[11].

The industry can be traced back to 1976, when Genentech launched the medical biotechnology industry. The company's goal was to develop a new generation of therapeutics created from genetically engineered copies of naturally occurring molecules, important in human disease and health. Within a few short years, Genentech scientists proved it was possible to make medicines by splicing genes into fast-growing bacteria that produced therapeutic proteins. Today, Genentech continues to use genetic engineering techniques and advanced technologies to develop medicines. It currently employs some 500 research scientists and produces and markets ten biotechnology products directly in the United States.

Fifteen of the currently approved biotechnology products stem from, or, are based on Genentech science. Net income for 2001 increased 24 percent to $404.5 million, compared to $325.1 million for 2000. Revenues for 2001 increased 27 percent to $2,212.3 million from $1,736.4 million in 2000. This revenue growth was driven primarily by sales of Genentech's BioOncology products, Rituxan® (Rituximab) and Herceptin® (Trastuzumab). Total product sales increased 36 percent in 2001 to $1,742.9 million from $1,278.3 million in 2000. Marketed products sales increased 36 percent in 2001 to $1,742.9 million from $1,278.3 million in 2000, with bio-oncology sales consisting of 67 percent of total product revenues, up from 56 percent in 2000. Research and development (R&D) expenses increased in 2001 to $526.2 million compared to $489.9 million in 2000. R&D expenses as a percent of revenues in 2001 were 24 percent, compared to 28 percent in 2000. Table 1.1 contains data on other large biotech companies in the US.

Table 1.1: Sales of Large Biotech Companies

	Sales ($ million, 1999)
Amgen	3,340
Biogen	794
Genzyme	772
Immunex	542
Life Technologies	410
Medimmune	383
Nabi	234
Charles River Labs	219
Gilead Sciences	169
Serologicals	130

Source: Cortright and Meyer (2002)

Recent estimates by Ernst and Young indicate that there are 4,284 biotech companies worldwide; 3,662 of these are private and 622 public. These employ over 188,000 people and generate revenues estimated at around $34, 874 million. Underlying this is a vast investment in R&D of $16,427 million last year.

11 Ernst & Young (2002) *Beyond Borders*

The US is by far the global leader in biotechnology. With almost 1,500 companies – 1,115 private and 342 public – the US represents 72% of global biotech revenue. European firms are still some way behind in terms of revenue generated, at $7,533 million – 22% of the global total – but Europe has more companies than the US. A significant proportion of these are private biotech companies so that Europe has 48% share of global private companies compared to the US with a 55% share of global public companies. This indicates a more mature industrial structure in the US with likely better access to finance, larger scale and more developed support systems. This also explains why Europe has a lower revenue share of the market.

In the US in particular, 2001 saw an aggressive phase of mergers and acquisitions. In general, many companies in the US have reached a critical crossroads. Despite having developed unique platform technologies, they cannot 'go it alone'. Meanwhile, pharma companies do not have a sufficient pipeline of new drugs to sustain growth. In addition to this, there was an unprecedented investment ($33 billion) in the technology companies, such as those in genomics, to develop new treatments or diagnostics based upon the code of a person's genome. These companies are now well placed to expand either vertically, whereby they become a fully integrated drug developer, or horizontally, whereby having accumulated a host of technologies they are a much sought after provider of research tools.

In the last five years, the biotech sector in Europe has experienced a doubling in the number of companies, a seven-fold increase in revenue and a three-fold increase in market value. This has been achieved by a dramatic increase in investment in the industry. In 2001, private equity funding totalled $1.3 billion. However, there is now the dilemma that the European sector, characterised by small, private, early stage companies is experiencing a capital demand of $2.6 billion during 2002.

There are estimated to be in the region of 1,788 companies in Europe. Of these, 38% are service providers while a further 18% provide technology services to the sector. Human healthcare accounts for 38% of companies and diagnostics for 13%[12]. The industry is concentrated in a small number of areas led by the UK, Germany, France and Medicon Valley. Projections for the sector show that the difficult conditions which emerged in 2002 in respect of financing, are likely to continue in 2003 with more defensive VC firms, lower investor confidence and less likelihood of IPO success. This is a particular problem given the average time period involved in drug development, after discovery, as shown in Table 1.2.

Table 1.2: Drug Development Periods (months)

	1986-90	1991-95	1996-2000
Phase I to Phase II	21	20	15
Phase II to Phase III	31	25	18
Phase III to Pre-registration	29	26	18
Pre-registration to Registered	19	15	12
Registered to Launched	9	10	8
Total	**109**	**96**	**71**

Source: Deloitte & Touche

The long payoff period involved in R&D means that well funded established companies are required to undertake the investments. The obvious candidates to play this role and undertake research are the pharmaceutical companies. In some respects, biotech may be seen as a novel departure for pharmaceutical companies, with their traditional 'chemical' focus. However, there are problems in some parts of industry, which have turned their attention towards biotechnology (see Appendix 4 for examples of biotech products currently in the development pipeline). On the basis of its research, PriceWaterhouseCoopers[13] (PWC) has concluded that the current approach by many of the large pharma companies – launching three New Chemical Entities per year, 1 blockbuster every 5 years – will provide an 8% annual growth in sales. However, this is based on 11% growth in R&D spend per

12 Deloitte & Touche (2002) *Surviving Uncertainty: the Pan European Mediscience Review 2002*
13 PWC (2001) *The Odyssey Continues – Charting a path towards Pharma 2010*

annum (the historic growth rate) to achieve an average annual sales of $420 million per product. This will simply not be sufficient and implies that Total Shareholder Returns will fall to approx. 6% per annum, an unacceptable level. As a result PWC conclude that:

> Some [pharmaceutical] companies are heading for a crash. Organisations that fail to find ways to cut R&D costs and lead times, generate additional sales revenues with innovative products, enter new markets and leverage e-business opportunities, will be taken over or forced to re-trench into niche operations[14].

PWC propose that pharma companies should redefine their business models – to produce and sell safe, effective and affordable drugs for individual customers. Their predominant approach to date to reducing risk in new product discovery is more rational drug design, as opposed to a more speculative discovery process, from which the industry grew initially. This approach may be considered to be well controlled and less wasteful on resources than serendipitous approaches. However, the number of promising lead compounds (new drug species worthy of further development) now emerging is disappointing. This has prompted the development of a strategy termed 'bio-pharma' representing the move of established companies to develop new drugs from life sciences research. These firms also realise that talent and expertise exists externally and can be exploited profitably if the correct conditions for this are created.

Firms in the biotechnology industry are beginning to redefine themselves as biopharmaceuticals. One implication is that they too will have to restructure their business models and realise the benefits in partnering. These include:

- exposure to a global market;
- establishing a foothold in a specific market; and
- capacity for launching a drug/compound.

This path of development is potentially important in Ireland given the established critical mass of multinational pharma companies with the result that bio-pharma is viewed as representing a significant opportunity. However, this opportunity will only be realised if all the conditions are created and if a number of other difficulties can be addressed. The fact remains that, globally, biotech is regarded as an industry that has promised much. However, if measured in terms of marketable products, that promise has barely been realised.

1.2.2 Managing Risk in Successful Commercialisation

Developments in the 1980s and 90s provided a significant spur to biotech through the need to develop drugs to combat AIDS, alongside technologies to diagnose this and other diseases for which specific, sensitive, rapid, safe and cost-effective diagnostics were required. Without doubt, biotech has delivered much in the area of improved diagnostics, while the goal of novel therapeutics has, time on time, yielded disappointing outcomes for doctors, patients and companies. Nonetheless, the knowledge yielded by the failures has often helped to advance basic understanding.

Intellectual Property

The importance of scientific knowledge as the driving force to progress the industry means that biotech is very dependent on intellectual property (IP). Key supporting skills and processes include the identification, protection (patenting) and exploitation of IP. One of the strategies used by successful biotech companies is the development of a mixed IP portfolio.

Trinity Biotech provides one example of this approach. The company was formed in 1992 and is a public company with production facilities in Bray, Ireland; Jamestown, New York; and Carlsbad, California. The company specialises in the development, production and marketing of diagnostic products, which utilise immunoassay technologies (antibody-based test kits). The company has expanded and assembled its product portfolio through in-house R&D and acquisitions and has achieved

14 Fergus Byrne, Partner, Global Head PWC Consulting

excellence in development, production and marketing. It markets over 120 products through distributors in 80 countries and attained its first full year of profit in 1997. This range of products includes over 100 different tests to assist in the diagnosis of auto-immune and hormonal disorders, sexually transmitted diseases, enteric infections, respiratory infections, drugs of abuse, cardiovascular diseases, infectious diseases such as syphilis, lyme disease and legionella and various other disease states.

The commercialisation process typically involves either the licensing of patented IP to existing companies, which are expanding their portfolios, or the formation of new companies. Whichever route is taken the IP owner will face an extremely long and expensive developmental process; this normally lasts 10–15 years and consumes typically $10 million – $100 million prior to marketing of a single product. Estimated global R&D biotech expenditure was over $16 billion in 2001. Funding for biotech is predominantly either by existing pharma companies or by venture capital. However, venture capitalists are often slow to invest. Many of the reasons for this are clearly understandable. These include:

1. Independent and informed scientific advice on the potential viability of the anticipated product is essential. Even when this is available, the risk of failure is often high as much new science may be discovered en route to final product;

2. There are few successful role models and many failures;

3. The payback time is extremely long;

4. Institutional or public sector investors are highly risk averse and so tend to steer clear of biotech;

5. Investors may fear the adverse impact of public opposition or new legislation. Public opinion on, for example, genetic modification, the use of human cells and tissue, animal research etc. is often contrary to the wishes of the industry. In many countries public education has not accompanied attempts to build a biotech industry. An exception to this is the work of North Carolina's Biotech Centre, which has, over more than 20 years, devoted resources to educational and outreach issues. One result is that public opposition to genetically modified crops has been very notably less in North Carolina than in Europe, an indication that these issues can be accommodated by a long-term strategic investment in education;

6. Much of the valuable IP has emerged recently from research institutes or universities and distinctions between the 'R' and the 'D' may be unclear. Investors have no desire to provide money that might enter a massive sink of basic research;

7. Investors would wish to take equity. Scientists are often conservative, sceptical of investors and unwilling to part with 'their' IP. Entrepreneurship and scientific excellence are rarely co-located; and

8. Early stage development is dependent on appropriate, usually very high specification, laboratory space. Patents generally emerge from good research laboratories. However, their exploitation cannot continue on those locations. New spaces can be provided in incubator facilities. Ireland has been slow to develop incubators although Enterprise Ireland is currently considering an incubation strategy. However incubators are usually provided as 'shell' spaces with only generic equipment installed. Finance to retro-fit incubators is extremely difficult to find, as investors are reluctant to finance infrastructure or plant that will be used only for a short period.

None of the above items indicate an insufficiency of venture finance in the right circumstances. In addition to private investors who emerged successfully from the ICT boom, several new funds have been developed in the UK and Ireland[15]. Issues in relation to the availability of VC in Ireland are dealt with in later chapters.

The flow of IP and of scientific staff necessary for its generation and development means that biotech is highly dependent on research universities and institutes. Top quality research underpins the generation and initial development of viable IP. In many instances aspects of the essential work can be undertaken at other locations where e.g. particular high-spec equipment is available. This implies

15 Examples include the Viridian Fund, Seroba Bio Ventures, and the University Challenge Fund.

a necessary level of collaboration and co-operation. There must also be a strong commitment to helping researchers to understand the stages and processes involved in IP protection and to facilitating access to the essential legal expertise.

This discussion shows that while there are good opportunities in this sector, there are also important difficulties that may undermine the ability or willingness of the private sector to play an adequate role in ensuring the required investment takes place. This arises due to the risks and the particular difficulties of protecting IP while achieving its commercialisation.

Relevant Educational Programmes

The rapid pace of development of the specialised scientific technologies employed in biotech means that taught programmes must be updated and relevant to the needs of the industry. The availability of R&D funding to ensure adequate infrastructure and research are essential. In parallel, undergraduate and postgraduate taught courses need to be informed by the research and students motivated through interaction with top, internationally recognised scientists. As discussed in Chapter 5, a significant threat is posed by the rapid downturn in the number of students entering science-based courses.

Regulatory Environment

For any product or technology that is expected to be applied to human patients, full clinical trials must be undertaken. Very considerable infrastructure is required for clinical trials that will meet the criteria of the world's major market places, e.g. FDA for the US market. Ireland and the UK have been relatively slow to develop the necessary infrastructure although a number of commercial ventures, such as Quintiles, are now present. This industry sector also needs a considerable skilled workforce.

Supportive Public Policy Framework

Clearly, given the importance of new knowledge for the growth of biotechnology, the certain availability of skills is a fundamental requirement of firms. Together these issues mean that the State through its policy initiatives has an important role to play in reducing risk through ensuring a favourable economic environment for investors, in creating a suitable legislative framework for the protection of IP and in facilitating the creation of the required skills.

1.3 Development of Biotechnology in Selected Locations

The growth of the Irish biotechnology industry will be determined by scientific advances that are made, by the ability of firms to find commercially viable ways to apply this new knowledge and the competitiveness of Ireland as a location for the undertaking of the basic research and its commercialisation. As a result of this final requirement, the research in this study is placed in the context of the international competitive environment that is emerging in the biotech industry. This has been done through a study of four countries and regions in which biotechnology industries are growing rapidly. The main results of this element of the research are detailed in Chapter 3. There, the prospects for the development of the Irish industry are discussed in terms of:

- an analysis of these regions as competitors for inward investment;
- the dynamics of the industry as evidenced by its development in other areas; and
- the supporting structures in terms of inter-relationships with other sectors that are required.

The four regions are the US, Medicon Valley, Scotland and Singapore. The US is chosen as it is the leading country in the development of biotechnology and will be the major source of investment as well as being a primary location for the underlying knowledge. The other areas provide indications of the role of policy and will be important competitors for inward investment.

1.4 Structure of the Report

Global economies are evolving at a rapid pace and to play a part in this changing knowledge-based environment, the acquisition of knowledge and the accumulation of knowledge capital is increasingly vital. The biotechnology industry is a particularly good example of these developments. In Ireland, changing demographic trends entail fewer young people entering the job market or pursuing further education than previously. In these circumstances the drive towards a more knowledge based economy means that the key drivers of success must be fully understood and vital systems in the economy must be able to respond to the development needs of the knowledge economy.

The analysis in this report can be split into three parts, each containing two chapters. Following the overview of the industry contained in this chapter, Chapters 2 and 3 provide an analysis of the biotechnology industry in Ireland and in leading foreign clusters. Chapter 2 contains a survey of relevant Irish studies and literature into the needs of biotechnology. On the basis of this survey, some initial conclusions are put forward in relation to Ireland's preparedness for the development of a competitive biotechnology industry. Chapter 3 is based primarily on the consultations that have been undertaken in relation to foreign clusters. It identifies the sources of competitive strengths, the role played by supporting sectors and systems, and the role of public policy in these centres.

Chapters 4 and 5 constitute the second part of the report, the identification of the demand for skills in biotechnology firms and the supply of relevant skills in Ireland. Chapter 4 presents a model of the industry based primarily on the experience in other areas. It also analyses company structures identifying the progression of products and firms and the changing needs of firms at each stage of growth. This allows for the identification of skill requirements for different types of biotech firms at different stages of development. The emphasis is on the identification of skills from the demand side – that is according to the requirements of industry – rather than according to supplied defined outputs. Chapter 5 provides an analysis of the Irish science education system and identifies developments and projects of output in the near future. It also identifies strengths and weaknesses of this system.

The final part of the report compiles the results of this study into an analysis of the structure of the labour market under alternative paths of development of the biotechnology sector in Ireland. The approach in Chapter 6 is on providing a clear understanding of the forces that will drive development and lead to different outcomes rather than speculating on projected growth rates. However, it is clear that one possible outcome is preferable and the requirements of this outcome are highlighted. The analysis provides the numbers of skilled personnel that will be required, against which likely supply is assessed to identify potential gaps.

The requirements placed on the Irish economy if this outcome is to be achieved lead to the recommendations of the report in Chapter 7.

This structure is adopted to emphasise the central lesson from this work; a highly skilled workforce is essential for the development of biotechnology, but in the absence of supporting factors, this workforce will not in itself be sufficient to lead to the development of a high value-adding industry that fully utilises these skills.

2 Review of Irish Biotechnology Policy

2.1 Overview of the Industry in Ireland

The biotechnology sector in Ireland is still in its infancy. The recent Ernst and Young report, *Beyond Borders 2002,* lists Ireland as having the second lowest number of biotech companies (approx. 30) out of 13 European countries, Norway being marginally lower. In comparison, Germany leads with over 350.

Within countries such as the UK, with its large population and relatively well organised National Health Service, the objective of achieving commercial return from aspects of its healthcare services is now beginning to be realised. The small population and less well-resourced healthcare sector in Ireland would preclude major developments. However international collaboration to achieve critical mass in patient numbers or access to sophisticated equipment such as MRI or PET scanners, offers potential.

Estimating the size of the biotech sector in Ireland means re-categorising companies in established sectors into certain groupings. This introduces a certain arbitrariness that may lead to different estimates of the size and scope of the industry being provided by different studies. In addition, many of the jobs in biotechnology exist in areas such as R&D and within research centres supported either directly or indirectly by commercial operations. Furthermore, the development of the industry has a major impact on employment in associated sectors, such as healthcare, where the new knowledge of biotechnology may impact on the processes that take place. However, there is also direct employment in sectors for the production of products that are closely related to the underlying developments in the knowledge base. These provide the underlying competitive base, from which it is likely that the biotechnology sector in Ireland will grow. These include areas such as healthcare, pharmaceuticals, chemicals and medical devices. Thus, identification of the potential for the industry in Ireland to grow can usefully include these sectors while accepting that this is not an accurate definition of biotechnology.

Figures from IDA Ireland indicate that there are 120 overseas pharmaceutical and chemical companies located in Ireland. This sector employs 20,000 people and exports $32 billion annually, representing over 29% of total exports. The IDA conservatively estimates the total investment by the overseas pharmaceutical sector in Ireland at $12 billion, with nine of the top ten global companies present. This is important and it has been accepted that Ireland has 'established itself as a world centre for biopharmaceutical manufacturing'[16].

The medical devices industry represents the other element of the sector as described earlier. This has grown in Ireland, but is quite diverse. Today, there are in the region of 80 overseas companies, including 13 of the top 25 global companies, located here. The medical devices sector employs over 22,000 people with exports over €3 billion in 2002[17]. Medical device companies use technology that is relatively familiar, the time to market is short ranging from a few months to a few years, and clinical trials pose less of a challenge than for new drugs. Many of the difficulties to do with early stage financing that are characteristic of biotech are also not relevant to this sector.

Table 2.1 shows data for turnover, value-added and employment in firms in biotechnology related sectors in Ireland 2000. It shows total employment of 29,668 in 226 firms with a turnover of €25.6 million in that year. This amounted to 11.6% of total employment in manufacturing industries that were included in the Census of Industrial Production in 2000, 37% of gross value-added and 26% of total turnover.

16 Henri Termeer, President and CEO of Genzyme.

17 Irish Medical Devices Association.

Table 2.1: Manufacturing Firms in Related Sectors in Ireland (2000)

	NACE Code	Firms	Turnover (€ million)	Gross VA (€ million)	Labour cost (€ million)	Number employed
Medical/Surgical Equip	3310	63	2,515	1,329	358	12,937
Measuring Instruments	3320	42	481	216	66	1,999
Inorganic Chemicals	2413	13	169	87	30	607
Organic Chemicals	2414	24	17,422	8,838	253	4,844
Agro-chemical Products	242	24	143	39	25	708
Pharmaceuticals	244	60	4,846	2,639	311	8,573
Totals		**226**	**25,576**	**13,148**	**1,043**	**29,668**

Source: CSO Census of Industrial Production 2000

Clearly this is an important area of employment but it is also evident that productivity per employee is well above typical levels in the economy. The sources of this discrepancy have been well discussed in the literature on the Irish economy and mean that there are difficulties in drawing overly strong conclusions on the basis of this aggregate data. An example of these difficulties is demonstrated in Table 2.2.

Table 2.2: Productivity in Related Firms in Ireland (2000)

	Average Turnover (€ million)	Average Employment	GVA as % of Turnover	Labour cost as % of Turnover	GVA per Employee (€000s)
Medical & Surgical Equip	40	205	52.8	14.2	102.7
Measuring Instruments	11	48	44.9	13.7	108.1
Inorganic Chemicals	13	47	51.5	17.8	143.3
Organic Chemicals	726	202	50.7	1.5	1,824.5
Agro-chemical Products	6	30	27.3	17.5	55.1
Pharmaceuticals	81	143	54.5	6.4	307.8
All Firms	**113**	**131**	**51.4**	**4.1**	**443.2**

Source: CSO Census of Industrial Production 2000

Table 2.2 shows that there are considerable difference between the size of firms and the productivity of employees within these firms. Firms are generally large with employment per firm well above the average 53 persons for industrial firms in the whole Irish economy.

For most sectors, Gross Value-added (GVA) averages around 50% of turnover, the exception being firms engaged in the production of agro-chemicals. Firms in this sector also tend to be smaller with much lower output per person. In many respects, these firms are more similar to the older traditional sector of the economy. On the other hand, firms in the organic chemicals and, to a lesser extent, the pharmaceuticals sectors are clear outliers in terms of very high GVA with the consequent outcome that expenditure on labour costs are much lower as a percentage of turnover. These firms appear to be much less integrated into the economy than other sectors, but may also be in the most progressive sectors.

It is likely that these companies will form the core of the emerging biotechnology industry in the sense of providing Ireland with a labour pool with experience in the pharmaceutical and related sectors. This thinking forms the basis of the approach adopted in the *Third Report of the Expert Group on Future Skills Needs*[18]. It identifies a number of industry sectors that are considered to draw from a similar labour market as would be the case with biotechnology and provides estimates of employment in these sectors up to 2006. These are provided in Table 2.3.

18 *Responding to Ireland's Growing Skill Needs.* Third Report of the Expert Group on Future Skill Needs, Forfás (2001).

Table 2.3: Sectoral Employment Projections (2001-2006)

	Pharma-ceuticals	Chemicals	Plastics	Medical Devices	Food	Drink & Tobacco	Indigenous Biotech
Annual Change	+8.8%	+3.3%	No change	+10%	+400 p.a.	+50 p.a.	Not provided
2001	16,600	10,200	11,300	14,400	48,000	6,100	700
2002	18,000	10,600	11,300	15,800	48,400	6,100	900
2003	19,600	10,900	11,300	17,400	48,800	6,200	1,100
2004	21,400	11,300	11,300	19,100	49,200	6,200	1,500
2005	23,200	11,700	11,300	21,000	49,600	6,200	1,900
2006	25,300	12,100	11,300	23,200	50,000	6,200	2,400

Note: Annual change was calculated over the period 1998-2006

Source: Based on Table 5.1, Third Report of the Expert Group on Future Skills Needs

These estimates were obtained by mechanically applying annual growth estimates to existing baseline employment. As such, they are subject to error intervals, but their usefulness is in indicating the relatively small numbers that are employed in indigenous biotechnology in Ireland. In addition, they serve to indicate the considerable pool of experienced labour in related sectors from which the emerging sector could draw for its general skill requirements and for some of its highly technical requirements. However, as identified in later chapters of this report, this does not cover the whole range of skill requirements in biotechnology and it is the ability of Ireland to supply these specific needs that will determine its competitive strengths in this area.

IDA Ireland has identified 11 foreign biotechnology companies that currently employ 1,800 people in Ireland. The indigenous biotech sector is smaller but recent estimates[19] identify 21 biotechnology companies that are involved in the development, production and/or trading of products and services derived solely or primarily from the application of some form of biotechnological activity. These companies employ 400 people[20]. This is fewer than the projections on which Table 2.3 is based. They had a turnover in 2001 of €32 million.

2.2 Irish Biotechnology Policy

2.2.1 BioResearch Ireland

Recognition of the potential of biotech in Ireland was highlighted first by the formation in 1987 of BioResearch Ireland (BRI), Enterprise Ireland's Programme in Advanced Technology for Biotechnology. BRI was set up jointly by the government and universities to facilitate commercialisation of opportunities arising from research in Irish third level institutions and other organisations. Campus-based, commercialisation/technology transfer management teams are a key component of BRI. The activities of these teams, supported by a central management group, include administration and technology monitoring of research projects and programmes, management of IP from funded research projects, management of technology transfer to industry, support and promotion of biotech-based start-up companies and training and education in biotech. BRI's activities have led to collaborations with major national and international companies and to the establishment of a number of spin-out companies.

Enterprise Ireland's (EI) strategy, *'Towards a Biotech Ireland'* (February 2002), aims to grow and develop Ireland's entrepreneurial-led biotech and life sciences industry. The strategy is an integral component of a partnership with SFI, IDA, the private sector and the universities. EI has identified five clear goals within the National Strategy Framework. Along with the formation of a Biotechnology Team to integrate the expertise and resources of BRI, the Campus Companies initiative, the High-Potential Start-Up Unit,

19 *Towards a Biotech-Ireland*, Enterprise Ireland (Feb. 2002); *Mapping the Bio-Island*, InterTradeIreland (March, 2003).

20 The medium-term objective of *Enterprise Ireland* has recently been stated (see Footnote 92) to be to increase the number of indigenous biotech companies from a current base of 20 to 60 within five years and in the same period to increase the number of people employed in the sector from 400 to 1,800.

the Established Industry Support activities and EI's international network, considerable progress has been made already in delivering the objectives of the biotech strategy. Examples of the objectives that have been set and progress towards achieving these specific aims are provided in Box 2.1.

Box 2.1:	**Identified Aims of *Towards a Biotech Ireland* and Progress**
Aim	Maximise the creation of new biotech companies – Increase the number of companies to 60 by 2006
Progress	In 2001 three companies, EiRx Therapeutics Ltd, Allegro Technologies Ltd and nEUtek Development Ltd received financial support.
Aim	Nurture the development of early stage biotech companies by: supporting applied research, facilitating technology transfer, providing funding at early-stage and first round and providing suitable incubation facilities.
Progress	In 2001, 13 biotech applied research projects totalling €5.1 million were funded under EI's Advanced Technology Research Programme. EI have commissioned a study to establish the availability of incubation units for early stage companies.
Aim	Attract foreign bio-entrepreneurs or early-stage companies to establish in Ireland.
Progress	A pilot marketing programme in New England, USA has been launched.
Aim	Fast track the development of established companies. Promote private sector seed and venture capital markets.
Progress	Seroba BioVentures has been established to provide early-stage equity capital to small and medium-sized, growth-orientated companies.

It is clear from the range of issues that are included among these initiatives that the aim is to create the conditions for the development of a cluster of biotech companies. This concept is discussed in greater depth in relation to the factors that have contributed to success in the leading biotech clusters analysed in Chapter 3.

A new seed and venture capital fund also has been recently launched in Ireland. The Growcorp €25 million European Bioscience Fund I is focused on identifying investment opportunities in the bio-science sector in Ireland and the rest of Europe, and on US scientists and entrepreneurs seeking to start a business in Ireland. Co-investors in the Fund include Enterprise Ireland, Irelandia Investments and PriceWaterhouseCoopers.

2.2.2 Skills Issues

In Ireland, the early 1990s saw a levelling off in the global interest in biotechnology, but in 1996 the Forfás strategy statement pre-empted the renewed interest in the sector in the late 1990s and identified biotech as a 'key enabling technology for Ireland's future industrial development'[21]. Also at this time Forbairt, the State Agency then responsible for indigenous industry, highlighted that both the 'Healthcare and Biotechnology Sectors represent significant opportunities for Irish industries to develop, hence creating additional employment and wealth for the country'[22].

Labour force skills were identified at an early stage as an essential prerequisite for the successful development of biotechnology in Ireland. As a result of the announcement by Science Foundation Ireland that €625 million is available for the development of the biotech and ICT sectors, it is predicted that 1,800 postgraduate students will be in receipt of funding in any given year from 2005. Output of PhDs across all disciplines was estimated at 417 in 1999. This number suggests that Ireland faces a potential shortage of skilled graduates to perform the expanded volume of research necessary to underpin the commercial developments. A solution would be to attract research graduates from outside Ireland.

21 Forfás (1996) *Shaping Our Future – A Strategy for Enterprise in Ireland in the 21st Century*
22 Forbairt (1996) *Irish Healthcare and Biotechnology Industry – An Emerging Growth Sector*

To address this issue, the Expert Group on Future Skills Needs commissioned an international comparative study to:

- Benchmark strategies and mechanisms, within the international market of researchers, to attract from abroad students to undertake postgraduate research leading to a higher degree and people to postdoctoral research positions; and
- Identify lessons to be learnt for Ireland from international practice[23].

The study looked at five benchmark countries. The UK and US were chosen for their long established scientific reputations and well-recognised world class institutions. These two countries are the top global magnets for the attraction of internationally mobile researchers. The Netherlands, Finland and Denmark were also selected as benchmark countries as they are seen as competitor countries in Europe with similar small research systems and modest international reputations.

The study found that Ireland differed from the benchmark countries in that it is now dealing with the sudden expansion of its academic research systems (due to substantial funding initiatives mentioned earlier) and is facing the challenge of supplying new graduates and researchers. All of the other countries (to varying degrees) have had longer time periods to implement their innovation strategies and historically greater resources to build up their research institutes, train their researchers and employ scientists. However, genuine skills shortages do exist in some of the benchmark countries. The UK and US have specific programmes and initiatives to attract foreign researchers. The UK, and to a lesser extent the US, have a 'dual-track' academic systems approach whereby there is a clear division between the national system of funding for graduate researchers and large additionality due to overseas students. Ireland has much more in common with its other European partners in the global competition for researchers. Generally, these countries have addressed skills' shortages by improving their current academic research systems. Any additional measures to attract foreign students (tax, immigration, marketing efforts) have been minimal.

The report highlighted four recommendations through which Ireland could address the skills shortage:

- Build up centres of excellence – this long-term strategy of building up internationally renowned research groups and universities will be a magnet for the best scientists;
- Improve international networks and visibility of Irish universities;
- Improve the status and remuneration of research graduates; and
- Make the move to Ireland as smooth as possible.

The indications are that the availability of a highly skilled cohort of experienced researchers, centred on individuals that possess outstanding skills is an important prerequisite for the development of a biotechnology industry; one that can move beyond the manufacturing stage, to compete in the higher value-added parts of the industry. In these areas the ownership and location of intellectual capital is a key determinant. Indeed, it appears unlikely that Ireland can hope to create such a core from indigenous resources and that the success of this approach will be important in determining the structure of the industry that emerges.

2.2.3 Irish Council for Science, Technology and Innovation

Biotech development received a significant boost in 1997 when the Irish government established the *Irish Council for Science, Technology and Innovation* (ICSTI) to advise government on all aspects of the strategic direction of science, technology and innovation policy. The current ICSTI membership comprises some 25 individuals representing industry and academia. Following a recommendation from the Government White paper on Science Technology and Innovation (1996), the ICSTI was requested to develop and undertake a *Technology Foresight Exercise*. Eight panels were formed addressing the needs of eight sectors, one of which was *Health and Life Sciences*. The 'horizon' for

23 Forfás (2001) *Benchmarking Mechanisms and Strategies to Attract Researchers to Ireland.*

each report was set to 2015. The reports were to provide information to Government when preparing the *National Development Plan* (2000-2006) for submission to the next round of EU structural funds.

This exercise identified seven major sub-sectors of the Health and Life Sciences sector that are important to the Irish economy:

- Pharmaceutical/Healthcare;
- Food and Drink;
- Agriculture, Forestry and Fisheries;
- Environment;
- Regulatory Affairs and Law Enforcement;
- Information Technology (in the form of Bioinformatics); and
- Medical Devices.

The Health and Life Sciences Panel report (published in April 1999) referred to the fact that one 'horizontal technology is radically influencing the global development of the health and life sciences – biotechnology'. This report also established that Ireland had the necessary key ingredients to enter into the 'second phase of biotechnological development'. Among the attributes that were identified were:

- A large pharma manufacturing sector;
- A thriving chemical industry;
- Reasonably well-established biotech programmes within Institutes of Technology and universities;
- BRI to manage the commercialisation of research output from Irish universities; and
- The Irish BioIndustry Association – formed by IBEC in January 1998 to meet the needs of the Irish biotech industry.

However, the report also identified ten negative factors that were inhibiting Ireland's progression up the biotech ladder as follows.

1. Irish Government science policy had not been consistent, it had been fragmented, had short-term objectives and had been poorly funded. After Greece, Ireland had the lowest level of government supported R&D, at less than 1 percent of total government expenditure[24].
2. It was determined that the combined Irish government funding of biotech through Enterprise Ireland, BRI, the Health Research Board and Teagasc could not sustain an adequate biotech infrastructure.
3. The overall structure of Irish biotech research programmes was weak. Furthermore, the output was small, the number of top quality biotech research groups was small, those which did exist were not securely funded by Irish money, and few could maintain steady lines of investigation for more than a few years. In summary, the number of world class biotechnologists was too small to sustain a biotech industry.
4. Irish biotech graduates were leaving the country in large numbers.
5. Irish science students were not encouraged or educated to become entrepreneurs.
6. Multinationals in Ireland carried out little significant R&D and virtually no basic R&D principally because the tax environment did not favour multinational R&D.
7. There was little funding for start-up companies and little understanding of the scale of investment required.
8. Irish venture capital funds had little experience of biotech.

24 See 'Executive Summary and Highlights' *Second European Report on S&T Indicators*, 1997.

9. Ireland was not perceived as an international centre of biotech.

10. The regulatory authorities were not sufficiently well resourced to process applications for product approval as rapidly as agencies in the United States and other European countries.

The Panel reiterated their belief that 'a biotechnology infrastructure can be created in Ireland'. However establishing a biotech cluster in Ireland would only be achieved by 'immediate investment, on a realistic scale, in a co-ordinated biotech programme which builds strong links between the universities, industry and agriculture and the financial and service sectors'.

The Panel therefore proposed the implementation of the Irish National Biotechnology Investment Programme comprising five sub-programmes:

1. Biotechnology R&D Programme – to provide technology, knowledge and expertise;
2. Biotechnology Translational Programme – to ensure that the technology and knowledge are commercialised;
3. Biotechnology Start-up Programme – to assist the start-up of indigenous bio-industries; and
4. Biotechnology Inward Investment Programme – to develop multinational R&D programmes in Ireland;
5. National Conversation on Biotechnology – to increase public awareness.

The drive towards a knowledge-based economy and society in Ireland brought with it the recognition that science, technology and mathematics (STM) education was critical to Ireland's future development. To address this issue the ICSTI began a study to benchmark school science, technology and mathematics education in Ireland against international good practice[25]. The study, which included Scotland, Finland, Malaysia and New Zealand as benchmarking countries, did not set out to propose recommendations on the STM education system. Rather it aimed to provide a factual, qualitative and quantitative description of STM in the Irish school system and help to identify those issues that required attention. Following extensive information gathering, consultations and questionnaire completion by education representatives from all five countries, a database was compiled under five categories:

- National education system;
- Curriculum;
- Pupil assessment;
- Teacher recruitment and education; and
- Education practice.

The study found that, in Ireland, the formulation and implementation of educational policy is overseen by government by a process of consensus building. Although this gives a strong sense of ownership, the process constrains policy development and curricular reform. A result of this is that, while the need for scientific and technological literacy is essential in building a knowledge-based society, Ireland is unique in that until recently, science has not been taught at primary level. Only in 1990 was the process of introducing a new science element into the curriculum implemented. Furthermore, Ireland has no assessment of practical work in science which leads to 'an incongruence between the objectives of the science curriculum and the system of assessment'. The report concluded that it is of key importance that the increased emphasis on development of a knowledge-based technology sector is reflected by the education system in the development of effective, modern and meaningful STM education provision in schools.

25 Irish Council for Science, Technology and Innovation (February 2000) *Benchmarking Science, Technology and Mathematics Education in Ireland against International Good Practice.*

In summary, the benchmarking report highlighted three main considerations:

1. A need to develop and implement STM policy on a time-scale that will meet the needs of a rapidly emerging knowledge-based society but at the same time continue to meet individual students long-term needs;

2. A need to recruit, train and retain high quality STM teachers by providing an attractive career path with opportunities for professional development and life-long learning; and

3. A need to change the teaching methods of STM education from a didactic approach to more experiential methods.

With increasing emphasis being placed on biotech through the 1990s, an inevitable curiosity and concern began to emerge among the general public. The ICSTI realised that there was a lack of independently validated and readable information on biotech for consumption by the general public. The Chairing Panel of the National Consultation Debate on Genetically Modified Organisms and the Environment had highlighted this issue previously in July 1999. This Panel recommended that a greater effort be made by the State to inform the general public about developments in modern biotech. It was essential that the information be based on the needs of the people and available in a language understandable to them.

To address this need, a Task Force comprising scientists, clinicians and industrialists was formed by ICSTI. The objectives of the Task Force were to examine the current application of modern biotechnology, to identify and consider certain issues that need to be addressed in a national context and to prepare a report that would take into account scientific, ethical and public concerns about biotech as well as highlighting potential benefits and risks[26]. The report provided information on the benefits of biotech but also noted the need to address public concerns related to its application. These concerns, mainly associated with the use of genetically modified organisms (GMOs) included issues such as antibiotic resistance genes in plants; gene therapy; virus genes in genetically modified plants and crop production. The recommendations from the report have gone some way towards educating the general public about the broad uses of biotech and alleviating concerns about the risks. For example the report recommends that the Irish Medicines Board (IMB) should be responsible for evaluating gene therapy protocols and that the Environmental Protection Agency (EPA) should play a role in regulating gene therapy research. The statement suggesting that there is no evidence for the transfer of intact genes to humans, either from bacteria in the gut or from foodstuffs, may have helped to lessen the fear associated with genetically modified foods.

The report recommends that an information centre should be established for science and technology that will provide information on current and proposed use of GMOs. In addition, the report also supports: informed choice and mandatory labelling of GM foods; that information be made available on applications for the release or marketing of GMOs; that research and clinical trials in gene therapy be regulated and that a fully independent biotech ethics committee be established. If there is to be an increase in the number of students undertaking education and training in biotech, and in the number of well educated people entering biotech careers, a positive attitude towards this science must be engendered amongst all echelons of Irish society.

2.2.4 Third Report of the Expert Group on Future Skills Needs

The Expert Group on Future Skills Needs was formed to develop national strategies to tackle the issue of skill needs, manpower forecasting and education and training for business and to act as the ‘central resource advising government on skills needs’[27]. The investment in R&D in Biotech and ICT by the Irish government since then has been considerable (see below). This was reflected in the third report of the Expert Group which was relatively more focused to the needs of the biotech sector[28]. The 3rd report indicated that in 1999/2000 there were 2,315 Full-Time students (570 Part-Time) and 2,011 Masters students (615 PT) enrolled in relevant courses. However, the general trend is for a reducing percentage of those following full time study to progress immediately to research. Therefore, there is a need to increase the rate of transfer of students from completed under graduate courses to postgraduate courses.

26 (Forfás, 2001) *ICSTI Report on Biotechnology*
27 Mary Harney, July 2001
28 *Responding to Ireland’s Growing Skills Needs.* Third Report of the Expert Group on Future Skill Needs, Forfás, July 2001

It is estimated that the new funding support initiatives will create 245 places for post-doctoral researchers (under the National Development Plan) annually by 2003 and 600 places for postgraduate per annum from 2003. Given existing output figures for PhDs (417 in 1999) across all disciplines, it is estimated that 1,800 postgraduate students will be in receipt of funding in any given year from 2005.

Since a PhD is 3-4 years in duration, a skills gap is likely to emerge. The recommendations of the 3rd report indicate that research should be made more attractive to undergrads. In addition, the international visibility of Irish universities should be increased and the move of researchers to Ireland made as smooth as possible.

The second report of the Expert Group had identified four main areas in Life Sciences where projections of labour demand exceeded projections of supply:

- Chemistry degrees;
- Biological Sciences degrees;
- Chemical and Biological Sciences Sub-degrees; and
- Chemical Engineering.

It recommended the need for a further 200 Biological Sciences, 80 Chemistry and 10 Chemical Engineering places per annum.

A response by the HEA to this request was implemented and is going some way to meeting the projected requirements. Therefore, the Third report recommended that no additional places on Chemistry and Biological Sciences degree programmes should be introduced, provided that existing output is maintained. In addition, due to a combination of changes in industry demand and changes in output, the 3rd report recommended that no intervention was required to increase places in Food Science and Agriculture Science.

2.2.5 Task Force on the Physical Sciences

The *Task Force on the Physical Sciences* was set up in response to the observed fall-off in interest in the study of science at a time when demand for scientific skills was rising. The Task Force observed that the demands of the labour market for these skills must be anticipated and strategically catered for, and a continued supply of the required skills must be guaranteed to ensure ongoing investment in the new technologies[29].

The work of the Task Force clearly identified the fall-off in science study at 2nd level and emerging problems at 3rd level. Low levels of science at primary level were found and while science is widely offered at 2nd level, there are problems. Most importantly, very low levels of student numbers undertaking science subjects at Leaving Certificate level in many schools raises the prospect that it may prove uneconomical for these schools to continue to offer the courses. In terms of the courses that are offered, the Task Force observed low levels of practical work and deficiencies in the facilities available.

However, a very important issue that emerged was that most students did not wish to study science subjects at Leaving Certificate level. This problem was attributed to two factors. First, there is a widespread perception that Physics and Chemistry are particularly difficult subjects in which to score high points. This is a very active disincentive. Further work by the Task Force, building on earlier work by the HEA among others, showed that there is a valid basis for this perception with these subjects showing a lower average return to students in terms of the marks obtained. The second factor is a lack of appreciation by students of the types of careers that are open in science and the rewards that are available. This is in contrast to many related subjects such as medicine where the career-specific training provides a clear career path and the prospect of high rewards.

29 Task Force on the Physical Science (2002) *Report and Recommendations*

The Task Force also identified deficiencies in the Irish science curriculum. It found that it:

- emphasises science education as a preparation for further study, rather than as a broad preparation for citizenship;
- is dominated by historical thinking and out of line with modern ideas, both scientific and pedagogic;
- promotes rote learning and recall of scientific facts, with insufficient emphasis on building higher-order skills;
- is too theoretical, missing opportunities to develop practical and investigative skills; and
- is lacking in relevance to students' own lives and fails to examine the role and contribution of science in society.

In addition, the Task Force identified that there is a particular frustration with the slow pace of curriculum change in science. It also found that there is almost universal support for including practical work as a component in assessment in support of changes in the curriculum. At 3rd level, the Task Force identified recruitment to science and retention both to completion of initial awards and to postgraduate level as key requirements. Ensuring high quality infrastructure was identified as an important factor in this.

The Task Force concluded that Ireland can achieve a world-class system in relation to science education and put forward a strategy based around six areas for action. These areas were identified as:

- Planning and Resources for School Science;
- Equity of Access;
- Teaching and Learning of Science;
- School Curriculum and Assessment;
- Promotion of Science and Careers; and
- Science Education at Third-Level.

The recommendations were that policy should:

- Ensure that science education is addressed in every school plan;
- Provide adequate resources to support practical science in schools;
- Enhance teacher allocation to post-primary schools with low physical sciences enrolments;
- Build school capacity to offer the physical sciences curriculum e.g. extend the number of schools offering Leaving Certificate physical science subjects;
- Establish a virtual learning environment for science;
- Promote innovation and research in the teaching and learning of science;
- Provide incentives for the recruitment and retention of teachers;
- Review pre-service training for primary and post-primary teachers of science;
- Prioritise curriculum reform in science;
- Establish science as a core subject in the lower secondary curriculum;
- Undertake a review of mathematics;
- Ensure equity in grading physical science subjects in the Leaving Certificate;
- Establish an annual forum on science education;
- Establish an integrated, national science awareness programme;
- Promote recruitment to higher education science, engineering and technology;

- Promote access, transition and transfer;
- Promote quality in teaching and learning within undergraduate science, engineering and technology; and
- Provide physical infrastructure to support quality in the teaching and learning environment.

The cost of the actions recommended was estimated at €178 million in capital investment, plus an annual recurrent cost of €66 million. The Task Force also recommended the establishment by Government of a high level *Science and Technology Implementation Group* whose function would be to source the finances and to otherwise ensure the implementation of its proposals. In addition, it recommended that ICSTI should report to Government annually on the state of science educational provision and that the relevant Oireachtas Committee should receive the annual report and be expected to comment on it.

2.2.6 The Role of the Universities

It is obvious that Ireland's universities play a pivotal role in establishing and developing its knowledge-based society. However the role of the university has changed considerably – it is no longer a *'place of light, of liberty and of learning'* (Benjamin Disraeli) but instead a 'big, complex, demanding, competitive business requiring large scale, ongoing investment' (Roger Downer, Chairman, CHIU, 2001).

Prof. Malcolm Skilbeck has investigated the demands on, and expectations of, universities in the emerging knowledge society, economic growth and rising human expectations[30]. This work identifies several forces that have and continue to transform societies and as a result are having a powerful impact on higher education policies. These include:

- Continuing growth in demand for ever higher levels of educational attainment;
- Increased recognition of the economic returns that follow investment in education and research;
- Expanding and shifting frontiers of knowledge;
- Rapid development and society-wide impact of communication and information technologies;
- Economic globalisation and internationalisation; and
- Quest for cohesion, justice and equity in social arrangements.

Universities have and continue to show a readiness to reform to societal changes, but there is some concern that the basic values of the intellectually free quest for knowledge and its diffusion (although still intact) have been put in new contexts and given many different forms.

These changes are pervasive throughout teaching, learning, research, administration and institutional culture and abound in all areas of the university – individual staff, departments, faculties, management and governing bodies and students. Systemic changes are occurring through legislation, policy-making, regulation, performance-targeting, monitoring and funding. Finally, new types of institutions and processes such as virtual institutions and new models of staffing e.g. contract-based, performance-based or entrepreneurial, are commonplace.

Universities are now expected to:

- Provide leadership and service at local, regional, national and global levels;
- Make efficiency gains;
- Maintain standards and high quality with reducing costs; and
- Obtain new sources of funding.

30 Skilbeck, M. (2001) *The University Challenged, A review of International Trends and Issues with Particular Reference to Ireland*

As Skilbeck puts it:

> ‘The university is now at the centre of a vast network of intellectual, social, economic, and cultural relationships, increasingly global in their reach’ (Skilbeck, 2001).

So what can the university-of-today do to meets the challenges of the future? Skilbeck has identified three areas where action is needed, namely the human factor, the functions/activities of an institution, and the university system.

His recommendations include the need for universities to:

- Develop programmes to attract new blood as well as developing the capabilities of existing staff;
- Recognise that students should organise their own learning;
- Create on-campus and virtual environments;
- Develop strategies for life-long learning;
- Increase and diversify sources of university income through sales of services, consultancy, management of intellectual property and entrepreneurial activities;
- Build and strengthen partnerships with other sectors; and
- Be part of a network and not function in isolation.

Traditionally Irish universities have operated on a small scale, with very modest budgets. They have been largely State funded with some additional private resources. As a result Irish universities have been shown to be effective and have experienced growth in enrolments. They have however been afforded some protection. The traditional society of national goal-setting and strategic planning is rapidly being transformed into a modern, knowledge and information-based society. Irish university reform will be a key factor in this transformation.

Skilbeck summarises that Irish universities must:

- Review and appraise their policies, structures, practices and capabilities;
- Reposition themselves as a system and not in isolation;
- Define their missions and strategies;
- Appraise the quality of their research, teaching and services roles;
- Set standards including international benchmarks;
- Broaden and enlarge their student intake (increase the proportion of mature and postgraduate students);
- Adopt more flexible teaching (include part-time study; develop a life-long learning mentality);
- Strengthen links with industry and the community;
- Seek to diversify funding resources; and
- Strengthen their collective capabilities by addressing the balance between competition for resources and co-operation for action.

2.2.7 Associated Issues

Creating the appropriate economic environment, promoting basic research and ensuring that skill needs are met requires an expansive policy approach. In October 2000, the Joint Committee on Education and Science produced a report on the current state of learning in science and related subjects at primary, secondary, tertiary and higher levels and its adequacy for an Ireland competing in the knowledge-based society[31]. Such was the seriousness of the findings and concerns about the strength of science education in Ireland that the committee recommended to Government that it

31 *Science and Technology* Report of the Joint Oireachtas Committee on Education and Science

undertake a major national initiative in Science. In addition, the Joint Committee recommended the formation of an Implementation Commission to include the departments of Education and Science and of Enterprise, Trade and Employment, to drive forward the necessary initiatives.

The report found that there is little or no science being taught at primary level. A one-off investment by the Department of £1 million for training of teachers and £1.7 million for equipment was deemed derisory. At secondary level, about 90% of students study science up to Junior Certificate level. However, there has been a steady decline in numbers continuing thereafter. Chemistry has suffered most with participation by only 10% of students, with Physics at 13.5% and Biology at 42%. In 1999/2000 there was a decline of 3,200 students taking Leaving Certificate science – a fall of 6.5% in one year.

Other findings revealed that one in every three schools did not offer the full range of sciences subjects; science equipment in schools was far from adequate and didactic teaching methods prevailed with limited practical forms of assessment[32]. The Committee concluded that the poor development of science at primary level and the erosion of the science base at secondary level were obstacles to Ireland's ambition of becoming a knowledge-based society. The report stressed that heavy investment at third and fourth level are not enough and therefore equal investment at primary and secondary level was required.

At 3rd level it was noted that the number of science graduates is in decline. Low student demands for science courses means that there are insufficient first preference applicants to match the places on offer. Given the increase in demand for postgraduates in the next five years, there is concern that, in addition to an immediately inevitable fall in the number of postgraduates, numbers will continue to fall due to the relative attractiveness of industry and the poor remuneration for postgraduate research. A glaring exception relative to many other countries is the lack of consideration given to the entry of mature students into further science education.

The Committee outlined several recommendations:

- an assessment of staffing levels in third level science courses should be undertaken to monitor the ability to deliver quality;
- a framework for life-long learning should be implemented;
- training partnerships should be established within industry which would lead to certification;
- postgraduate remuneration should be benchmarked with other countries; and
- public-private partnerships for research should be developed with a target of industry funding 25% of research.

Prior to the publication of the report on Biotechnology by the ICSTI in 2001, the Government established the Inter-Departmental Group on Modern Biotechnology (March 1999). Its formation was prompted by the range of concerns raised by the area of genetic modification. The Government underlined specific areas for the Group's consideration including the dissemination and co-ordination of information on genetic engineering; the need for a biotech ethics committee and future policy and administrative co-ordination on genetic engineering.

The group comprised individuals from the departments of Environment and Local Government; Agriculture, Food and Rural Development; Health and Children as well as representatives from the Food Safety Authority of Ireland, Department of Education and Science, Forfás and Enterprise Ireland. Their recommendations were published in November 2000 and focused mainly on the use of Genetically Modified Organisms (GMOs), the need for compliance with EU legislation and the recommendation that a National Biotechnology Ethics Committee be established under the auspices of the Royal Irish Academy.

Regulatory Framework

There is an extensive body of regulations in Ireland covering biotechnology[33]. The regulatory framework is derived predominantly from EU Directives that have been transposed into domestic legislation and from EU regulations that are directly applicable and legally binding in Member States.

32 At Junior Certificate level, Science-Local Studies has practical assessment, as has Agricultural Science, at Leaving Certificate level.

33 This section is based on information contained on **www.biotechinfo.ie**

Genetically modified organisms (GMOs) are defined as bacteria, viruses, fungi, plants and animals in which genetic material has been altered in a way that does not occur naturally by mating or natural recombination. Regulation of GMOs in Ireland is under the authority of the Environmental Protection Agency (EPA). While the development and use of genetic engineering techniques has brought many useful applications in agriculture, food processing, pharmaceuticals, environmental clean-up and other areas, there are concerns about the potential risks to human health and the environment of GMOs. In response, the EU has passed legislation covering the contained use of GMOs (Directive 90/219/EEC) and deliberate release (Directive 90/220/EEC). Regulations (S. I. No. 345 of 1994) to implement these directives, were made in November 1994, and the EPA was nominated as the competent authority to administer the regulations in Ireland. The commencement date for implementation was 1 January, 1995.

2.3 Developments in Northern Ireland

Northern Ireland (NI) currently does not have a well-defined biotechnology sector. Approximately eight companies in Northern Ireland are truly biotech in nature and are included within the broader ‘life and health technologies’ sector. This latter sector currently consists of 44 companies, employing 3,000 with an annual revenue of £170 million[34]. In the past the sector in Northern Ireland has included various categories of company – medical devices, diagnostics, pharmaceutical, medical packaging, and medical equipment. However the difficulties in establishing a true definition for the sector in Northern Ireland has led to a number of companies being excluded. It could in fact be argued that there are some 80 companies that fall under the ‘life and health technologies’ definition in Northern Ireland.

Several reports, commissioned mostly by Invest Northern Ireland (Invest NI) or its legacy organisations (IDB, IRTU and LEDU) have all indicated that although biotech is very much in its infancy in Northern Ireland there is potential for the sector. In November 1998, Ernst and Young carried out a detailed survey of the sector[35]. Their findings highlighted the need for government to truly recognise that the life and health technologies sector in NI should be prioritised as a sector that has sound potential growth. They recommended that the establishment of an industry-led ‘driver’ was essential to take the sector forward. This ‘driver’ or group would comprise businesses, the two universities, the financial sector, government and the NHS, and would have responsibility for formulating policy, setting objectives, undertaking initiatives, encouraging entrepreneurship and measuring performance.

A further report was conducted to develop previous strategies and to identify growth opportunities for the sector in NI[36]. The approach in this study was to identify and build on areas of research capability and sector infrastructure that will bring competitive advantage to NI and to identify the potential for achieving growth through a combination of inward investment, indigenous growth and joint ventures. Their recommendations focused on the need to exploit the research excellence that exists within the province. Of particular note were the areas of Biomedical Sciences at the University of Ulster (UU), Oncology at Queen’s University Belfast (QUB) as well as various other centres of excellence such as the Northern Ireland Bioengineering Centre (NIBEC) at UU and Queen’s University Environmental and Technology Research Centre (QUESTOR) at QUB.

Other areas that were identified as having competitive advantage were in the pharmaceutical industry, medical devices, telemedicine and bioinformatics, clinical trials and biotech. These strengths were then grouped into 3 categories in which progress could be made:

- Outsource Northern Ireland – contract manufacturing;
- Bio Northern Ireland – biotechnology, oncology research and bioscience research; and
- Med Info Northern Ireland – bioinformatics and telemedicine.

---

34 Source: Invest NI
35 Ernst and Young (1998) *Sector Working Group on Health Technologies*
36 Frontline Consultants 2001 *Health Technologies Sectoral Study*

A major criticism of previous strategies that emerged from the report was that progress of the sector in NI was of a 'stop-start' nature due to the non-commitment of Government funding and a grant culture for finance. However, the sector has progressed well in the last two years. Invest NI have now defined a sector strategy. However, certain issues still need to be addressed. These include:

- **Science Base:** The University of Ulster and Queen's University have both demonstrated a commitment to biomedical research and have also established technology transfer facilities and incentives for academic staff to pursue the commercialisation of research. However, investment in research is considerably lower than in other parts of the UK, and comparisons with the Republic of Ireland would indicate that NI is falling behind. Funding was $40 of government funding for university research per head of population in the Republic of Ireland compared to $25 in NI in 1998, a ratio that has probably moved more in the Republic's favour due to the current substantially increased funding for basic research in the Republic.
- **Weak Entrepreneurial Culture:** Northern Ireland does not have a history of entrepreneurial activity. Continuing focus on role models and education about entrepreneurship will be necessary to foster these skills. Invest NI and the Northern Ireland Centre for Entrepreneurship are addressing this issue.
- **Growing Company Base:** The NI biotech industry is extremely young, but is growing. Despite the encouragement of growth, the danger might exist that the most entrepreneurial scientists at each university have now commercialised their ideas, and that the rate of new company formation could slow down in the near future, although there are no indications yet that the highest point has been reached.
- **Ability to Attract Key Staff:** Northern Ireland currently has a shortage of managers experienced in entrepreneurial ventures. The programs being pursued by NICENT and the visibility of entrepreneurship in Invest NI's corporate plan are hopeful starting points to train the next generation of managers.
- **Availability of Finance:** Prior to 1995, no venture capital existed in NI. Now, a number of resources are in place to provide seed funding in the order of £100,000-£750,000. This will provide the money necessary for the first 1-2 years of a startup. The next stage will require creating funds capable of structuring deals larger than £2 million. However, the risk exists that a number of biotech companies will stagnate due to lack of funding before they are able to attract outside venture funding.
- **Premises and Infrastructure:** Both UU and QUB have incubator facilities to assist biotech startups. The next issues to address are highly practical concerning, e.g. rent agreements and refurbishment costs, with the recognition that many biotech companies cannot agree to a long-term lease.
- **Business Support Services and Large Companies in Related Industries:** Northern Ireland lacks more established companies to provide synergy with its startups. If the 2 larger players, Randox and Norbrook, become more involved in biotech, they could form significant networking relationships and partnerships with small biotech companies. Otherwise, larger companies are unlikely to establish a presence in NI unless they enter into significant joint venturing of collaborations with local biotech companies.
- **Skilled Workforce:** A base of biomedical/biotech programs exists for training scientists within Northern Ireland, many of which have developed with advice and input from industrialists and the public sector. The availability of 'sandwich' degrees means that students spend up to a year in industry and obtain additional qualifications in recognition of their achievements. However, net emigration continues to be a source of competitive disadvantage.
- **Effective Networks:** A Northern Ireland *BioIndustry Association* has been established to represent industry and interface productively with university research.

2.4 Funding for Biotechnology in Ireland

The central role of basic research in biotechnology has been mentioned earlier and is discussed in greater detail in later chapters. The allocation of funding is not a guarantee of good research and certainly is no guarantee that the research will be of commercial value. However, it is clear from international experience that the public provision of funds for research is a central and basic requirement in advance of the development of a dynamic and sustainable biotechnology industry.

The involvement of public money is essential from a number of viewpoints. First, it is well known that the private sector will under-invest in research given the very high risks involved and the difficulty of ensuring that the benefits of the investment accrue fully to the investor. As a result, at least in the early stages, there is a good argument that standard appraisal procedures will lead to under-investment. Second, it is very clear from the way in which the industry has developed to date that public money for research provides a very strong and clear signal to private investors that the government is committed to providing a good location for their investments. As a result, private money is likely to follow public money, provided its allocation is credible. Finally, whether there is an underlying rationality or not, a competition has emerged among governments for the best talent with only the highest payers in with a chance of success. Ireland, if it is to develop as a biotechnology centre, must compete in this 'auction'. Indeed, as shown in subsequent chapters, Ireland needs to be able to attract the very top talent, as it is not an early mover but one of many locations that are attempting to develop biotechnology at this time.

Public funds have been provided in Ireland for research under a number of important programmes. This funding has increased considerably in recent years.

The Programme for Research in Third Level Institutions (PRTLI) was formed in 1999 and has now completed its third round of funding to the order of €320 million. Of this, €142 million is to support research personnel and €178 million is for buildings and equipment. The strategic areas of biotechnology and health sciences received over 50% of this funding. Many of the proposals funded are collaborations involving more than one institution. Projects that received major funding were: a human genomic partnership (€44.8 million); a proposal to establish a national institute for cellular biotechnology (€34.3 million); an Institute of Neuroscience and a National Neuroscience Network (€28 million), and a Centre for Synthesis and Chemical Biology (€34.5 million).

The funds provided by PRTLI to basic research in Ireland have amounted to €605 million up to April, 2002. However, PRTLI funding for new projects has been paused in the 2003 Budget. This raises the possibility that at the time when Science Foundation Ireland (SFI) is providing funds to undertake research, there may be delays in providing essential infrastructure. This has a clear direct impact, but the decision also raises fears that the historical uncertainties that have surrounded research funding have not been eliminated. Consistent long-term funding is an essential requirement to signal Ireland's intent in this area.

The National Development Plan 2000-2006 allocated €2.5 billion for Research, Technology & Innovation Activities in Ireland. Biotechnology was identified as a priority for this investment. As part of the implementation of this plan and in an effort to make Ireland an international centre of excellence for high technology research in Biotechnology and ICT, the Technology Foresight Fund of €646 million was created. SFI was launched in July 2000 to evaluate research projects and to manage and allocate this funding.

As of May 2003, SFI has invested €218 million in research in Ireland. Through its Principal Investigator (PI) Awards and Fellow Awards, SFI is supporting a small number of outstanding researchers and their teams. The awards, of up to €7 million each, provide a major stimulus to basic research in Ireland. Apart from giving Irish-based research scientists the opportunity to conduct a major expansion of research activity, they also bring to Ireland a number of scientists who are recognized internationally as being at the leading international edge of research in their disciplines. SFI has a budget of €646 million, half of which will be allocated to biotechnology.

2.5 Assessment of Ireland's Competitiveness

2.5.1 Innovation

The evidence suggests that, although there are problems to be addressed, it is likely that the global biotechnology industry will grow rapidly into the medium-term. There are indications that Ireland has moved to put in place the foundations necessary for the development of a competitive biotech industry. One result is the decision by Wyeth to invest more than $1 billion to expand its production facilities in Ireland with the construction of a multi-product biopharmaceutical Campus at Grange Castle in Clondalkin. This new Campus will employ 1,300 people at full production, bringing the total Wyeth workforce in Ireland to 3,000 producing pharmaceuticals, infant formula products, and animal vaccines.

However, international comparative research into innovation indicates that there are particular strengths but some weaknesses in terms of the competitive position of Ireland in preparing the environment for the growth of the biotech industry. The EU's Innovation Scoreboard analysed statistical data on 17 indicators in four areas: human resources, knowledge creation, transmission and application of new knowledge, and innovation finance, outputs and markets[37]. Although the scoreboard was not specific to any one sector within a country's economy it could be seen as an indication of the overall progress that a country was making towards instilling an innovative culture and therefore establishing a knowledge-based economy. The results, summarised in Table 2.4, show that Ireland was the EU leader in 2 disciplines, was among the top three in 3 disciplines and above the EU average in a further 3 disciplines.

Table 2.4: Strengths in Ireland's Innovation Performance

	Ireland (%)		EU average (%)
SME's innovating in-house (EU leader)	62.2	1st	44.0
High tech value-added in manufacturing (EU leader)	20.5	1st	8.2
Supply of Science and Engineering graduates (aged 20-29 years)	15.6	3rd	10.4
SME's innovation co-operation	23.2	3rd	11.2
Sales of new-to-market products	8.4	3rd	6.5
Total workforce employed in high-tech services	4.0		3.2
% home internet access	36.0		28.0
% population with tertiary education	22.2		21.2
% total workforce employed in medium-high and high-tech manufacturing	7.3		7.8
Business expenditure on R&D as % GDP	1.03		1.19
Innovation expenditure as % of all turnover in manufacturing	3.3		3.7
New capital raised on stock markets as % GDP	0.9		1.1

Source: EU (2001)

37 European Commission *European Innovation Scoreboard*, September 2001

Such positive results were encouraging, however, the research did reveal major relative weaknesses as shown in Table 2.5.

Table 2.5: Weaknesses in Ireland's Innovation Performance

	Ireland	EU Average
Public R&D expenditure/GDP	0.35	0.66
Life-long Learning	5.2	8.4
EPO high-tech patents/population	13.3	17.9
USPTO high-tech patents/population	3.8	11.1
% venture capital investment/GDP	0.65	1.08

Source: EU (2001)

These findings are important as they coincided with the global downturn of the IT sector and an upsurge of support for the biotech sector in Ireland and other countries.

2.5.2 Research and Commercialisation

It is clear that the research capacity of an economy is the key issue for the long-term development of the biotechnology industry. Forfás examined Ireland's position in relation to the relevant research areas in 2001 and the results are instructive in a number of respects.

The research found that the biotechnology research base in Ireland constituted 368 principal researchers and their teams. However, these are very widely distributed with 85 distinct departments within 12 institutions. Despite the increasing feminisation of the sciences, females make up less than 20% of the research community. The age profile is low with 70% under 45 years with most in their posts for less than 7.5 years. Virtually all hold PhDs or equivalent, but there are very few post-doctoral fellows in the group.

The quality of research, when measured through bibliometric indicators was found to be high and citations have risen markedly over the past decade. Areas of particular excellence were found in:

- Biochemistry and molecular biology;
- Microbiology and chemistry; and
- Veterinary sciences, neurosciences, biotechnology and applied microbiology, and genetics & heredity.

However, past performance is not always a great indicator of current strengths and the allocation of funds is changing. The strong linkage between resources and achievement in the life sciences means that the current significant allocations will change the pattern of outcomes measurable in 5-10 years time.

There are also areas of weakness. These include functional genomics, proteomics, structural biology and genomics, nucleic acid chemistry, transgenics, stem cell research, cell imaging and developmental biology. There were also weaknesses in bioinformatics despite some pockets of expertise. Lack of access to core facilities was found to be a major cause of these weaknesses. It is also worth noting that there were clear weaknesses in the numbers of patents and in publications in industrial journals.

The research identified a number of factors that have resulted in these problems. These include:

- Lack of funds and lack of continuity in funds;
- Lack of an appropriate career structure for post doctoral researchers and very little research for post doctoral persons to undertake in industry;
- High teaching loads, partly because personnel are seldom specialised researchers but mostly lecturers;
- Poorly structured PhD programs with training tied to a single supervisor in a single department;

- Lack of staff to supervise postgraduate research in a number of areas that are key to the development of biotechnology;
- Poor physical infrastructure and lack of access to large-scale facilities;
- A culture that promotes individualism and restricts sharing often leading to poor collaboration and replication. Resources are seen as belonging to departments rather than the university or to the system;
- Overly diverse interests in too many locations preventing the emergence of a critical mass (although with a very few exceptions);
- Emphasis on teaching means that experts are required in all areas and these interests drive research interests, rather than the reverse;
- Variation in leadership quality with little training in management;
- Inappropriate incentives in relation to the generation of IP and commercialisation;
- Insufficient assistance in commercialisation and technology transfer in general; and
- Old fashioned HR structures.

A number of these issues are indicative of experience in general in universities. Of particular relevance regarding the provision of researchers for industry is the lack of cross-departmental training in PhD programs, low levels of co-operation generally, and wide diversification of researchers' interests. The research concluded that there were a number of systems failures, in many respects arising from the long-term lack of adequate funds. However, there is no guarantee that providing extra funds would reverse this in the short or medium-term. Most of the specialist areas of research that will be most important are poorly developed and even where plans were expressed to enhance work in these areas they lack co-ordination. The result is that progress is slow. Much more concentration on a limited number of areas is required and funds need to be allocated according to strategically determined overall needs rather than historical practice or the needs of individual departments. In addition, there is resistance to change.

Ireland has areas of research strength that, if undertaken within a co-ordinated system, would, when allied to the strengths provided by the existing pharmaceutical industry, provide a strong foundation for the development of the industry. Some progress is being made towards achieving this type of co-ordination through the co-operation of a number of universities, state agencies and leading pharmas. One clear message emerging from this is that the co-ordination must exist not only between these agencies but also across discipline boundaries within the universities. That these initiatives are already emerging in Ireland indicates that competitive strengths are present given that, even in the leading clusters discussed above, creating multi-disciplinary research teams and providing students with skill sets that similarly cross traditional boundaries remain difficult and often elusive objectives. As well as combining skill sets within the broader sciences area – for example, courses that combine medical training with scientific research specialities – these skills also need to combine science with management and industry specific skills.

In a sense, the particular positioning of Ireland provides an opportunity for basic cutting-edge research to transmit very quickly through to industry and for the needs of industry leaders to be transmitted into academic research and leading institutions. However, it is generally acknowledged that this linkage between academic research and commercialisation in Ireland remains poorly developed.

The difficulties that exist in commercialisation in Ireland are demonstrated by a study of an Irish start-up operation. The company in question has been in existence in a university setting for about 18 months and is seeking first round funding. The promoters of the venture include:

- A research scientist with over 25 years experience in Ireland and the US, including a number of years experience working on a research team for which the leader was awarded the Nobel Prize in Chemistry;
- A recently graduated PhD researcher; and
- A businessman with a background in science.

The advisory team and directors of the company also include the Nobel Laureate referred to above and a number of notable individuals from, mostly university, research centres in Ireland and the UK. This clearly provides the firm with a strong starting point.

The main intellectual property of the company concerns the identification of catalysts for use in drug development. The role of these catalysts stems from the observation that molecules in a compound can exist as mirror image 'hands' of each other. Each variant can have different effects on the body. For example, in one case, one 'hand' of the molecule acts as a drug for reducing the risk of heart problems while its mirror image acts as a contraceptive. Therefore, the FDA has determined since 1992 that trials must test both hands, and the mixture of both. Increasingly, the products approved for market are single hand versions of the molecules. Various methods have been developed to enable drug developers to comply with this requirement among which is the use of catalysts. The IP of the case company facilitates this in a manner that reduces costs and time lags considerably.

The revenue of the company, following much further research and development, would accrue from the sale or licensing of these catalysts to drug developers and producers or the manufacture and sale of products using these catalysts. However, the company now requires seed funding in the region of €2.5 million to further their development. Ideally, the capital providers to the company would include an Irish VC organisation, an international VC knowledgeable in the sector and Enterprise Ireland. While a business case has been developed in detail, the promoters have been unable to secure this funding to date, although their experience in dealing with Enterprise Ireland has been positive.

The global financial situation throughout the biotech industry in 2002 has not been conducive to the acquisition of capital funding. This cyclical factor is not in any way a unique feature of Ireland in the current climate, but the promoters also perceive a number of structural weaknesses in Ireland. The most notable is that there are very few VC providers in Ireland with significant experience of biotechnology and the funds under their control are very small. This is the case even for funds that have been provided from state development sources. Most importantly, there is little real understanding among local VC providers of the circumstances and likely growth profile of biotech start-ups. This is a key skill deficiency and is further underlined by deficiencies in other areas. In summary, there is little experience or expertise available to assist in making the transfer from the university setting to the next stage of development. In other words, the technology transfer system from a campus to a commercial setting is very weak.

The danger is that, as the cyclical problem with VC begins to unwind, the improvement will not be even but will be much more concentrated in those areas with strong supporting factors. In other words, the VC industry learns from each successive iteration of the cycle and in the next period concentrates its attention on those areas that performed best over the whole of the previous cycle including the downturn. This process means that the strong areas get stronger while the weaker areas face ever more difficult competition. This evolutionary analysis is compatible with both the observation that biotechnology has developed in highly concentrated geographical areas and with the dynamic and self-reinforcing nature of the cluster model that was observed in the leading centres.

This analysis, while indicating areas of strength, gives cause for concern. The system needs reform, not just expansion. However, as in any reform, there will be relative winners and losers and there may be absolute losers also. It remains to be seen however, if inertia in the existing system can resist the changes that are required. There are weaknesses at the stage of basic research but also opportunities for these to be addressed. However, this is only the first stage and even greater problems would appear to lie in terms of Ireland's system for the commercialisation of research.

2.5.3 Ireland's Potential as a Biotech Hub

So, how well is Ireland placed to develop a biotech industry? Many of the required elements have begun to be put in place to provide Ireland with an opportunity in biotechnology. The industry's development is being driven by important and on-going leaps forward in both the basic science and in the development of means for its commercialisation and application. For example, the elucidation of the sequence of the Human Genome has propelled the disciplines of proteomics and genomics to the forefront of Biotechnology research. Bioinformatics is becoming more important as huge amounts of biological data are being produced. Computational biologists, formulation chemists, biomedical engineers as well as degrees in Scientific Law, are just some of the skills that will be required to serve a burgeoning biotech industry.

As the industry develops, demands for new skills are emerging. Although the final structure of the industry remains somewhat uncertain, it is clear that to a considerable extent it will comprise three main product sectors – medicine, agriculture and food ingredients – and will employ people in two main categories – production and research. In addition, each of these activity groups will require supporting skills such as management, marketing, regulation and financing.

While there will continue to be considerable R&D in this area, the experience of the Irish economy and the current situation suggests that Ireland's future in this area will be concentrated in bioprocessing, unless a comprehensive strategic approach to create a research-based cluster is developed. Bioprocessing is a high value-added activity which requires a different, but nonetheless sophisticated, skill set from that required in pure research activities. Somewhat similar arguments can be applied to the large protein medicine sector except that it is less clear that the existing pharmaceutical industry will provide the basis for the development of this sub-sector. Instead, the main drivers may be the availability of the appropriate capital infrastructure and diverse, high-level skills required for the synthesis of the products.

The requirements of genetic engineering are more complex. In both cases, the existing commercial applications are limited and there is considerable R&D required for the foreseeable future. Ireland does not have the strengths to play a leading role in this area at present. In addition, these activities raise important ethical and regulatory issues and it is arguable the Ireland is not an attractive location under these headings either. Similar arguments can be made in respect of agricultural products although there are already important commercial activities developed in respect of these products.

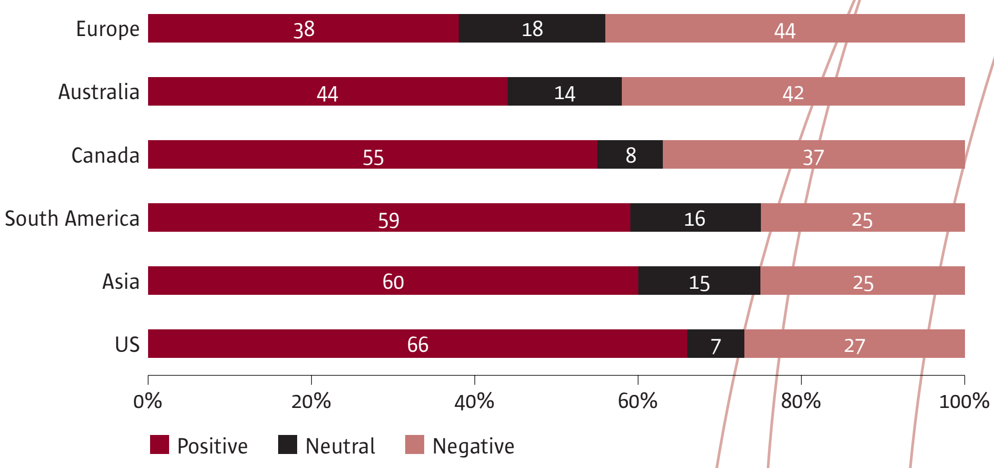
The food ingredients sector is at the stage where there are important commercial applications at present and the prospect of considerable further development in the future. Ireland, through a well developed food sector has an important foundation on which future development can be based. Furthermore, Irish food companies are in strong positions in a number of sectors already. However, as with the R&D requirements of medicine-related products, Ireland is not sufficiently endowed with the basic requirements to develop a leading role in this activity.

This analysis indicates that Ireland is positioned to develop in biotechnology areas where bioprocessing (i.e. the deployment of biotechnology on an industrial scale for commercial production of pharmaceuticals etc.) and commercial applications are currently or soon to be available. A number of the key infrastructural components necessary for the development of biotechnology in Ireland are in place or, through strategic planning and implementation, could be provided rapidly. However, strategic decisions and actions are required in relation to the precise type of industry that is preferred. The provision of a sufficiently large, appropriately skilled workforce, encompassing a wide range of high level skills, will be very important in each case.

One further issue, particularly if FDI is to play an important role, is the extent to which the development of the industry would be welcomed and supported by the public. Ireland like most of Europe has taken a rather negative view of biotechnology, the extent of which is indicated by Figure 1[38].

38 North Carolina State University (2002) *Biotechnology and Humanity at the Crossroads of a New Era*. Report from the Institute for Emerging Issues, Raleigh, NC.

Figure 1: Attitudes to Biotechnology



Source: NCSU (2002)

Figure 1 is based on work undertaken in the US. Respondents to a survey were asked whether they believed that biotechnology's benefits would be greater than the risks involved. Agreement that the benefits outweigh the risks was noted as a positive opinion of biotechnology. Opinion in Europe is certainly negative towards biotechnology, although it is clear that the concerns that give rise to this result are present to different degrees in all areas.

It would be wrong to conclude from this that the development of the industry in Europe as a whole will be greatly restricted. US firms in particular will require access to Europe's resources of skills, infrastructure and research, as well as access to its markets. In addition, there is tension in the US due to the perception of having to deal with an overly bureaucratic FDA. Europe is perceived as more attractive since individuals with industry experience, and thus a greater understanding of the difficulties facing industry, are not precluded from working in regulatory authorities to the same extent as in the US. It is thought that this would lead to a less bureaucratic approach, although all the standards of the FDA would have to be met fully. Concentrating on this at the level of individual states would provide an area for the development of competitiveness. However, positive public support would greatly enhance the attractiveness of individual regions within Europe, a point considered by the Interdepartmental Group on Modern Biotechnology in 1999.

The US is likely to be the pre-eminent source of FDI in biotechnology for the foreseeable future. Given the size of the market and the supporting infrastructure in Europe, much of this FDI is likely to flow towards the EU. Since a lot of it will not be cost driven or responsive to tax competition to the extent that the pharmaceutical industry is – although this will be relevant for some of it – a positive and supporting public will be one element that will determine the ultimate location. This is an important area in competitiveness that will need to be addressed in Ireland.

2.5.4 Overall Assessment

Ireland has a number of strengths but some important weaknesses. The main strengths are:

- Ireland already has critical mass and global presence in production of pharmaceuticals and medical devices;
- There is significant commitment by the Irish Government of financial resources in support of scientific research in Ireland which will have a positive impact on postgraduate output e.g. SFI and PRTLI;
- Pockets of research excellence already exist in some universities and institutions;
- Research and education are increasingly recognising the interface subjects, e.g. bioinformatics;
- Indigenous companies are most likely to emerge successfully in fully functioning clusters; and
- The demand for increased fermentation capacity globally is an opportunity for Ireland.

The principal weaknesses include:

- Ireland is several years behind other countries in Europe and worldwide in biotechnology;
- There is a low quantity of R&D in existing pharma firms;
- Slowness of venture capital investments in biotech exists;
- There is a lack of organised large-scale clinical trials facilities;
- A shortage exists of staff skills in all aspects of IP, in management skills in biotech and in required science backgrounds at all levels;
- Ireland faces the challenge of a declining school population coupled with a poor image of science among students;
- The Irish education and university system must redefine itself and respond to the individual requirements of industry which calls for the specialized application of skills; and
- Research institutes and universities in Central and Eastern European Countries (CEECs) are good and will be a major source of competition following expansion of the EU.

Of course, not all these problems are exclusive to Ireland and the current stage of development presents some opportunities. The dot.com downturn is releasing highly educated workers some of whom have expertise and experience that can be converted to meet needs in biotech and the much enhanced availability of significant research funds provide an opportunity for reform and for problems to be addressed.

3 Analysis of Biotechnology Clusters: Selected International Experience

3.1 Overview of US Clusters

This chapter is based primarily on international consultations that were undertaken with key personnel in the preparation of this report. These were supplemented by published material relating to each area. A full list of these consultations is contained in Appendix 1.

The US biotechnology industry is composed of over 1,450 companies with a combined market capitalisation in recent years in excess of $450 billion[39]. Annual revenues exceed $28 billion from about 130 products that have been commercialised and are growing at almost 11% per annum. With only 50 profitable, publicly-traded companies, the industry is still largely composed of emerging companies with important research activities. R&D expenses in 2001 exceeded $15.5 billion – 55% of revenues – and the combined net losses of firms in the industry was almost $7 billion. However, with over 1,400 proto-products in various stages of clinical development, over 400 of which are in late stage pivotal clinical studies, the industry is expected to grow very rapidly in the medium-term future. In excess of 190,000 people are employed in the US industry. This has been growing at 14-17% annually over the last five years, and is expected to reach around 500,000 by 2010. This growth is indicated by the fact that the industry raised $7.9 billion in finance in 2001. However, the extent of the deterioration in the VC industry and stock market last year is reflected by the fact that this amount was a 76% fall on the $33 billion raised the previous year.

The biotechnology industry has developed in the US over the past 30 years. Growth has been rapid but volatile and is concentrated in a relatively small number of areas. Work at the Brookings Institution has identified nine leading areas of concentration that have emerged[40]. These are Massachusetts (Boston), Los Angeles, New York, Philadelphia, Raleigh-Durham, San Diego, San Francisco, Seattle and Washington/Baltimore. Along with Chicago, these regions account for 84% of biotechnology companies with more than 100 employees in the US.

A number of different explanations have been identified for the leading position of these regions. For example, New York and Philadelphia are the centres of the pharmaceutical industry in the US while Massachusetts (Boston) and San Francisco have gained their leading positions through the existence of excellent research centres. The strengths of areas such as San Diego, Raleigh-Durham (Research Triangle Park, North Carolina) and Seattle lie in their success with commercialisation and the ability to attract venture capital. Washington has emerged primarily due to the location of the federal government and above average receipts of funding, while Los Angeles has attained its position as a result of certain companies, particularly Amgen the largest biotech company, locating their headquarters in the region. These last two areas are clearly special cases, similarly the prior location of the pharmaceutical industry in the first two areas suggests that they too should be considered to be special cases. This leaves five regions where the biotech industry has prospered and has grown from indigenous strengths. Table 3.1 contains an overview of the industry in these centres.

Distinguishing biotech from other sectors is difficult given the way in which the data are presented, nevertheless, there is general agreement that the leading centres by far are Massachusetts (Boston) and San Francisco in terms of existing and emerging biotechnology firms. Among the second wave, the San Diego area is strong in terms of commercialisation while North Carolina, although having a strong presence in research activity, is more dependent on attracting maturing companies to the area.

39 Ernst & Young (2002) *Beyond Borders: the Global Biotechnology Report*

40 Cortright, J. and H. Mayer (2002) *Signs of Life: the Growth of Biotechnology Centres in the U.S.* Washington D.C.: The Brookings Institution Centre on Urban and Metropolitan Policy.

Table 3.1: Regional Concentrations of Biotechnology in the US

	Firms with >100 employees	Share of Market Capitalisation (%, 2001)	Value of VC Investments ($million, 1995-2001)	Value R&D Alliances ($million, 1996-2001)	Number of Patents (1990-99)
Massachusetts (Boston)	33	12.9	1,920	3,924	3,725
San Francisco	46	20.2	3,029	1,205	5,578
San Diego	31	6.0	1,505	1,615	1,865
Raleigh-Durham	13	2.4	380	192	1,027
Seattle	7	3.6	420	579	872
New York	36	12.8	639	1,729	11,810
Philadelphia	10	1.5	457	127	5,202
Los Angeles	18	20.2	180	69	1,835
Washington	23	5.6	85	358	2,753

Source: Cortright and Meyer (2002)

The work in this report in relation to the US concentrates on three of these areas where strong biotech clusters have emerged. These are San Diego, the North Carolina Research Triangle and Massachusetts. Of these, the Massachusetts area is by far the leading cluster and is rivalled in the US only by the San Francisco area. It can be considered to be a mature cluster with a leading role. The other two areas are leaders of the second wave but are quite different in many respects. In summary, the San Diego cluster is remarkable for the number of start-up firms that have emerged and while policy is important in explaining performance, the cluster in North Carolina is the result to a much greater extent of planning and policy decisions stretching back over twenty years.

In all the leading areas, a very important role is attached to the presence of a strong and well-funded research infrastructure. Indeed, in the three areas of close study, this feature emerges as the key element that prompted the emergence of the cluster and that sustains it now. The data in Table 3.2 show the scale and importance of research in these areas.

Table 3.2: Biomedical Research and Funding in Leading US Centres

	Life Scientists (1998)	Employment in R&D	PhDs Granted (1999)	NIH* Funding ($million, 2000)
Massachusetts (Boston)	4,980	11,249	355	500
San Francisco	3,090	9,674	215	473
San Diego	1,430	7,487	82	379
Raleigh-Durham	910	3,356	166	440
Seattle	1,810	5,499	68	379
New York	4,790	14,328	519	763
Philadelphia	1,410	4,539	139	432
Los Angeles	2,450	4,522	218	433
Washington	6,670	7,499	241	679

*Note: *National Institutes of Health*
Source: Cortright and Meyer (2002)

Patents for biotechnology-related discoveries increased from about 5.6% of all US patents in 1995 to 8.8% in 1999. Ownership is divided between private firms and universities and, while private ownership is rising as a proportion of the total, university owned patents remain an important part of the revenues currently being generated. Ownership by pharmaceutical firms accounts for the high proportion of total patents in the New York and Philadelphia regions, but no one firm owns a large proportion of these assets.

All the evidence indicates that the presence of strong research and funding in an area is a prerequisite, but is not a guarantee of success. Cortright and Meyer identified four centres in the US mid-West that received high research funding but where commercialisation was a lot less evident than in the East and West Coast states. Indeed, analysis shows that the industry is considerably more concentrated than the distribution of research funds. This is a direct result of differing relative strengths in commercialisation. This makes the study of San Diego and North Carolina clusters particularly relevant since they have strengths in commercialisation, although these strengths are evident at somewhat different stages of the life cycle of the firms concerned.

3.1.1 Massachusetts

The rapidly evolving nature of the US biotech industry is impacting on both the nature of its current and future workforce and, ultimately, on the competitiveness of companies. It is clearly an industry that is undergoing considerable change. Within this evolving structure, Massachusetts has become a world leader in biotechnology and is rivalled in importance only by the San Francisco Bay area. It has achieved this prominence because of a unique proximity to world class academic institutions with 17 universities within the Greater Boston area, major teaching hospitals and a well-financed, aggressive venture capital community. These components for success are nurtured further by several factors. These include a favourable regulatory environment, a technologically driven entrepreneurial spirit (including amongst leading academics) and the best-educated workforce in the US.

Along with the San Francisco area, Massachusetts has the greatest concentration of biotech activity in the world. Presently, some 300 companies employing 28,000 people state-wide are researching, developing, manufacturing and marketing a wide range of products, including:

- Human Therapeutics;
- Diagnostic Tests;
- Vaccines;
- Artificial Organs;
- Genetic Disease Screening;
- Drug Delivery Systems;
- Agricultural Products; and
- Nutritional Food Ingredients.

Despite their diverse profiles – ranging from publicly quoted 'large-cap' companies to micro-firms operating from rented laboratory space – Massachusetts biotechnology companies hold one thing in common; all apply an advanced understanding of living systems to develop and manufacture commercial products. Currently there are 33 companies with more than 100 employees in the area. The market cap of these companies was in the region of $50 billion in 2001, equal to about 13% of the total capitalisation of the US biotech industry.

Massachusetts is the top recipient of National Institutes for Health (NIH) funding per capita. Additionally, during the period 1995-2000, Boston was the number one city – trailed by New York, San Diego, Philadelphia and Baltimore – in terms of attracting research money from the NIH. There is a definite link between the amount of federal funding the State receives and the success of the commercial biotech sector, although other factors are also important in the commercialisation. This link is indicated by the data in Table 3.3.

Table 3.3: US Federal Research Funding and Commercialisation

	Top 9 Areas	42 Other Areas
NIH funding ($ million, 2000)	812	104
Biotech patents (1990-99)	2,641	263
VC investments ($ million, 1995-2001)	957	27
New Biotech firms (1991-99)	35	3
Biotech firms with 100+ employees	24	2

Note: The identity of the top nine areas was discussed above. The other areas include the remaining 42 urban areas in the top 51 urban areas in the US.
Source: Cortright and Meyer (2002).

The industry is *driven* by basic research and rises and falls according to the amount and quality of basic research done in universities, hospitals and laboratories. Many, if not most, of the biotech products undergoing pre-clinical development, in clinical trials, or already approved and in the market place had their beginnings as federally funded research. The Boston area has 17 universities, three of which would be considered to be in the top rank of research universities in the US. A total of 355 biological sciences PhDs were awarded in 1999 and the area received over 12% of NIH funding to cities in 2000. The value of funding rose by almost 60% in the period 1995-2000 and the area has 10 venture capital firms highly active in the biotechnology sector. The area is a major centre of alliances between biotech and other firms – mostly in the biotech or pharmaceutical sectors – with R&D alliances in excess of $4 billion taking place in the period 1996-2001. It is estimated that the number of employees in R&D in Life Sciences in the area exceeds 11,000 in almost 300 establishments, making it second only to the Greater New York region on this measure.

The biotech industry in Massachusetts can be considered to be maturing in the sense that its leading companies are now expanding outside the area. A number of important issues are driving this development, including different resource requirements experienced by firms as they move towards the production end of the process, and the need for additional locations to reduce costs, remove risks that are associated with a single location and to move into new markets. As a result, companies have become generators of FDI, some of which have located to Europe. Those primarily engaged in the production of synthetic biopharmaceuticals have an industry model in the pharmaceutical industry and expansion has typically been in alliances with the pharmas. However, new issues are arising in other product areas.

A currently important issue is a severe deficit of manufacturing capacity for protein-based therapeutics. There are about 1,000 biotech drugs in all phases of development with around 400 in Phase II/III clinical trials. About 25% of all newly launched medicines, devices and diagnostics are biotechnology derived. Of these, about 150 to 200 are protein therapeutics. The protein therapeutics sector is growing at 15% per annum compared to 7% overall in pharmaceuticals. There are 250 to 400 monoclonal antibody-based products in the pipeline and similar products in the future will require large volumes per patient. Currently, there are 133 marketed biopharmaceuticals, but 10 approved monoclonal antibodies (mAbs) consume 75% of biologics manufacturing capacity[41]. These products represent 20% of sales of biologics and are growing much more rapidly than biologics in total. In addition, the economics of the sector are skewed due to the presence of a large proportion of 'orphan' drugs in this sector that require low volume and flexible manufacturing technologies and processes.

It has been estimated that demand for manufacturing capacity in biologics will exceed current capacity up to 2005 by a factor of four[42]. The reason for this is the high risk that is associated with putting this infrastructure in place with the result that investors have been slow to create capacity in advance of requirements while output cannot grow without the capacity for use in clinical trials as well as production. Global capacity in 2001 was 400,000 litres. This has probably risen by around 100,000 litres during 2002, of which Genetech with 200,000 litres, Biogen with 90,000 and BI with 75,000 litres, were the largest. These firms have been operating at 100% utilisation. Further details on ownership of capacity are shown in Table 3.4.

41 Bamforth, M. (2002) 'Developing an integrated, flexible manufacturing strategy'. Paper presented to BioLogic 2002 Conference.
42 *The State of Biologics Manufacturing*, J.P. Morgan Securities, March 2001

Table 3.4: Biologics Manufacturing Capacity

Company	Capacity (l)	Planned Installation
Amgen	Unknown	
Abbott Labs	12,000	Installing additional 6,000
Baxter		3 sites planned, 2 FDA approved
Biogen	90,000	Additional being developed
Boehringer Ingelheim	75,000	Additional 75,000 in 2003/04
Bristol Myers	10,000	
Centocor	Excess 2,000	For sale
Covance	6,000	
DSM	4,000	
Genetech	200,000	Adding 50,000
Genzyme	8,000	Adding 5,000
Glaxo SmithKline	10,000	
Human Genome	2,000	Additional planned
IDEC Pharmaceuticals	6,000	Additional planned
Imclone	30,000	
Immunex/AHP	62,000	Additional planned
Icos	5,000	
Lonza	17,500	Additional planned
Medarex	Pilot scale	
MedImmune	5,000	
Novartis		New capacity planned
Roche	Capacity for 5 products	

Source: Based on J.P. Morgan (2001) updated for known developments in 2002

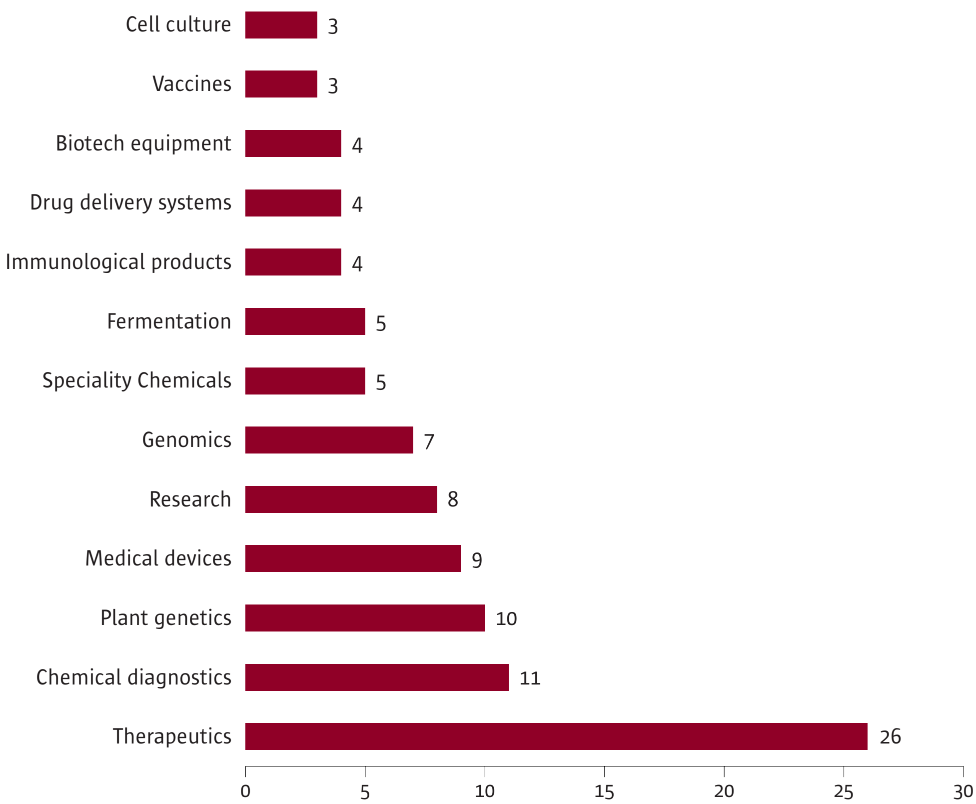
Capacity in 2001 was being completely used with between 150-200 protein therapeutics in clinical development. It is estimated that the current shortage could amount to a production shortfall affecting 50 new therapeutic protein products. This situation will be temporary and there are plans to create considerable capacity such that, at current growth rates, there could be a surplus after 2006, particularly in light of the high attrition rates that accompany product development in this area. Biogen has developed a competitive competency in the development of the reactors that facilitate fermentation. Furthermore, to the extent that providing these services is likely to emerge as a substantial revenue generator in its own right over the next few years, they are likely to be the only company with excess capacity. This is further underlined by the development of 100,000 litres of capacity at its new Danish plant.

3.1.2 Research Triangle, North Carolina

The biotechnology industry in North Carolina is clustered in the Raleigh-Durham-Chapel Hill region, in an area known as the Research Triangle Park (RTP). There are two main sub-sectors of activity; firms in pharmaceuticals (including work in specialised fields such as genomics and bioinformatics) and firms in agricultural or environmental-related biotechnology activities. The industry has strengths in several high-end skill areas, such as basic medical research and agricultural bioscience, along with a strong performance in developing pharmaceutical and packaging products. However, areas such as bio-manufacturing are also important (it should be noted that these activities still require very high levels of skills relative to traditional, "old economy" manufacturing industries). As a result, it has a comprehensive cluster displaying most areas of activity and North Carolina now ranks as the 4th most important US state for the biotech industry after California, Massachusetts and Maryland[43].

There are currently 156 firms that comprise the cluster, amounting to about 11% of core US biotech firms. These employ 17,000 people in the area and generated revenues in the region of $3 billion in 2001. Clinical research is particularly strong accounting for about 50% of firms making NC the leader in this field. The main sub-sectors are illustrated in Figure 2. In addition, there are firms specialising in areas such as gene therapy, bioinformatics, toxicology and proteomics located in RTP.

Figure 2: Main Biotech Firm Activities in RTP (number of firms in each activity)



Several factors have contributed to this previously relatively underdeveloped area, that specialised in tobacco, engineering and textiles, gaining a competitive position in the newly emerging biotechnology industry. These include:

- The location of the Research Triangle Park;
- The early presence of some large pharmaceutical firms;
- The presence of research centres in 3 major universities; and
- The early identification of biotechnology as an industry for the future and the formulation of a comprehensive policy agenda to put the required input in place.

Development in the RTP can be traced back to the building of a research laboratory by Chemstrand in the region in 1959. Two federally-backed research institutions – the National Institute of Environmental Health Sciences and the United States Environmental Protection Agency – stimulated further development in the region. These research facilities created the foundations to attract other businesses that concentrated on environmental research[44]. Partly as a result of its strategic location, the RTP became home to several large

43 Ernst & Young (2002) *Beyond Borders: the Global Biotechnology Report.*

44 Porter, Oct 2001. Clusters of Innovation Initiative – Research Triangle.

pharmaceutical companies. GlaxoSmithKline moved to the RTP and their presence attracted other large pharmaceutical companies, such as Novartis, Bayer and BASF. The attraction to these companies in the RTP was to gain access to local competencies, particularly research talent in agricultural genomics and pharmaceuticals, but other areas of expertise of interest to bio-manufacturing had also emerged.

In 1981, the North Carolina Biotechnology Center was established in the RTP to act as a catalyst for the development of the industry by promoting interaction between individuals from industry academia and public bodies in the area. Like UCSD Connect in San Diego (discussed below), the Centre acts as the conduit between the business community and research institutions, attracting grants and venture capital for creating new biotechnology firms. The centre provides more than 500 grants to 20 North Carolina universities, concentrating on research and innovation[45]. Since the 1990s, funding levels for new start-ups have increased through the availability of venture capital. However, in the 1970s, many firms lacked seed capital. For instance, when Sphinx Pharmaceuticals was established, it was mainly through the efforts of the North Carolina Biotechnology Centre as local capital was difficult to source. Other organisations like Biogen and Covance have benefited directly from funds made available through the centre.

The diversity of companies in the RTP reflects the intellectual resources prevalent in the region. The presence of these industrial and supporting establishments subsequently attracted other supporting businesses, such as, computer and communications businesses, software companies, real estate developers, lawyers, etc., which together, have created a diverse set of skills and talent within the region. Over time, these supporting industries have seen the birth of other leading edge technologies in biotechnology, particularly Bioinformatics.

North Carolina is home to six major research centres[46]. The North Carolina State University's agricultural program supports leading edge research in agricultural genomics, bioinformatics and combinational chemistry. The Duke University Medical Centre, which houses the Duke University Comprehensive Cancer Centre, is one of the most widely recognised medical centres in the US. Along with other research institutions, like the University of North Carolina-Chapel Hill, Duke University has spun off a number of new firms, including Trimeris. In addition, it generates revenues around $77 million each year from licensing fees, royalties, stock dividends and collaborative research funding.

One additional impact of this has been that the availability of contract research work has encouraged the growth of new firms for this purpose in the region and several large companies outsource their research work to relatively small research-based companies[47]. Through processes such as this, the cluster has obtained a dynamic such that development is increasingly driven by industry with policy playing a supportive rather than a leadership role.

3.1.3 San Diego

The biotechnology industry in San Diego is renowned for its research capabilities and for strengths in innovation, product discovery and commercialisation. This has resulted from the convergence of several factors, in particular, the presence of world-class research centres, close interaction between commercial organisations, research institutions and venture capital funds, vibrant small, entrepreneurial companies, and public sector support.

An important catalyst for the emergence of the biotechnology industry was the creation by two UCSD scientists of Hybritech in 1978 to commercialise their discoveries. At that time, moving from academia to private enterprise was not viewed favourably in the academic world, but the firm grew having received VC funding. This move gained collaborative support from other scientists and organisations and gave rise to a distinct characteristic of small companies in the region. As a result, Hybritech became a 'training' ground for many other new start-ups and over time, particularly after its sale to a large pharmaceutical, many of the managers and scientists from Hybritech went on to form companies in their own right. To date, 50 other biotech/pharmaceutical companies have been established through the talent initially fostered in Hybritech as illustrated in Appendix 5.

45 *Clusters of Innovation Initiative: Research Triangle.* Report by Michael Porter in association with Monitor Group, ontheFRONTIER and the Council on Competitiveness: (October, 2001).

46 Research Triangle Institute (1958), National Institute of Environmental Health Sciences (1955), Duke Clinical Research Institute (1969), Duke Comprehensive Cancer Centre (1971), UNC Lineberger Comprehensive Cancer Centre (1975), UNC Comprehensive Centre for Inflammatory Disorders (1999).

47 See case study of Paradigm Genetics in Chapter 4.

The expansion of the biotechnology companies in the region through this manner has created a business environment and culture of cohesion and co-operation among companies for which biotechnology in San Diego is renowned. It is important to note that the nature of competition among research institutions is different due to this collaborative climate.

The success of Hybritech was particularly important in several ways. It highlighted the fact that there were viable commercial rewards in biotechnology, it challenged other scientists and managers to take the risk to seek capital to form companies in their own right and it encouraged the development of entrepreneurship in biotechnology. A strong web of informal networks, supported by more formal organisations has resulted from this structure and, today, San Diego is home to 499 biomedical companies.[48]

The driving force behind the industry's success in San Diego is the intellectual capital inherent in the region. The presence of intellectual capital and skills is no coincidence. San Diego is home to several world-class research institutions that include the University of California San Diego, The Scripps Research Institute, The Salk Institute, The Burham Institute, The Sidney Kimmel Cancer Centre, The Neuroscience Research Institute and The La Jolla Institute of Allergy and Immunology. Collectively, these institutions spend more than $1 billion per year on biomedical research with the National Institute of Health (NIH) providing a large proportion of the funding[49]. Generally, California receives more than 10% of the entire institutes' research grant budget, with San Diego being a bigger recipient than any other county in the state. It is also estimated that between 1995 and 1999, the biotech firms in San Diego received $421 million in venture capital.[50]

Institutions such as UCSD Connect and BIOCOM have played an important role in developing new businesses by strengthening the linkages to institutions and large biotechnology firms, as well as bridging the gap between local government, the regulatory environment and the biotechnology community. UCSD Connect has been effective in fostering links between research talent in universities and the business community, and in providing access to business knowledge and venture capitalists, while BIOCOM concentrates on public policies, business networking and education. Public policy has been very positive toward the needs of the industry, partly as a result of the difficulties that faced San Diego in the early 1990s as an important military centre following the ending of the Cold War. However, the success of the region goes well beyond the impact of public policies, important as these have been in the past.

Interaction between local start-ups and big biotechnology corporations has also been important in attracting inward investment to the area. Large pharmaceutical companies as well as venture capital funds, aware of the sophisticated skill base and talent in the region, have invested considerable sums either directly, or through joint ventures, alliances, contract agreements, and royalty licences. Previous studies show that these large corporations often partner with small companies at the idea-generation stage of a new product, indicating the inter-dependence of firms on the local research capabilities in the region. For example, Elan has invested in 10 biotechnology companies in the San Diego area, Johnson and Johnson's largest dedicated genomics-based drug discovery operations is based in La Jolla, and Novartis is planning to invest $250 million over the next decade in its Genomics Institute based next to the Scripps Research Institute.[51] Not only does this provide finance for smaller companies and contract opportunities, but large corporations also supply sophisticated management skills to the region that aid in continually creating and supporting a class of successful entrepreneurs and biotech firms.

In this respect, San Diego differs from North Carolina. Although research institutes led the development of biotechnology in both regions, in North Carolina large corporations were attracted to the region due to its well developed research site – the RTP – and associated public policy initiatives. In San Diego, the presence of local talent in small, entrepreneurial firms attracted large corporations into the region.

The leadership of institutions such as UCSD, the Scripps Research Institute, and the Salk Institute have shaped the biotechnology industry in San Diego. An orientation towards research in bioscience and technology transfer through local enterprises, has been strengthened over the past decades giving rise to the characteristics that the San Diego biotech landscape embodies today – research capabilities and entrepreneur-led small companies.

48 CHI/PriceWaterhouseCoopers. "2002 Biomedical Industry Highlights, San Diego County". Biomedicine: The Next Wave for Southern California's Economy, 2002.

49 Royston, I. "San Diego's formula for biotech success." Union-Tribune, June 19, 2002

50 Porter, Clusters of Innovative Initiative, San Diego. May 2001, p 73

51 CHI/PriceWaterhouseCoopers. "Big Pharma Banks on San Diego R&D". 2002 Report on California's Biomedical R&D Industry.

Case Study: Commercialisation and Network Organisations in San Diego

Commercialisation as an issue has received considerable attention and the problems that are encountered often appear intractable. The problem centres on the process of taking a promising idea from an academic setting and putting it into a commercial environment in a manner that allows it to develop over time. In a very real sense, this is a move from aiming towards one set of objectives in an environment that promotes those objectives to a setting that lacks the required supports and introduces a new set of often conflicting objectives. In many cases, since the universities or research institutes have a real interest in retaining ownership of the intellectual property, the process has involved these centres developing commercial competencies to aid their researchers in commercialising their products. However, with biotechnology increasingly involving the transfer of the research function to the commercial sector – as distinct from the transfer of the results of research to the commercial sector – an alternative system has also begun to develop. The San Diego area has been particularly successful as a location for commercialisation and the role of network organisations has been particularly important.

UCSD CONNECT was founded in 1985 for the San Diego region to link high-technology and life science entrepreneurs with the resources they need for success, including technology, money, markets, management, partners, and support services. It is part of the University of California, San Diego (UCSD), but is concerned with emerging businesses outside the university rather than the transfer of internal IC to the commercial sector. Its role is to provide targeted, high-level expertise to technology businesses by bringing together individuals in small firms, prominent industry-specific organisations and individuals, and UCSD resources such as the School of Medicine, Jacobs School of Engineering, San Diego Super Computer Center, and the Scripps and Salk Institutes.

Since its inception, it has assisted more than 800 technology companies and its programs serve as a catalyst for the development and exchange of ideas, a forum to explore new business avenues and partnerships, and an opportunity to network with peers. The programs involve active participation by experts from areas of high technology, life sciences, law, accounting, investment banking, marketing, and communications bringing valuable expertise. Management is provided by business professionals and capital providers with a focus on exploring innovative business opportunities. It is entirely self-supporting through membership dues, course fees, and corporate underwriting for specific programs with a sizeable proportion of its funding being provided by the VC industry.

In practical terms, CONNECT addresses management diseconomies of scale and allows small firms to get access to big company management expertise. This involves activities such as putting together presentations for funding, by providing a database for small firms to access local specialised expertise and by organising events. In this way, the benefits of the cluster are as accessible to small firms as to larger firms. The pay-off to the university is primarily not in terms of revenues from licences it holds but rather in the contribution that the organisation makes to the development of technology industries in the area. This in turn attracts leading researchers and funds to the university and enhances its standing.

BIOCOM is a membership and representative organisation for the life sciences industry in the San Diego area that has developed operations in a number of very practical areas that aid commercialisation. Its focus is primarily on established firms but, given the structure of the industry in the San Diego region, it is inevitable that the interests of start-ups attract considerable attention. Its main areas of interest are infrastructure, workforce development in universities and through its own courses, networking and collaboration, and enhancing the buying power of small firms.

BIOCOM's work in the first two areas is of interest to all member firms in the region and the involvement with the universities in designing specialist courses has been particularly important. For firms at the first stage of commercialisation, providing access to other companies and the operation of buying specialist products such as lab equipment in bulk and selling on to members have proven very important in cutting costs. In addition, its courses help specialist researchers who are taking on management functions often for the first time to develop a working knowledge of general and specialist management areas.

3.2 Emerging Competitor Locations

3.2.1 Medicon Valley

Medicon Valley, a cross-border pharmaceutical and biotech cluster comprising greater Copenhagen in Denmark and Skane in Southern Sweden, is home to approximately 60% of the Scandinavian pharmaceutical and medical industry. The two countries are now linked by the Oresund Bridge and the region has set a target of becoming Europe's most attractive bioregion by 2005. Recent estimates indicate that there are 112 biotech companies (80 of which are in Denmark), 71 pharmaceutical companies, 125 medical device companies, 16 clinical (CRO) firms and over 260 others including service suppliers related to the medical sector. The sector employs about 40,000 people in a region with only 3 million inhabitants.

Foreign investment has been very important to the region. In not much over a decade, the region has attracted a considerable contingent of subsidiaries of US and third-country biotechnology companies along with indigenous companies that have remained headquartered there. FDI is encouraged by the allocation of substantial financial resources to supplement an already excellent biotechnological R&D environment. The objective is to make the region surrounding Copenhagen the best possible for biotechnological entrepreneurs as well as for established biotech companies wishing to expand in Europe. In the last 3-4 years, GenMab, Acadia Pharmaceuticals, Maxygen, Structural Bioinformatics and Ciphergen located to Medicon, while Biogen is currently building a new bio-manufacturing facility north of Copenhagen.

It would be wrong however to conclude that large scale investment of public funds has been the over-riding variable. In fact, Government investment has been quite low and has focused on building excellence at the basic research level as opposed to financing start-ups. Instead, the growth of the biotech sector in Medicon is more a direct result of the availability of large amounts of funds from within the Danish medical/health industry. For example, private funding has largely supported the building of 5 Science Parks – 3 in Copenhagen, 1 in Lund and 1 in Malmo. However, government initiatives are relevant, with initiatives such as the Danish Business Development fund providing financial support for start-ups.

There are some weaknesses in terms of the ability of the region to progress to the next stage of growth. There is evidence that there is probably insufficient high quality, innovative research internally when compared to the leading centres in the US, leading to a need to import ideas and technology from other regions. Furthermore, despite the efforts of the networking Medicon Valley Academy to assist knowledge transfer between universities and the private sector, the public sector has not provided sufficient incentives to motivate more academics to enter into business.

Furthermore, there is predicted to be a shortage of suitably qualified personnel since universities in Denmark and Sweden are not producing enough life science graduates. Initiatives have been formulated to address this problem. For example, the DanSing programme run by Medicon universities aims to negotiate for the opportunity to educate 1,000 Singaporean life science graduates in Medicon over five years.

However, the area has managed to produce skills in terms of providing personnel with the work culture that is desired by biotech companies. In particular, despite the reticence of the public sector to provide large incentives, the general stance of public policy is seen to be credible and committed to the development of biotech. This is seen in terms of a clear objective of the type of industry that is required and a strong performance in areas such as the regulatory regime that exists and the development of skills in niche areas such as IP protection and transfer. The clear lesson is that the area that is successful supplies the precise skills that are required by the industry, not the skills that suit the structure of the provider. This demand driven approach, rather than the volume of public funds, has promoted the credibility of policy.

3.2.2 Singapore

The life sciences sector is already quite well established in Singapore with production by local and international companies. Output has been growing rapidly in recent years. Process and production development is present, particularly among pharmaceutical companies who are undertaking clinical development in Singapore. Medical devices make up approximately 23 percent of the industry with companies like Applied Biosystems and Siemens Medical Instruments. Some medical devices companies, such as Becton Dickinson and Biosensors already undertake new product development, process automation and product customisation. However, activity in research and development in molecular biology and biotechnology is still weak with relatively few companies engaged in upstream R&D.

Singapore's physical and scientific infrastructure is well developed and there is a strong long-term government commitment to developing biotechnology. However, to emerge as a vibrant biotechnology hub, Singapore needs to develop beyond manufacturing and become competitive in product discovery and development, pre-clinical and clinical development, and healthcare delivery. Four main weaknesses have been identified:

- a shortage of local researchers and, thus, a heavy dependence on foreign talent;
- a shortfall in the skills and infrastructure required to bring scientific discovery to the commercial arena;
- lack of experience in business and venture capital sectors with biotechnology; and
- lack of manpower with biotech industry experience.

The Economic Development Board (EDB) has overall responsibility for the development of industry in Singapore. The EDB's blueprint, called Industry 21 (or I 21) is specifically targeted at developing knowledge-driven industries placing a strong emphasis on technology, innovation and the development of skills and capabilities. This is aided by a set of policies to encourage multi-national corporations to anchor more of their key knowledge-intensive activities in Singapore. The overall goal is for Singapore to be a leading centre of competence in knowledge-driven activities and a choice location for company headquarters, with responsibilities for product and capability charters.

Over the next 10 years, I 21 is anticipated to account for 40% of Singapore's annual GDP and create 20,000-25,000 jobs every year. Of these, manufacturing and exportable services are expected to contribute 25% and 15% of GDP respectively. The key industry sectors that are being targeted to achieve this are:

- Electronics;
- Chemicals;
- Engineering;
- Life Sciences;
- Education;
- Healthcare;
- Logistics; and
- Communications and Media.

Singapore has stated its strategic intent to develop as a hub for Biotechnology. Policy in relation to the development of biotechnology in Singapore could be described as attempting to leap from what is currently a mostly production-based sector to a leading cluster. This is high risk but the belief is that an incremental approach will not work and would consign Singapore to growing lower value production industries. In developing biotechnology, the EDB is joined by the National Science and Technology Board (NSTB), which has formed the Biomedical Research Council, to co-ordinate and fund biomedical research in the public sector. The policy approach that has been developed builds on the existing strengths through four sets of initiatives:

1. Initiatives to ensure that there is a comprehensive regulatory infrastructure to support biotechnology activities. For example, with a view to increasing research and development in the Life Sciences industry, Singapore is concentrating on developing its own capability in drug evaluation so as to support the registration of new pharmaceutical and biotechnology products not previously approved in other countries. This is being undertaken by the Centre for Drug Evaluation and the National Pharmaceutical Administration. The intention is that this will help bridge the gap between Singapore's existing strengths in manufacturing and the higher value-added research activities;
2. The encouragement of industrial collaborations based on the recognition that biotechnology requires strong ties and collaborations between industry and a number of research institutes that have been set up to support the R&D activities of existing companies. Examples include the Institute of Molecular and Cell Biology set up in collaboration with Glaxo Wellcome and the Bioprocessing Technology Center, a joint venture with Genset;
3. Initiatives to attract talent to work in the industry. This has been a long standing element in the policy approach of the Economic Development Board in many industries. Currently about 70% of researchers at the Institute of Molecular and Cell Biology come from outside Singapore; and
4. Concentration on developing a vibrant venture capital industry to fund R&D efforts through to commercialisation. The EDB and NSTB have established a joint venture investment company – Life Sciences Investments – to make selective, direct equity investments in projects with industry. This initiative is also designed to promote the spin off of companies from the local research institutes. The EDB will invest (up to 10% of the firm's equity) in a particular company and when the company is due to expand, EDB suggests that they locate in Singapore. Venture Capital companies in Singapore – 30 of which focus on Biomed – can receive funding from the EDB.

Particular attention has focused on skills development. Interest in science has always been strong but the policy is designed to alter perceptions away from applied sciences to more research-oriented interests and skills. Overall policy is to integrate life sciences into educational programmes at all levels with the result that there has been a 50% increase in the number of university students enrolled in life sciences since 1999. Various other initiatives at primary and secondary level exist. At university level the National Science Scholarship effectively pays PhD students while at university abroad. It guarantees employment for a set period on their return, but with the requirement that recipients must return to Singapore to fulfil 'bonding' requirements at a relevant research institute, university, hospital or industry. Funding initiatives in this area amount to approximately $1 billion over five years. Other initiatives include the Biomedical Sciences Manpower Advisory Committee, which predict workforce needs and the Biomedical Research Council, which actively identifies and recruits foreign talent.

Given the importance of research and development in biotechnology, attention has been particularly focused on promoting technology transfer to and from the universities and the various research institutes. The Agency for Science Technology and Research (A*STAR) was established in 1991 with the responsibility of raising the level of science and technology in Singapore and is currently implementing the 2005 plan with a budget of $7 billion. This includes managing university intellectual property, technology licensing and the formation of spin-off companies and venture development. It also provides early stage technology transfer and seed capital to new spin-off companies. Senior industry researchers and managers can also be appointed to undertake part-time R&D work in the University. Research institutes have an in-house patent office, which concentrates on technology transfer. A series of high profile awards are presented to individual researchers involved in commercialisation.

A key strength is that the regulatory framework has kept pace with developments in technology and there is a good manufacturing base. Singapore has also developed its legislation in relation to issues such as stem cell research in a relatively liberal manner that makes it attractive as a location to companies in this area[52]. IP protection legislation has also been strengthened.

52 See 'Send in the Clones', *Economist*, August 22, 2002

The sector has grown quickly as a result of public policies and incentives but problems are beginning to appear. It is likely to take about 5 years to recruit and establish a sustainable research base and there is a danger that these world-class recruits might use Singapore as a stepping stone from China to the US, Europe and Australia. This makes the development of local talent even more important if the biomedical initiative is to be sustained.

Singapore has made a clear commitment to the industry it intends to develop and has placed significant funds to this end. Policy accepts that the economy will lose many of the production jobs that are currently located in the country and has been adjusted to replace these with higher value-added activities. However, the risks involved are great.

3.2.3 Scotland

Scotland currently has 68 biotechnology companies, 25% of the UK's total, employing about 11,000 people. Most are relatively small with average employment below 50, although the merger of Dundee-based Shield Diagnostics and the Norwegian company Axis Biochemicals created one of the UK's largest medical diagnostics companies.

Scotland has some important initial strengths in the biotechnology area as a result of the strength of research, particularly into cancer in Dundee and in genetics in the Roslin Institute in Edinburgh. The science base is particularly strong in the universities. With 9% of the UK's population, Scottish universities produce 17% of the UK's honours graduates and 18% of postgraduates in the life sciences. Research is also concentrated in some of the key disciplines involved in biotech, including genetics, molecular and cellular biology and bioinformatics.

In recent years, the number of core biotechnology companies in Scotland's biotechnology industry has grown. Policy initially concentrated on attracting in foreign industry, initially targeting England's cluster of indigenous firms around the Cambridge area. This policy has been reviewed and the importance of indigenous development and niche strengths is being stressed. The problem was that it was often unclear if small companies had the resources to develop the technologies they were researching. As a result, policy in relation to FDI has increasingly targeted the larger firms with proven technologies and an ability to form collaborative efforts. Recent FDI includes the US company Viragen, who cited the availability of highly trained staff as one of the main reasons for locating at Pentland Science Park near Edinburgh. In addition, a new company (Pantherix), has invested at the West of Scotland Science Park in Glasgow to develop the next generation of antibiotics.

In addition to the fundamental research strengths, there is a rapidly increasing network of science parks and increasing support from national and local enterprise companies. Work is advanced at Scotland's first dedicated bio-manufacturing centre in Midlothian, near Edinburgh. The BioCampus, a £100 million flagship initiative, will have space for up to 10 firms and aims to create up to 900 high value jobs. A skilled workforce is required to sustain growth. Responding directly to industry feedback, a pre-recruitment initiative was launched in January 2001. National and International networks have also been created.

Launched in August, 2001, the Scottish Executive's first integrated Science Strategy identifies five key objectives:

1. Maintaining a strong science base;
2. Increasing the effective exploitation of scientific research;
3. Ensuring that enough people study science to meet the future needs of Scotland;
4. Promoting the awareness, appreciation and understanding of science across society; and
5. Ensuring the effective use of scientific evidence in policy formulation and resource allocation by government.

Targets have been set for policy that include doubling the number of biotech companies and support & supply organisations and doubling employment to 24,000. To assist in achieving this growth, strategy focuses on 3 key areas:

1. Building critical mass, through new firm formation, foreign direct investment and engaging companies which are not currently in the cluster;
2. Improving performance to strengthen skills and compete internationally; and
3. Strengthening local and international networks.

Policy intervention is concentrated in areas such as commercialising research, improving access to finance for start-ups, improving skills and strengthening networks. Overall, the main focus of policy has shifted away from targeting FDI, although it will certainly be accepted but is seen as a bonus, towards the longer-term objectives of developing indigenous strengths. In this respect, niche policy interventions to encourage spin-offs and commercialisation are being developed. There has been some success in this respect and the benefits have gone beyond the employment created.

Scotland was a pioneer in biotechnology when researchers there demonstrated in 1987 the feasibility of using new technologies to create transgenic animals that would produce human proteins in their milk. Due to restrictions at the time on public institutes owning equity in spin-outs, an independent organisation was set up to commercialise the technology. Licences to Roslin Institute's cloning technology were subsequently granted to this entity and to a new start-up company created in 1998, in which the Roslin Institute was a joint shareholder with venture capital provider 3i. This provided an influx of £6 million into research and ensured that the research team that pioneered the technology remained central to its further development. When the company was bought in 1999, by the US biotech company Geron, the deal provided £12.5 million funding for research over the next 5 years.

However, the experience is that the creation of spin-out companies is demanding and costly. Furthermore, the number of individuals in the UK with the necessary commercial expertise is small and this may be a limiting factor in the development of the Scottish biotech industry, at least in the short-term. Another limitation is the small number of venture capital providers in the UK with sufficient expertise in biotechnology.

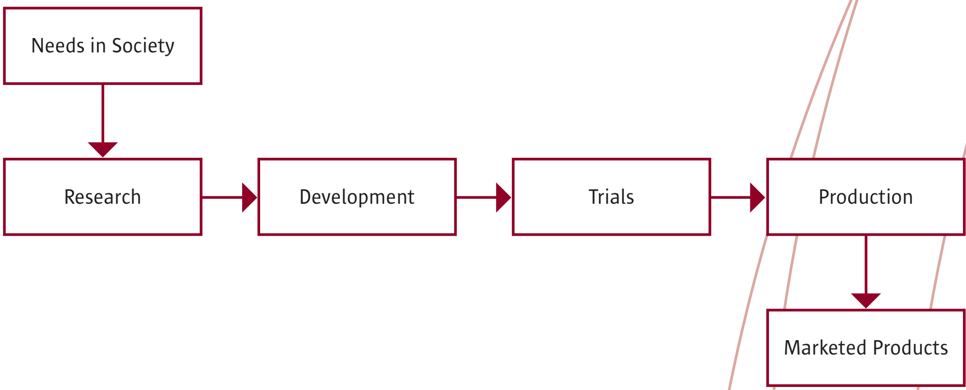
The experience of Scotland indicates that reliance on FDI is an unreliable way to develop a wealth creating biotech industry. The economy has some very important strengths in basic research and a proactive policy environment. However, there are also some important weaknesses in niche areas of expertise and in VC that suggest that development will be a slow process. Policy appears committed to the indigenous development of the industry supplemented by FDI where the incoming firms have proven capabilities and strengths.

3.3 Industry Dynamics in Clusters

The biotechnology industry as it has developed, is not a stand-alone sector and what is most developed to date is a biopharmaceutical industry, in the sense that some basic research has led to synthetic products after a prolonged period of clinical trials. For the most part, these products have been brought to market by the established pharmaceutical firms or, in a small number of cases, biotechnology companies working in collaboration with pharmaceutical firms have delivered them. However, it would be wrong to suggest that the term biotechnology does not have a meaning as a description of an increasingly important industrial sector. There are firms that should be termed biotechnology, and there are processes and technologies that amount to biotechnology. These are distinguishable from the traditional approaches to medicine and other chemical-based industries.

One way to visualise the interaction of these firms as part of a set of processes is to see biotechnology as a continuum as shown in Figure 3. At one extreme of the continuum is the observation that there are needs in society. At the other extreme of the continuum, there are products and services to meet these needs.

Figure 3: The Biotechnology Industry as a Continuum



Towards one extreme is basic research followed at various stages by technology transfer, development, commercialisation, product development, production and marketing. Depending on the stage of progress along this continuum, various supporting factors and services, such as the university system at the early stage, agencies to facilitate technology transfer, the training and education system and venture capital, play their part in ensuring that all elements are present.

It is tempting to understand this continuum as a description of the progress over time from basic research of a new area through trial to final product. However, this is not really an accurate description of what may occur except in the case of biopharmaceutical products. Rather, this continuum can be read as a snapshot at a particular time of a comprehensive set of biotechnology firms and activities that describe a biotechnology industry. Although each product and service will have undergone its own process of development, these will vary and different types of products do not fit neatly in terms of progressing along this continuum. For example, many firms will specialise in niche research activities and services for this stage. The Case Study of Paradigm Genetics provides one such example.

It is still far from clear exactly what type of industrial structure will emerge in proteomics or customised medicine. While the big pharmaceutical companies are important in biopharmaceuticals, their business model is not necessarily optimal for these areas. Looking even further ahead, it is difficult to say whether it will make economic sense for individual firms or collaborations to take genetic research through to production, or to exist at a stage along the continuum, supply their services and pass the information along, having extracted value. What this means is that it is unclear if the biotechnology industry will be similar to the pharmaceutical industry even though the first products will follow similar development paths.

In developed clusters virtually all stages of this continuum are present. Where this happens it is certainly the case that the dynamic nature of the cluster can be identified. This shows that the large numbers of suppliers and demanders of both products, services and labour providers, which are located within the cluster, can reduce transaction costs. Furthermore, this can be achieved to the extent that the savings achieved outweigh the additional costs that may exist from the need to compete for a presence in the cluster. In this way, there is conferring of a competitive gain, although of itself, this is insufficient to explain the extent of agglomeration that is observed.

Another cluster approach emphasises the possibility of increasing returns to scale playing a key role in industries where information is a key input or where risk is important. The conclusion from models based on this assumption is that once a region has gained a lead, however slight, in a sector, due to some difference in starting conditions, it can build on this to gain an unassailable lead. This idea gains further credence when cycles exist in the economy. In effect, a downturn will cause decision-makers with control over resources to reallocate them towards stronger areas to reduce risk. In doing this, there is a process of learning that reinforces the increasing returns.

Increasing returns also mean that it cannot be assumed that the wealth creating effect of the leading areas will just flow out to other areas. This suggests that there will be an important role for policy to bridge the gap and that this policy must be designed and implemented in a manner that overcomes the risk that is perceived by decision makers when considering an investment outside the cluster. This idea is relevant to a number of areas in analysing the development of biotechnology.

Case Study: Paradigm Genetics, Inc., RTP, North Carolina

Paradigm Genetics was founded with the goal of industrialising gene function discovery with a particular concentration in agricultural biotechnology. The company is also active in human medicine. As such, its activities are designed to provide input primarily at the research and early development stages of processes that may eventually generate revenue-earning products. Thus, it is mainly positioned, in terms of the industry continuum, towards the research end and its revenue earning activity will remain highly skilled, as distinct from the production activity of biopharmaceutical products.

Its main assets are undoubtedly the very high intellectual capital of its staff but this has been built upon by a valuable portfolio of research partnerships – including major players such as Bayer and Monsanto – and the development of market competitive competencies in areas such as information management. The firm employs about 200 people of whom 25% hold PhDs. If a part of the firm that is engaged in production is separated, the proportion of PhDs is higher. As such, being part of a biotechnology cluster is seen as vital as is being close to a source for the output of highly skilled personnel. Competition to hold onto staff is also intense but this is addressed through ensuring that the work is at the cutting edge of research. As a result, the benefits of being part of this cluster outweigh the problems this creates.

Being highly dependent on the vibrancy of research rather then production, the business is vulnerable to downturns in the volatile biotech industry and the current downturn has led to restructuring and a refocusing of the business towards the revenue earning elements. Revenues for the year ended 2003 are projected at $28 million and are projected to grow at 20 to 25% per annum thereafter. However, projected expenses in the year ended 2003 are $35 million growing at 10% per annum thereafter. The company is undoubtedly in a transition stage as it must move from the start up stage to a higher growth stage in order to be able to generate the funds that will further its continued development.

Paradigm's strategy is to build on integrated sets of profiling technologies to discover biomarkers for improved drug development success. The firm's core expertise is in transcript profiling. As a promising product or process moves along the research path, this develops from genetic transcript profiling (genes) to metabolomics (the interactions of proteins and vitamins in cells) to pathobiology (organs) and finally patient profiling. In essence, this captures the leap forward that biotechnology implies over chemical research into disease treatment since the starting place is the body rather than the chemical. However, the key to the successful implementation of these processes is data integration at and between every stage. From this, Paradigm has developed leading competencies in informatics and has built a knowledge base in data integration. This has developed into a leading revenue generator as the firm engages in research partnerships with product developers and is an important element in future strategy given the vital requirement for the pharmaceutical industry to improve its drug discovery competency.

There are clear reasons to desire the emergence of a dynamic cluster. However, it may be that this comprehensive cluster will be the exception rather than the rule for those areas and regions that are hoping to develop a competency in biotechnology but who are not in the first wave. The fact is that at the moment about 200 separate regions worldwide are independently attempting to implement policy initiatives to develop this competency. This suggests that late-comers to the industry, unless they have identified some overwhelmingly important competitive advantage, may be better advised to adopt a niche-based approach to development. This would involve a number of stages.

The first is to identify what current competitive factors could lead the region to competitively develop at some stage along the spectrum. A good example is the observation that the presence of the pharmaceutical industry in Ireland may mean that Ireland has the basis upon which to develop productive capacity for biotechnology products (bioprocessing). However, this as an approach has its drawbacks given that the value-added at this stage of the development is less than that at the research end of the spectrum; nevertheless, it is still a high-value activity. If Ireland were to develop closer to the research end, it is clear that this would require major investment in attracting world class researchers (‘stars’) to Ireland. A second potential problem with this approach arises with the very high risks that are associated with the research.

The creation of a successful biotechnology cluster is critically dependent on the availability of extremely high levels of scientific skills; hence the fact that first class research scientists, or ‘stars’, are a prerequisite. In contrast, bioprocessing, while still requiring very good scientists, will require a broader, more diverse albeit still high-level range of skills. For example, there will be a requirement for ICT, legal (regulatory affairs), financial and marketing expertise. It should be noted that the level of scientific expertise required to operate a bioprocessing facility is very high due to the delicate nature of the bio-chemical processes involved.

However, if a dynamic self-reproducing cluster or community is created then the initial impact of the funds leading to a spin-off is likely to attract, through reputation and signalling, more funding perhaps from the private sector and more researchers. However, this is not only high risk but is unlikely to occur within a period of less than 15-20 years.

3.4 Role of Policy and Supporting Sectors

Development of a biotechnology cluster is an extremely long-term prospect whether driven by policy or organic growth. The leading centres trace their development back 20 years or more and are still only in the early stages of development with very few actual products in full-scale production. This review of leading and emerging biotechnology centres has identified important supporting sectors for biotechnology and a number of key areas for policy.

Core research expertise is by far the most important requirement for the growth of an industry in an area. This is demonstrated by all the successful sectors and is a key area for policy development in emerging areas. This remains the case even when the main source of new research is no longer the local university system. Over time, the story of biotechnology has been of research activity leaving the universities and moving into firms. This is quite different from the idea of technology transfer as usually envisaged, although this remains important at the early stages of development. These centres continue to develop skills and are a strong signalling device attracting skills and capital to an area. In this way, they remain the core of the clusters. In this respect, conscious efforts and long-term commitment from the government can play a key role in strengthening the biotechnology industry. Dedicated funding contributes substantially to the research centres’ funding needs.

An important issue is the recognition that investment in basic research cannot be justified using standard evaluation techniques even when these are applied from the point of view of society. The payoff is extremely long-term and arises from factors that are very intangible and non-marketed. Successful regions have developed mechanisms to overcome this problem. The support for other institutions to create the required linkages to the business community and to advocate public policy, adds to the robustness of the biotechnology environment and to its competitiveness. However, the key to enabling successful institutions is not only the presence of scientists to facilitate the studies, but also of leaders of these educational institutions to build the vision and strategy to transform the educational environment in biotechnology.

Different regions demonstrate different areas of strengths around this core. For example, in San Diego the success of biotechnology has relied on a number of key developments. Most important has been the development of key areas of talent over time. While the basic core competencies have been in existence for a long period, it was a conscious shift in educational focus to research in bioscience that paved the way for this. There is a strong culture of co-operation in the region between academia and the business community, and among firms. Other regions have tried to copy this culture. This close interaction creates mutual benefits and enables technology transfer that continues to shape their industry favourably. As an industry grows, it attracts other support services specialising in biotechnology, such as software developers, real estate developers, suppliers, and lawyers, to support both local start-ups and corporations. This attracts venture capital, which acts as a catalyst for the growth of more firms, rooted in commercialising new products and drugs.

The evidence indicates that the biotechnology industry displays two distinct types of industry models[53]:

1. A sector specialising in knowledge-intensive clusters; and
2. A sector specialising in production processes or *bioprocessing*[54].

Both models require different skill levels, with the former requiring intellectual assets, in particular successful scientists, key business leaders, and local talent whereas the latter requires a broader, more diverse albeit still high-level, skill base. In addition to scientists, there will be a requirement for ICT, legal, financial and marketing expertise. It should also be noted that the level of scientific expertise required to operate a bioprocessing facility is extremely high due to the delicate nature of the bio-chemical processes involved. In knowledge-intensive clusters, well-recognised research institutes are important to attract the right mix of skills and organisations. Firms at the research end of the activity are highly dependent on top quality researchers. High skill levels remain important at development stages but the number of jobs at these stages is quite small in comparison with the level of investment that is required. A much different skill set is required at later stages and the successful regions have developed a range of education and training courses to supply these skills. UCSD, San Diego State University, the Scripps Research Institute and the Salk Institute are among several institutions that offer courses in bioscience at multiple levels. The courses offered vary to equip students with the skills to cater for the differing demands and needs of the industry in the region.

Collaboration between research centres and organisations are key to enabling technology transfer. In both of the models, a key component is the availability of funding – either to create development sites and facilities to attract multi-nationals, or to promote local start-ups, and support research efforts. This is often obtained from a combination of sources; government grants, venture capital or IPOs. The government also plays a key role in other aspects; being responsive with legislative and policy issues, and fostering links between the business community and institutions. Independent bodies can assist in filling this gap. However, a more in-depth study is required to determine how the nature of particular types of legislative issues has been successful in driving development in the industry.

A sector specialising in leading technologies bases its competitive advantage on local talent. Small entrepreneurial companies can serve as a research arm for large corporations through research contracts, joint ventures, alliances, partnerships, etc. A sector concentrating on its bioprocessing base, on the other hand, would draw its competitive advantage through cost and quality.

The growing interaction between business organisations and educational institutions is seen in a programme designed by Biogen at the Wake Community College. Developed with the assistance of the North Carolina Biotechnology Centre, the programme allows students at the college to train with Biogen, in partial fulfilment towards an associate degree. This collaborative effort between educational institutes benefits both groups. The students obtain relevant hands-on training through job inductions, while the organisations ensure relevant skills are developed further in the cluster.

The main difficulty encountered in terms of skills is often not shortages of scientific skills but deficiencies in specialised areas such as regulation and management. Joint ventures are often pursued to access these skills. Following on, the greatest skill shortage is in terms of ability to work in a biotech environment – i.e. work experience. Conversion courses are being developed to overcome this. A key feature is the availability of niche skills. The difference this makes is demonstrated not only by the main centres but also by differences between Scotland and Denmark, discussed in Section 3.2.

All successful areas emphasise the importance of a biotech community and a high standard of living. Networking organisations are a very important feature of the successful localities and undertake a very broad range of activities including close collaboration with universities. These networks perform very important functions, the most important being to act in enhancing the perception of a community and providing assistance in commercialisation. Most biotech firms are deeply rooted

53 This reference framework is developed more fully in Chapter 4.

54 The deployment of any of a range of biotechnologies on an industrial scale for various stages of the commercial production of bio-products e.g. culturing cells for bulk synthesis, separation and purification.

in their areas and do not foresee future movement. However, this may change as production becomes a more important activity.

Policy initiatives have been very important in all areas. The core features of these initiatives are the early identification of the industry and its central requirements, and large-scale funding of basic research and scientific training. In addition, the RTP experience has shown the success of:

- Reallocating funds toward the industry, for example, the use of federal tobacco industry settlement funds to finance the expansion of biotech;
- Intensive study to gain a precise and ongoing understanding of the needs of biotech, particularly in relation to funding;
- Recognition and provision of the infrastructure and facilities required;
- Promotion of networking and trade associations;
- Targeted provisions in tax policy to serve the industry;
- Development of research parks and incubators;
- Promotion of commercialisation and business development initiatives; and
- Targeted workforce development programmes.

Consistent government support has contributed significantly to the development of the industry over the last few decades. Government intervention has been particularly helpful in aligning three components; links with the private sector, shaping legislation to create a favourable environment and providing grants. Co-operation between government and the private sector has been strengthened in all areas of policy response. In addition there has been the creation of a suitable legislative climate for the development of this industry. This has been most obviously demonstrated in North Carolina. These include, the creation of the Research Triangle Park, the provision of R&D funding, the creation of supporting organisations, such as the North Carolina Biotechnology Centre and by promoting policies and legislation that respond positively to the needs of biotech firms e.g. tax credits for angel and seed investors. The Centre also provides recommendations on policy and legislative issues to shape the regulatory environment and changes have been made to the previously complicated regulatory environment that existed in the region in the 1990s.

These findings indicate that biotechnology, as it has developed to date and is expected to develop, should not be equated with the IT industry and it remains unclear to what extent it will develop along the lines of the pharmaceutical and healthcare industries. The evidence is that the biopharmaceutical sector will eventually form along these lines but this is only the first element of the industry to reach production. The biotech industry will continue to grow into the future but the emphasis for most biotechs to achieve growth is not on the blockbuster product as is the case in pharmaceuticals and no one expects that a single big breakthrough is imminent. However, there is a very widespread belief that the industry is in its infancy and will continue to grow for many years, although the growth path remains uncertain.

The analysis shows that success of the industry depends not solely on one component or another, but on the alignment of many factors. These include including human expertise, a conducive legislative environment, availability of capital support from various non-commercial institutions and collaborative effort between private enterprises and institutions to enable effective technology transfer. Successful biotechnology clusters derive their competitive advantage from the alignment of these four key components:

a) intellectual capital;

b) a collaborative culture or formal networks that promote interaction between the business and research communities;

c) access to finance; and

d) Government support.

Coupled with the right support through government support and funding from grants and venture capital, research institutions, small entrepreneur-led companies and the wider business community will drive performance in the region.

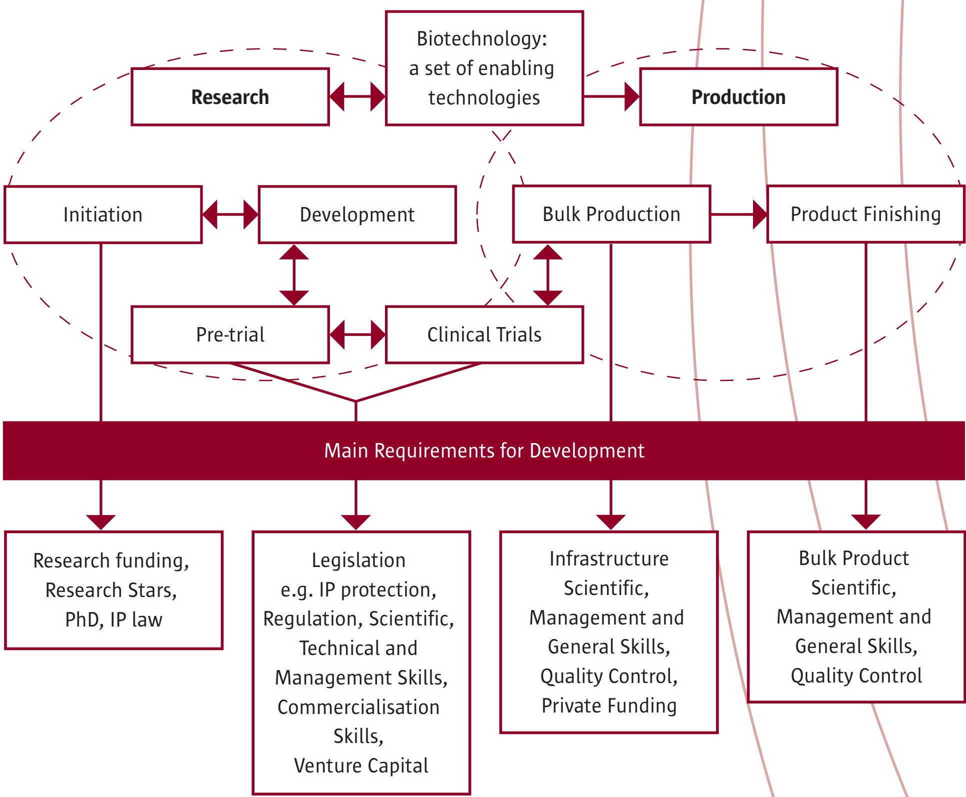
Two major conclusions emerge. Firstly, a range of skills will be required and in the foreseeable future in Ireland, the demand is likely to be concentrated towards the bioprocessing end of the spectrum, requiring skills similar to those in the pharmaceutical firms today. Secondly, in the medium-term, the evolution of the industry will offer opportunities for niche activities, since the concept of a comprehensive cluster may not be applicable to a late starter. However, this does not mean that no effort should be made to develop the research processes since in the long-term these provide the highest value-added and offer the prospect of dynamic growth.

4 Demand for Biotechnology Skills in Industry

4.1 Modelling the Biotechnology Sector

The most fundamental classification of biotechnology firms' activities is between research and production. Within each of these activities further division can be undertaken according to the ultimate product markets that drive both production and research directions. In the medical area, these include pharmaceuticals, large molecule proteins, genomics and xenomedicine, while other areas include food ingredients and agricultural products. Within this classification, large molecule proteins would appear to offer the best prospects for Ireland. Building on this, the model in Figure 4 identifies the main areas of activity where skills are required for successful commercialisation.

Figure 4: Schematic Model of the Biotechnology Industry



4.1.1 Research

The division of research into the initiation phase and further development has been carried out regularly in the literature. Sometimes, the activities of firms or organisations engaged primarily in the former are identified as R&d while the latter are described as r&D reflecting the different focus. The nature of the organisations at each of these phases tends to differ also with universities and dedicated research institutes undertaking R&d (basic research) while commercial interests are more visible in the latter. In addition, while R&d creates the enabling technologies that define biotechnology, r&D concentrates on the application of these technologies in new or existing areas. This latter phase brings the large pharmaceutical companies centre stage.

Initiation has two basic requirements, funding to pay for the research and the availability of the specialised talent that is required. Since the activity is high risk in the sense that the time period to payoff is impossible to determine for any particular pieces of work, there tends to be a large public funding requirement at this stage. However, the potential payoff is large. This is partly because there is a possibility of a breakthrough – however small the odds may be – and to a great extent because it is the availability of this initial stage that tends to provide the core for the organic growth of clusters in a number of centres. The examples of Massachusetts and San Diego are particular illustrations of this. The availability of funding has a direct bearing on the creation of the highly skilled labour force that is required.

The requirements of the second stage as the IP moves through to the trial stage appear similar but are subtly different. There is a greater involvement of the private sector in funding the research although the very long time periods involved can be a problem. There are also two important additional requirements. The first is the need for legislation to protect IP and to regulate the trial stage. This also gives rise to skills requirements so that firms can comply with the regulatory requirements, which tend to be very strict at this stage. Clearly, public support and agreement on regulatory ethics are important issues here. Newly emerging research centres, particularly in Asia, are keen to develop their own approaches in this area and there is a distinct possibility that these may provide a more benign environment for the undertaking of this work than exists in Europe.

The second important issue that is present in successful clusters in the US and Europe is that a social and regulatory infrastructure is required to promote the commercialisation of the emerging research. This along with IP protection and funding will be a key requirement to attract leading researchers.

4.1.2 Production

The model divides production between bulk production and product finishing. At this stage, the activities are under the control of private companies who will provide the necessary finance. As discussed in Section 4.2, a wide range of skills is required here with considerably less emphasis on highly specialised scientific skills. The size of firm that is involved also increases as the product moves into this stage.

Along with the provision of finance and the availability of the required skills – in areas such as technical management, support and quality control – the capital infrastructure is a key requirement for the development of bulk production. Currently there is a worldwide shortage of reactor capacity. This is also a problem for clinical trials although the volume required in trials is relatively low. This problem has arisen due to the risks associated with creating sufficient capacity in advance of firm results regarding the viability of new proto-products. The very high time delay between initial trial and marketing is also an issue. The importance of this specialised infrastructure also means that this part of production is not footloose and would have beneficial upstream impacts in terms of developing the skills that can be used in research.

Product finishing is a quite different operation and is likely to be much less embedded into the local economy. A very wide range of skills is required from scientific and technical skills in quality control and backup, to finance and marketing. However, a further distinction is required since, although this is a labour intensive activity, it is possible to divide the activity among different locations. For example, it is possible that a finishing operation would be located in Ireland but marketing might be undertaken in the US.

4.2 Principal Skill Sets Employed in Biotechnology Companies

4.2.1 HR Structure of Biotechnology Firms

To a very considerable extent, the labour market for research is separate from that for production and will require a separate set of policy initiatives. Furthermore, the labour market for much of the production activity is common with other industries that currently exist in Ireland. For example, the pharmaceutical and other high-tech sectors will compete for specific technical skills, while the wider economy will have a common requirement for general management and back-up services.

Dahms and Bourque[55] examine the educational, discovery and applied research, and developmental research-training skills needs of potential future employees in biotechnology, through an analysis of the biotechnology industry in Massachusetts. This cluster is chosen because it is widely recognised as being the most mature biotechnology cluster in the world. As a result, the data on its approximately 250 companies and 30,000 employees reflect the industry as a whole. A rather more narrow focus would be achieved using data from an area such as San Diego, which is heavily focused on start-up firms, or other areas that are only in the process of emerging.

While the Massachusetts biotechnology industry operates in a number of market sectors, including ag-bio, genomics, human diagnostics, medical devices, medical therapeutics, scientific equipment, scientific services, environmental protection and veterinary, the largest sector is medical therapeutics. This provides the main focus for the analysis. There are many jobs that require science-trained personnel, but that there are also major requirements for skills in finance, business development, human resources, information systems and administration. Furthermore, as companies mature and move from discovery research into product development, skills in sales and marketing, planning, public relations, investor relations, government relations, distribution management, material planning, accounting and finance and law become important.

The types of skills required depend not only on the stage of the product life cycle with which the firm is primarily concerned but also the size of firm involved. In medical therapeutics companies, these changes tend to coincide with three company sizes:

- Small companies of between 1 and 49 employees involved in research and development;
- Medium sized growing companies of between 50 and 149 employees engaged in developing processes and products; and
- Large companies engaged in manufacturing production, with 150 employees or more.

The Massachusetts Biotechnology Council has designed three human resource overviews that identify the types of skills that are required at each of these stages[56]. These are shown in Appendix 6 and form the basis for the skill demand projections in later sections of this report. Examination of these schema shows that as the firm grows the main areas of new employment tend to be in production activities and supporting services. These services include general and functional management and also technical services such as IT. Dahms and Bourque found that the greatest employment growth areas are in pre-clinical and clinical research and development, and in manufacturing. The stage of development of the industry is also important and there are a considerable number of companies that emerged in the late 1980s and early 1990s that have products that are nearing clinical and/or commercial manufacturing. These larger companies are expanding their product base and their manufacturing capacity and in most cases are developing their own marketing and sales divisions. As a result, it is these areas that will see the fastest expansion beginning over the next decade. However, there is a general trend for biotech firms to fill these positions with personnel that are already employed in the pharmaceutical industry who have industry-specific experience.

4.2.2 Qualifications and Experience

The analysis leads to the conclusion that demand in this industry is composed of two major elements along with a number of smaller skill-set requirements. The main opportunities are for trained scientists with strong technical skills within relevant disciplines and for individuals with specific knowledge of the kinds of problems and opportunities that the biotechnology industry faces at each stage of a company's development. On the basis of their research in Massachusetts, Dahms and Bourke set out the qualifications and experience that biotechnology firms require. This is shown in Table 4.1 for technical roles[57]. Other skills will be required in general management, finance, administration and other support services.

55 Dahms, S. and J. Bourque (2002) *Biotechnology And Related Industries: What Do Our Students Do In The Industry And What Degrees And Training Are Necessary?*

56 Available at **www.massbio.com**

57 This table should be read in association with Appendix 6 to indicate the specific skills required at each stage of a firm's development. The qualifications have been expressed in the Irish equivalent of the US qualifications used in the original.

Table 4.1: Qualifications and Experience Required in Biotechnology Firms
(numbers refer to years' experience required in addition to qualification)

Job Description	PhD +	MSc and BSc +	BSc +	Technical PLC +	Leaving Certificate +
Research: Discovery and Pre-clinical					
VP of R&D	15				
Scientific Director	12				
Associate Scientific Director	10				
Principal Scientist	10				
Senior Scientist	5-10	8-10			
Scientist II	2-5	5-8			
Scientist I	0-2	2-5			
Principal Research Associate		5-8	8-10		
Senior Research Associate		2-5	5-8		
Research Associate		0-2	2-5		
Research Assistant			0-2	0-2	
Laboratory Technician				0-2	1-2
Laboratory Support					0-2
Software Engineer		0-2			
Scientific Engineer		7+			
Scientific Programmer (DNA)			2+		
Database Application Programmer			4+		
Database Administrator			0-5		
Automated Systems Designer		0-5			

Table 4.1: Qualifications and Experience Required in Biotechnology Firms – continued

Job Description	PhD +	MSc and BSc +	BSc +	Technical PLC +	Leaving Certificate +
Operations: Process/Product Development, Manufacturing and Production					
VP of Operations	10-12	15+			
Director of Product Development		5+	8+		
Process Development Supervisor		5-8			
Process Development Associate			0-5	5-8	
Process Development Technician			1-4	0-2	
Director of Manufacturing		8+	8+		
Manufacturing Manager			8+		
Manufacturing Supervisor			3-5		
Manufacturing Associate			2-5	5	
Manufacturing Technician			1-4	0-2	0-2
Aseptic Fill Supervisor			3-5		
Aseptic Fill Associate			0-2		
Aseptic Fill Technician			0-2	0-2	
Facilities Manager			5		
Facilities Technician				0-5	
Metrology Supervisor		4-6			
Metrology Technician				0-2	
Quality Control and Assurance					
Director of Quality		6-10	6-10		
Quality Control Supervisor (Chem.)		3-5			
Quality Control Analyst			2-5		
Quality Control Technician				0-5	0-5
Quality Control Supervisor (Biol.)		1-2			
Quality Control Microbiologist			0-5		
Quality Assurance Supervisor			8		
QA Documentation Specialist			2-5		
QA Technical Writer			1-2		
QA Documentation Co-ordinator				0-2	0-2
Validation Manager		5-7			
Instrumentation Technician				0-2	

Source: Dahms and Bourque

Within each of these roles there will be a number of specific areas of competence and experience that will be vital to the biotech companies. At least some of these areas are likely to be in short supply. Work carried out in San Diego by California State University in association with biotechnology firms in the area indicates the areas of greatest skill need being experienced by these companies[58]. The firms were asked to score almost 80 specified skills according to greatest need (5.0 = highest need) with a view to identifying the elements that should be included in university training programs designed to meet the needs of companies making the transition to commercialisation. These skills were classified according to a number of general functional activity areas, 3 of which are shown in Table 4.2 along with the scores attached to each skill. The 3 areas that are identified are: regulatory affairs (RA), clinical affairs (CA), and quality control (QC). The other skills are mostly related to general management and scientific expertise.

It is striking that non-science skills score much higher than the core science skills. The handling of regulatory affairs is clearly a major issue. Furthermore, among those activities that are classified under the clinical affairs and quality control functions, it is clear that it is the management of these activities – design and data management – rather than the scientific input that is regarded as the greatest need. Most core science skills obtained scores of 3.3 or less.

It is possible that these results are influenced by the particular structure of the labour market in Southern California in 2000 when biotechnology would have been competing with other industries such as the booming ICT sector for these skills. As a result, the results are not necessarily wholly transferable. However, they are quite stark. Furthermore, the biotechnology industry in San Diego is particularly concentrated in firms at the earlier stages of development when discovery, R&D, trials and commercialisation are most concentrated. It would generally be expected that this stage of the product cycle would require the greatest intensity of scientific knowledge, when compared to production and finishing, as discussed earlier. However, these results indicate that more general skills, including scientific education to degree level, and specialised management skills are very important at this earlier stage also. This means that it is the specialised application of the skills rather than the inherent nature of the training that is the most important. In other words, to a very large extent the biotechnology industry will be competing in a labour market that is common to many different industries for many of its skills needs.

Table 4.2: Biotechnology Firms' Identification of Skill Needs

Score	Area	Skill Need
5.0	RA	FDA compliance
4.5	RA	IND, NDA and other regulatory submissions
4.5	RA	cGMP, GCP and GLP requirements
4.2	CA	Clinical trial design and modelling
4.1		Technical writing
4.1	RA	cGMP documentation
4.1	QC	Process validation
4.0		Project management
4.0	QC	Team based approaches
4.0	QC	Analytical method development and validation
4.0	QC	Materials and document control
4.0	RA	cGMP training
3.9	QC	Quality and production
3.9	RA	Regulatory strategies and negotiation

58 Biocom (2000) *Biotechnology Company Identification of Areas of Extreme Need: Targets for Public Universities who want to Develop Programs and Speciality Courses to Address the BS and MS Training Needs of those Companies Transitioning to Commercialization.* In association with California State University Program for Education and Research in Biotechnology

Table 4.2: Biotechnology Firms' Identification of Skill Needs – continued

Score	Area	Skill Need
3.9	CA	Clinical trial statistical analysis
3.9		Principles of information systems
3.8	CA	Clinical data management
3.8	CA	Implementation of clinical trials
3.8		Control systems
3.8	CA	Clinical trials administration
3.8	QC	Team based biotech development and production
3.8	RA	cGMP audits
3.7	RA	International regulatory affairs and ISO-9000
3.7	QC	Systems documentation
3.6	QC	Facility validation
3.6	QC	Global CMC (chemistry, manufacturing and control)
3.6	CA	Clinical trials audits
3.5		Corporate partnering
3.5	RA	Regulatory affairs professional training
3.5	CA	Process development strategies
3.5		Bioinformatics
3.5	CA	Good statistical practices in drug development
3.5	QC	Statistical process control
3.5		Hazardous waste management
3.4	RA	Electronic document management and submissions
3.4		Pharmaceutical formulation and stability
3.4		Pharmacogenetics
3.4	QC	Computer and software validation
3.4		Communications
3.4		Manufacturing process technologies
3.3		Optimising of chromatographic techniques
3.3		Pharmacokinetics
3.3		Pharmacodynamics
3.3		Drug discovery-conventional and rational drug design
3.3		Functional genomics
3.3		Proteomics
3.3		Small molecule manufacturing and scale-up issues
3.3		Toxicology and toxicokinetics
3.3		Sterilisation

Table 4.2: Biotechnology Firms' Identification of Skill Needs – continued

Score	Area	Skill Need
3.2		Facility design
3.2		Principles of industrial hygiene
3.2		Biotechnology and drug design
3.2		General pharmaceutical science
3.2		Design controls
3.2		Facility management
3.2		Basic biochemical engineering
3.2		Combinational chemistry
3.1		Pharmaceutical delivery systems
3.1		Separation and purification
3.1		Protein stability and formulation
3.0		Statistical process control
3.0		Pharmacoeconomics
3.0		Manufacturing personnel training
2.9		Instrumentation in downstream monitoring
2.9		Bio/pharmaceutical technology management
2.9		Management of development and innovation
2.8		Combinatorial biology
2.8		Bio/pharmaceutical marketing
2.8		Computers in bioprocess engineering
2.8		Mammalian cell perfusion reactors
2.7		Fermentation strategies
2.7		Drug release technology
2.6		Robotics in drug discovery
2.6		Management and organisational behaviour
2.4		Biochemical reactor design and configuration
2.3		Intelligent bio-manufacturing

Source: Biocom, San Diego

These findings also support the approach that was adopted in the previous sections where the industry was classified not according to the technologies involved but according to the identification of the life cycles to bring a product to the market. This allows a better identification of the skills that are required since it is market driven – as are the firms involved – rather than driven by the technologies and scientific disciplines that are present.

A further important issue is worth noting. The approach taken here provides an indication of the entry-level achievements that are required in the industry. However, there are problems with basing the assessment on university qualifications. This has been examined by Dahms and Leff who found that a number of factors contribute to this problem[59]. First, new employees with four-year university

59 Dahms, S. and J. Leff (2002) *Industry Expectations for Technician-level Technical Workers: The US Bioscience Industry Skill Standards Project and Identification of Skill Sets for Technicians in Pharmaceutical Companies, Biotechnology Companies and Clinical Laboratories*

or college degrees in biology or related fields are not always actually prepared for the beginning-level technical jobs they enter. Managers use the four-year degree as a *de facto* standard, but while this degree provides the theoretical framework, depending upon the extent of undergraduate laboratory experience, undergraduate degree holders can often lack the practical, hands-on experience needed in the workplace.

Second, many programs designed to prepare people for specific occupations sometimes fail to do so because their instructors do not understand what skills and knowledge the occupations require. Employers and educators often report that the most effective work preparation programs are those designed with the active participation of industry. The identification of industry-generated and industry-validated skills standards can provide a solution.

Third, many degree holders experience a high degree of dissatisfaction after entering technician level jobs, resulting in high turnover rates. Retention has emerged as a major issue in the US biotechnology industry. This results in higher costs for retraining or for replacement and is being responded to by some universities by modification of their existing academic courses.

This emphasises an important issue. Close university-industry linkages are required to promote the development and commercialisation of new research. However, even in the absence of new products, these linkages can be used – and are vital – to improve the industry orientation of university courses. As a result, it must be stressed that the skills set that is required is not just one of numbers and quality, no matter how well defined the skills are. The availability of the range of appropriate skills is the key issue. In this respect, since many of these skills are common to firms across many industry sectors, the biotechnology industry will ultimately be competing in a common labour market for many of the most important skills it requires.

4.2.3 Scientific and Specialist Skills

A large number of disciplines, form the academic and research basis of biotechnology and qualifications will be required in many of these. The precise orientation of these will depend in part on the research specialisms that are chosen by the new research centres, but it is also possible to identify areas that will be required for Ireland to create a competitive basis for further development.

Research over a long period by the Massachusetts Biotechnology Council (MBC) has resulted in a comprehensive listing of the positions that will typically be available in biotechnology firms. A summary of the findings from this research is contained in Table 4.3 and indicates the qualifications and types of experience that are required.

The MBC data analyse the HR structure of firms under six headings:

1. Research and Development;
2. Operations;
3. Quality Control;
4. Finance & Administration;
5. Clinical Research; and
6. Business Development.

The numbers employed and the precise structure of employment will depend on the sub-sector within which the firm operates and its size. The first four divisions are present in all firms, the 5th is likely to be present in firms with greater than 50 employees, while only larger firms, who will be located towards the production end of the industry, but with vertically integrated development activities, will have all 6 divisions. However, it is probable that some of the jobs that are identified as tasks for specialists in larger firms would also be carried out in smaller companies by generalists, particularly in management areas[60].

60 The HR structure of various sized firms has already been discussed above (and in Appendix 6) and a summary description of qualifications and experience required was provided.

Table 4.3: Jobs and Qualifications for Biotech Firms

PhD and Equivalent	
VP of Research and Development	PhD in Science and experience
Scientific Director	PhD in Science
Associate Scientific Director	PhD in Science
Principal Scientist	PhD in Science
Senior Scientist	PhD in Science or MS with experience
Scientist II	PhD in Science or MS experience
Scientist I	PhD in Science or MS with experience
Vice President of Operations	PhD in Engineering or Science
Director of Product Development	PhD in Chemistry
Bioinformatics Scientist/Engineer	PhD in Bioinformatics
Bioinformatics Analyst/Programmer	PhD in Molecular Biology
Molecular Modeler	PhD in Chemistry
Toxicologist	MSc or Doctorate in Toxicology
Medical Director/Associate	MD/PhD
Medical Affairs Director	MD
Veterinarian	Doctor of Veterinary Medicine
Patent/IP Attorney	Juris Doctorate and BS in Science
Labour/Employment Law Attorney	Juris Doctorate and BS in Business Administration
Contract Attorney	Juris Doctorate and BS in Business Administration
Bio-statistician	MSc or PhD
Masters and Equivalent	
Principal Research Associate	BSc/MSc in Science
Senior Research Associate	BS/MS in Science
Research Associate	BS/MS in Science
Process Development Supervisor	BS/MS in Science
Process Development Associate	BS/MS in Science
Director of Quality	BS or MS in Chemistry
QC Manager/Supervisor	BS/MS
Director of Manufacturing	BS/MS
QA Documentation Specialist	BS/MS
Librarian	BS/MS in Science and/or MSL
Director of Project Management	BS/MS in Science
Associate Director	BS/MS in Science or MBA
Clinical Research Manager	BS or MS in Science
Medical Writer	BA/BS/MS
Director of Regulatory Affairs	BS/MS in Science

Table 4.3: Jobs and Qualifications for Biotech Firms – continued

Regulatory Affairs Associate	BS/MS
VP of Business Development	MBA and BS
Director of Business Development	BS, MBA
Manager of Corporate Planning	BS/BA
Business Development Analyst	BS/MS
Vice President of Marketing	BS in Science, MBA
Product Marketing Manager	BS or MS Science
Validation Manager	BS/MS in Science
Environmental Engineer	BS/MS in Engineering
Primary Degree Level	
Manager (Animal Sciences)	BS in Biological Sciences
Process Development Technician	BS in Engineering
Manufacturing Manager	BS in Science or Engineering
Manufacturing Supervisor	BS
Manufacturing Associate	BS in Biology
Documentation Associate/Assistant	BS
Marketing Research Analyst	BA in Economics
Purchasing Agent/Buyer	BS in Business
Aseptic Fill Supervisor	BS in Biology or Chemistry
Aseptic Fill Research Associate	BS in Science
Aseptic Fill Technician	BS or Experience
Facilities Manager	BS
Quality Control (QC) Analyst	BS in Science
QA Manager/Supervisor	BS in Biological Science
Validation Specialist	BS
VP of Finance & Administration	BS in Accounting or Finance plus MBA
Chief Financial Officer	BS in Accounting or Finance with an MBA
Director of Finance	BS in Accounting or Finance, MBA
Accounting Manager	BS in Finance
Public/Investor Relations Manager	BA in Marketing
Government Relations Manager	BA
Director of Human Resources	BA in Business
Human Resources Representative	BA in Business
Manager of Information Systems	BS in Computer Science or MBA
Systems Analyst	BA/BS in Computer Science
Analyst/Programmer	BS in Computer Science
Clinical Research Associate	BS in Science

Table 4.3: Jobs and Qualifications for Biotech Firms – continued

Clinical Database Manager/Analyst	BS in Computer Science
Project Manager	BS in Science
Project Assistant	BS in Science
Post-leaving Specialist Diploma	
Research Assistant	Leaving Certificate plus Diploma in Science
Lab Assistant	Leaving Certificate and Diploma or experience
Manufacturing Technician	Leaving Certificate and Diploma or experience
Instrumentation Technician	Leaving Certificate and Diploma or experience
Facilities Technician	Leaving Certificate and Diploma or experience
Environmental Technician	Leaving Certificate and Diploma or experience
Quality Control (QC) Technician	Leaving Certificate and Diploma or experience
QA Documentation Co-ordinator	Leaving Certificate and Diploma or experience
Accounting Clerk	Leaving Certificate and Diploma or experience
Clinical Data Manager/Associate	Leaving Certificate and Diploma or experience
Safety Manager	Leaving Certificate and Diploma or experience
Leaving Certificate only	
Payroll Clerk	Leaving Certificate
Shipper/Receiver	Leaving Certificate
Material Handler	Leaving Certificate
Glasswasher	Leaving Certificate
Receptionist	Leaving Certificate
Administrative Assistant	Leaving Certificate

Source: Massachusetts Biotechnology Council

In many of these cases, specialised knowledge of operations within the job specifications is important. In general, this is described as experience in the MBC analysis but it is also the case that, where experienced personnel may be in short supply, targeted courses of education and training could be developed to provide detailed tailoring to firms' needs. One example of this is in relation to regulatory affairs where US biotech firms have experienced particular difficulties in recruiting. The provision of these skills is a clear prerequisite for the development of the industry in Ireland. This is true in all areas but particularly if the industry is going to develop activities in addition to production. The numbers involved in regulatory affairs are not high, probably 2 or 3 people per firm of which at least one will need considerable prior experience. The problem is that there is a very limited supply of such people in Ireland, although the pharmaceutical industry at present may provide some potential supply. The development of such skills would be at postgraduate level, probably leading to an MSc.

Another area that is undergoing rapid growth and is experiencing a skills shortage is bioinformatics. To fill this growing need, redundancies from ICT might be accessed, although this would entail a considerable amount of retraining. The shortage of bioinformatics graduates exists not only in the US but throughout the pharmaceutical industry. Niches such as this provide Ireland with an opportunity to get a competitive edge if courses are provided to increase output considerably. This approach to policy making leads to results and recommendations that the incremental application of annual growth rates to the industry will not. In the absence of Ireland entering and concentrating on niches such as this, areas such as India will lead the world in bioinformatics, although to date, India cannot yet deliver on quality and standards.

4.2.4 Functions and Skill Sets for Technicians in Bioprocessing

One of Ireland's key strengths in developing biotechnology is the prior existence of the pharmaceutical production industry, although this falls far short of a prototype for the growth of a sustainable biotechnology industry. Nevertheless, the labour pool from which the pharmaceutical industry draws may provide a source of experienced labour for *bioprocessing* (i.e. the deployment of biotechnology on an industrial scale for commercial production of pharmaceuticals, etc.). *Bioprocessing* is the area of activity within the biotechnology industry where employment will be created in the greatest numbers in the near- to medium-term future globally. It is the most likely focus for FDI and consequently, bioprocessing offers an important opportunity for Ireland to gain a competitive presence in the industry.

Examination of the employment structure of biotech firms shows that a broad range of sophisticated skills are required. There is a need for graduates and postgraduates in a range of disciplines spanning the physical sciences, ICT, financial, legal (regulatory affairs) and sales and marketing.

In addition, a certain proportion of the employment is also made up of technician jobs. The key issue for employment in these jobs are basic skills, some knowledge of the culture that operates in a biotech operation and some specialised knowledge. Filling these positions has often been found to be difficult and the industry has taken the lead, along with specialists in universities, in defining the precise skill sets that are required. Some of this has been published and a summary of activities undertaken by technicians in research, development and manufacturing, and in regulatory affairs and clinical trials sections is contained in Table 4.4[61].

Table 4.4: Job Functions for Technicians

Research Development and Manufacturing *Job titles include:* Assistant Materials Specialist, Associate Systems Specialist, Bioprocess Associate, Bioprocess Technician, Manufacturing Services Technician, Materials Analyst, Pharmaceutical Manufacturing Technician, Pharmaceutical Materials Specialist, Research Assistant, Research Associate *Functions:* Routine laboratory support; assist with R&D; manufacture product or provide service; maintain work environment; perform documentation
Regulatory Affairs and Clinical Trials *Job titles include:* Regulatory Affairs Associate, Labelling Compliance Associate, Clinical Research Associate, Regulatory Affairs Specialist, Flow Cytometry Specialist, Histological Technician, Research Technician, Laboratory Aide *Functions:* Support clinical research through data and literature management; review, process and communicate data; co-ordinate regulatory compliance with other departments; interact with regulators

These activities have associated skills sets and these should be noted in advance of development in this direction. Research indicates a number of facts about the sector that determine the skills required[62]. Over 80% of jobs in existing facilities are in production and related areas with only 7% in R&D. The operation of production facilities still requires high-level (graduate and postgraduate) skills due to the sophisticated and delicate nature of the bio-chemical processes involved. It also requires skills at technician (diploma, certificate) level. A key issue for workers at this level is experience of the working environment in the industry.

Bioprocessing is not a single product industry but a multi-product, multi-market sector, the various areas of which share a number of features in general, particularly in terms of the underlying technologies and processes. The types of products include bulk organics, biomass, organic acids,

61 *Biotechnology and Biomedical Skill Standards,* State of Washington Board for Community and Technical Colleges.
62 North Carolina Biotechnology Centre (1997) *Window on the Workplace*

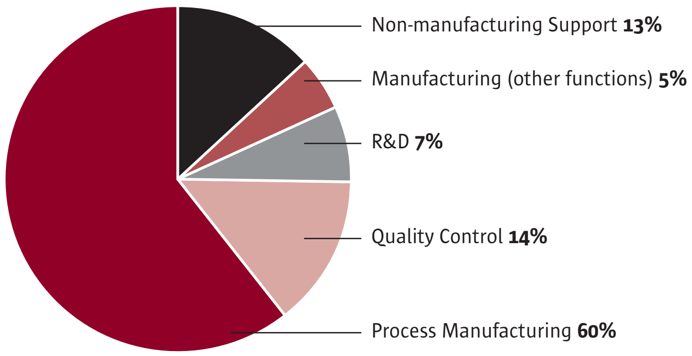
amino acids, microbial transformations, antibiotics, enzymes, vitamins, vaccines, therapeutic proteins, monoclonal antibodies and others. The three main technologies involved are:

- Fermentation – the growth of micro-organisms in bioreactors to carry out biochemical transformations;
- Downstream processing – the separation of the required product from other elements in the mixture and its purification to desired standards; and
- Bio-transformations (the culture and use of micro-organisms to break down harmful products such as pollutants).

The scientific research underlying these activities is developed, although there is also recent and ongoing investigation. It is obvious that when this is transferred to an industrial setting that the activity will be quantitatively different from the R&D stage. However, it is also qualitatively different. The researcher would be involved in almost all stages of planning and operations whereas operations in industry become much more specialised with individual concentrating on single parts of the process. The scale causes difficulties in quality control requiring the highest standards at all time on a vast scale – mistakes cannot be undone nor new ways tried. Protocols cannot be modified, not least because of FDA requirements, and mistakes cost millions of dollars. Equipment for handling the products are on a vaster scale and also more specialised as a result. Crucially, the process must operate continuously with no slacking in monitoring requirements irrespective of the time of day. Finally, double-checking and record keeping is a central requirement at all times.

The effect of these differences is that the production process is repetitive, disciplined and co-operative, characteristics that do not describe research where innovation, individualism and the minimisation of strict protocols and repetitive tasks is desirable. This does not mean that there are no high skill areas in these operations, but the disciplines are different from equivalent skill areas in research. Figure 5 indicates the job functional areas in bioprocessing[63]. Clearly, both the working environment and the skill requirements will vary between these categories, but with 90% of employment in production related areas, requirements here are of most importance. The technology and scale of the bioprocessing operation, the regulatory climate, and the need to maintain the highest standards at all times mean that a highly collaborative and disciplined approach to working is a basic and vital requirement.

Figure 5: Employment Functions in Bioprocessing



The basic requirements of good employees identified by firms are abilities to:

- Communicate effectively;
- Collect, record and analyse data;
- Identify and address problems;
- Consider the impact of decisions;
- Be adaptable to change;

63 In Figure 5, the Manufacturing (other functions) category includes activities in areas such as product finishing, engineering and maintenance, while non-manufacturing support jobs are in regulatory affairs and customer support.

- Strive for continuous improvement;
- Learn continuously;
- Train others; and
- Work as a member of a team.

The key requirement is that these skills are applied continuously and reliably, with common sense a very desirable quality. The problem is that they are not taught or developed in academic environments. In fact, research in North Carolina, where bio-manufacturing is an important sub-sector, has found that the greatest skill deficiency is in the ability to communicate for all categories of graduates, while higher graduates tended to have deficiencies in terms of their expectations of the work environment and team skills.

This feature is Ireland's great strength in the short to medium-term since these people are available in the pharmaceutical and other sectors where FDI has been important. The weakness is that they may need to be converted to biotechnology.

There are skill shortages for process operators in terms of knowledge of bioprocessing operations including fermentation and separation technology. Validation is also a key area with deficiencies. Other areas requiring specialised skills include process equipment maintenance, process control, aseptic processing and measurement. For the most part, these do not require degree level qualifications but the availability of skills in these areas would be a key competitive advantage in attracting firms. Indeed, even where graduates are required, firms in this industry are less interested in the specific subject of the degree than in the knowledge and skills that have been acquired outside the strict academic setting, general personality traits and aptitude of the available workforce and in particular, work experience.

Availability of an experienced workforce would increase Ireland's competitive advantage when pursuing FDI in the biotechnology sector. This potentially gives rise to a *chicken and egg*-type of paradox: how do workers acquire the experience required to entice foreign businesses to Ireland, in the absence of a well established biotechnology sector? However, useful lessons can be drawn from the experiences in the Irish Financial Services sector, where the problem in recruiting experienced staff was (and is) addressed by temporary secondment of staff to Ireland from foreign arms of multi-nationals setting up here, to lend their experience to the new venture. Simultaneously, these staff cultivate the requisite experience among the indigenous staff. Alternatively, the Irish ex-patriots working in the industry can be attracted home to take up positions in the new ventures. However, the falling attractiveness of Dublin as a location due to rising costs will undermine this approach.

Two key conclusions emerge from this analysis.

- Ireland, in the short-term, can stimulate the development of biotechnology by concentrating on bioprocessing while working to strengthen weaknesses for longer-term growth.
- The skill sets for many of the jobs created by biotechnology do not fit nicely into existing training definitions and structures. However, the industry has set out the types of skills it requires. These will sometimes require MSc level instruction but other levels are also needed.

The key finding for Ireland is that to create a competitive position in terms of the skill base it offers biotechnology companies, the skills produced will have to be based very precisely on the requirements of firms. These are not necessarily the types of skill sets that the education system has traditionally been designed to produce and any strategy must define the required skill sets accordingly. This means that it is inadequate to approach this matter through prior defined skill disciplines alone, since these are inevitably defined according to the prevailing discipline structures in the universities. In effect, this means adopting a demand-based approach and not a supplier-based approach. This implies the creation of a highly flexible and responsive education and training system that leads the development of the industry.

5 The Supply of Skills: Current and Recent Trends

5.1 Primary and Secondary Education

5.1.1 Background to Primary and Secondary Level Science

There are many political, ethical and societal issues surrounding modern bioscience, such as the cloning of animal and human cells and genetically modified foods that require consideration in regions that have identified biotechnology as an engine for future economic development. However, of fundamental importance for success is the creation of the basic knowledge and the skills to manage that knowledge in a commercial environment. As a result, education in science will play an important role. However, even if biotechnology does not develop as a leading sector in Ireland, science education can prepare students not only for the option of further study and careers in science and/or technology, but also provides them with enhanced ability to play an active part in a 'knowledge' society.

There has been concern expressed in Ireland that, at the very time when science is becoming increasingly important within business, there is a decline in the uptake of science subjects among second and third level students[64]. Indeed, it has been concluded that the present science, technology and mathematics (STM) education system in Ireland is failing in its ability to prepare students for further scientific study and careers in science and to create a realistic level of scientific literacy among school leavers[65]. The launch of government initiatives that aim to build Ireland's knowledge-based economy, must, therefore, be accompanied by a sustained effort to enhance the STM education system.

In this regard, there has been some good progress recently. Grants to support the introduction of the science curriculum were provided to primary schools in 1999, 2001 and 2002 to the value of €3.9 million, €3.5 million and €2.9 million respectively. A once-off grant to support the implementation of the new Junior Cycle science programme has recently been announced.

Taken together these developments represent an advance in the provision of science education at primary level. However, it is imperative that this momentum is maintained and that the outstanding recommendations of the Taskforce on the Physical Sciences are implemented in full.

The OECD has stated that 'interest in science, technology and mathematics develops at the primary and secondary levels of education … it is very difficult to fill gaps left in early years'. The content, methods and practice of education at primary level can have a determining influence on individuals' educational development throughout their lives and ICSTI has previously welcomed the proposed revised primary school curriculum, which would include social, environmental and scientific education[66]. Before this revision, the primary school curriculum, introduced in 1971, had contained only limited elements of natural and environmental studies. However, since the reintroduction of science at primary school level in September 1999, only 5% of primary schools have had the opportunity to participate in the new programme. The Joint Committee on Education and Science were critical of the approach being taken and stated that:

> 'Far from being fast tracked within the new curriculum, it [science] has been pushed to the latter phase of implementation'[67].

64 Issues surrounding the declining levels of participation in physical sciences at secondary and tertiary level, discussed further below, were examined by the Task Force on the Physical Sciences – Report and Recommendations (March 2002). Two Working Groups were formed within the Task Force. One focused specifically on primary and post-primary science education. The other, the third level/industry-working group, was concerned with the role of third level institutions and industry in contributing to a reversal of the decline in numbers of students taking the physical sciences.

65 ICSTI (1999) *Science in Second Level Schools* November.

66 ICSTI (1998) *Science in Primary Schools*, May.

67 Joint Committee on Education and Science (2000) *Report on Science and Technology,* October.

However, some progress has been made on this front recently and the new primary science programme is due to commence in September 2003. In anticipation of this, three days of in-service training are being provided to teachers in the current school year.

ICSTI's benchmarking study[68] of primary and secondary level science, technology and mathematics (STM) education in Ireland highlighted various characteristics of secondary science education that were inhibiting Ireland's potential national competitiveness:

- falling proportions of students in physical sciences;
- skills shortages in sectors of Irish industry;
- above average proportions of lower grades in some science subjects;
- gender imbalance in the uptake of science subjects;
- the nature of student assessment; and
- provision of facilities at school.

The report made specific recommendations for action on science education to government, education and business sectors. These included:

1. Developing and implementing timely policy;
    - Changes in the content or process of STM education takes years to affect the pattern of entry into the labour market, therefore delays in determining and implementing necessary changes in curriculum and assessment must be minimal.
2. Teacher recruitment, training and retention;
    - Graduates of physics and chemistry should receive special scholarships to encourage entry into teacher training.
    - Provision of 3rd level science education for teachers should be co-ordinated through a Centre for the Teaching of Science.
3. Teaching and Assessment;
    - Practical assessments should be implemented within 3 years.
    - Procedures should be introduced to address the problem of the relatively high proportion of students attaining lower grades in science subjects.
    - Science should be made more relevant and attractive to all students.
4. Environment for Education;
    - The private and public sectors should increase the effort to promote awareness of and interest in science and technology through interactions with schools.

In October 2000 the report of the Joint Committee on Education and Science listed some 31 practical and imaginative measures which it believed would lead to a strengthening of science education in Ireland. These recommendations were summarised earlier in this report.

5.1.2 Junior Certificate Level

There are 733 post primary schools in Ireland engaged in the provision of the Junior Certificate (JC) and the Leaving Certificate Schools programme. Data for 1999-2000 show that Science was provided in 99.6% of all schools[69]. In 2001, only 5 schools had no students enrolled in Science. Therefore, of the 180,998 children enrolled in JC programmes only 110 Junior Certificate students were at schools that did not offer science. When schools are divided by size, these data show that 100% of schools in Category 1 (<300 pupils in all courses), 99.4% of schools in Category 2 (301-600 pupils) and 99.5% in Category 3 (>600 pupils) provided science.

68 Irish Council for Science, Technology and Innovation (February 2000) *Benchmarking Science, Technology and Mathematics Education in Ireland against International Good Practice*. This document, which has been discussed earlier in Chapter 2, was a means of assessing STM education and assisted in the preparation of the ICSTI's own statement on Science in Second Level Schools.

69 Expert Group Report to the Minister (July 2001) *Analysis of the Deployment of Teachers at Second Level.*

These figures are encouraging as a snapshot. However, the data in Table 5.1 show a decline in the number of students taking JC Science, from a peak of 187,545 in 1993/94 to 156,977 in 2001/02[70]. The major demographic shift that has occurred in Ireland over recent decades, with a dramatic reduction in the birth rate, is now feeding through into a much smaller cohort at JC level. This fall in total numbers – by 13.2% since 1991/92 – has been paralleled by the fall of 12.4% in the numbers taking science at this level. In addition, the percentage of students taking JC science suggested an emerging trend of decline in the late 1990s, but the slightly increased uptake in 2002 would suggest some recovery in the participation rate in science may be beginning. On balance, the percentage doing JC-level science has remained fairly steady at just under 90% when viewed across the whole period.

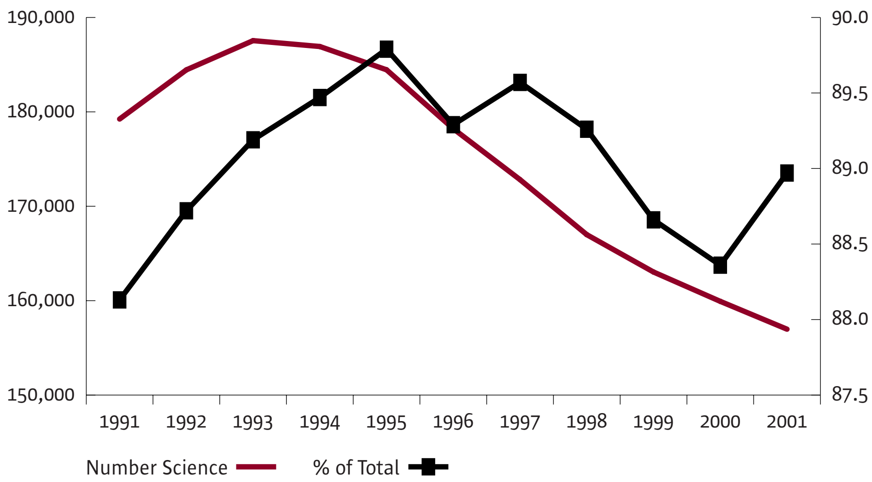
Table 5.1: Numbers Enrolled in Junior Certificate Science Cycle (1993-2002)

	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02
Total enrolment	210,257	208,917	205,417	199,571	192,944	187,068	183,883	180,998	176,434
Science enrolment	187,545	186,923	184,455	178,211	172,817	166,991	163,033	159,927	156,977
% Science	89.19%	89.47%	89.79%	89.29%	89.57%	89.26%	88.66%	88.36%	88.97%

Source: Data from Department of Education and Science

The trend in science study at JC level since 1991 is shown in Figure 6.

Figure 6: Science Students at Junior Certificate Level
Number (l.h.s) and Percentage of total JC Students (r.h.s.)



Required subjects at Junior Certificate level are set out by the Department of Education and Science[71]. Recognised candidates – that is, students for whom a capitation grant will be paid – must undertake:

1. Irish;
2. English;
3. Maths;
4. History and Geography;
5. Civic, Social and Political Education; and
6. Not less than two subjects from the approved list of examination subject. Science is on this list along with languages, arts and a number of vocational/technical subjects.

70 Junior Certificate Science includes 'Science' and 'Science with local studies', (Codes 8 and 9).

71 Department of Education and Science (2001) *Rules and Programme for Secondary Schools 2001/02*

This means that science is not compulsory at this level. There are a number of possible explanations for the failure of around 10% of students to study science at JC level. These include a widespread perception among young teenagers that science subjects at Leaving Certificate level are difficult, a poor appreciation of the importance of science, little or no promotion of the career opportunities available in science and in some instances poor resources for science teaching. This situation is in marked contrast to that in Singapore which is also attempting to develop its biotechnology industry.

However, many of these issues are now being addressed in accordance with the recommendations of the Taskforce on the Physical Sciences. The grading of subjects at Leaving Certificate level is currently being reviewed. These developments are welcome, but it is crucially important that they are sustained.

5.1.3 Leaving Certificate Level

At Leaving Certificate (LC) level, 730 schools (423 Secondary, 226 Vocational and 81 Community & Comprehensive) are engaged in the provision of the Leaving Certificate (Established) and Leaving Certificate provisional programme. Science subjects offered at LC include physics, physics/chemistry, biology, chemistry, and applied mathematics. Analysis of the 1999-2000 October returns shows that:

- Physics was provided in 77.8% of all schools;
- Biology was provided in 96.6% of all schools; and
- Chemistry was provided in 72.5% of schools.

However, as shown in Table 5.2, there is a considerable difference when schools are divided according to size with smaller schools much less likely to teach Physics as single subjects and somewhat less likely to teach biology.

Table 5.2: Science at Leaving Certificate Level (% of schools providing science)

	School Size Category (total pupils)			
	1 (<300 pupils)	**2 (301-600 pupils)**	**3 (>600 pupils)**	**All**
Physics	48.9%	81.5%	96.7%	77.8%
Biology	90.6%	98.5%	99.0%	96.6%
Chemistry	41.1%	76.8%	92.4%	72.5%
Physics/Chemistry	17.2%	12.1%	9.5%	12.6%

Source: Report of the Expert Group to the Minister for Education and Science: The Allocation of Teachers to Second Level Schools*, Nov 2001*

Although the proportion of schools offering science is high, there has been a sharp fall-off in the number of science subjects taken at Leaving Certificate level[72]. The percentage of Leaving Certificate students taking Chemistry, Physics and Biology in 2001 fell to 12%, 16% and 44% respectively, down from 21%, 21% and 51% respectively the previous year[73]. Overall, the number of science subjects taken (measured by enrolment) dropped by 23% between 1994 and 2001[74].

Given that the proportion of JC students taking science has remained close to 90%, it is clear that the problem resides in the transition to the senior cycle.

Various reasons have been put forward for this development. One suggestion is that the decline in numbers taking LC Science subjects is a resource or supply issue, perhaps due to fewer teachers or insufficient facilities resulting in these subjects being offered in fewer schools. The evidence suggests

72 The number of science subjects is not the number of students taking a science subject but is the aggregation of the numbers of students taking chemistry, biology, physics and chemistry and physics combined at Leaving Certificate level. Since many students take more than one subject, the expression of this number as a proportion of total LC student numbers does not indicate that this percentage of students take science. Indeed, the number of science subjects could conceivably exceed the number of students if take-up was improved.

73 An important exception to this trend is Agricultural Science which has actually grown in popularity over the period 1999/2000; it is available in 22% of schools, approximately twice as many as provide the Physics & Chemistry combined course.

74 Department of Education and Science figures.

that this is not the case. Analysis of science subject provision at LC within Irish schools since 1998 indicates that on a proportional basis, as shown in Table 5.3, there were marginally more LC science subjects available in 2000-01 than 1997-1998.

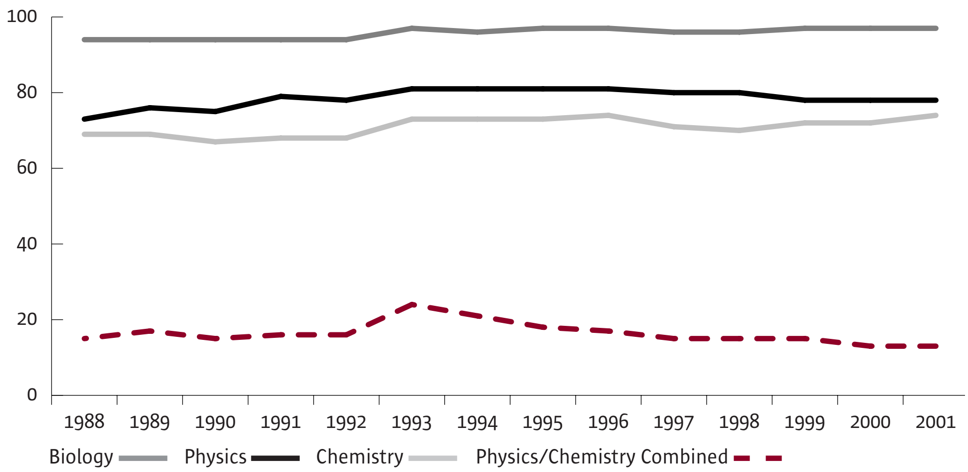
Table 5.3 Percentage of Schools Providing Leaving Certificate Subjects

	1995	1996	1997	1998	1999	2000	2001
Physics	81%	81%	80%	80%	78%	78%	78%
Chemistry	73%	74%	71%	70%	72%	72%	74%
Biology	97%	97%	96%	96%	97%	97%	97%
Physics/Chemistry	18%	17%	15%	15%	15%	13%	13%

Source: Task Force on the Physical Sciences

Furthermore, there is no evidence from the long-term trend shown in Figure 7 that any change in the provision of courses is the key variable in this regard.

Figure 7: Percentage of Post Primary Schools Offering Science Subjects



The problem almost certainly relates to demand for LC science subjects and this has received considerable attention in recent years. It is likely that there are two main influencing factors. The first is the labour market. In the 1990s, IT and associated electronics sectors became the desirable areas in which to work and areas of greatest interest to LC students. Other 'winners' in this respect were languages and business-related subjects as they were perceived to be related to these attractive areas. Areas of the economy, which might be seen as more closely related to science, did not have the same image advantage. A second issue is that there is a perception, which has been explored and found to be not without foundation, that science subjects are difficult areas in which to score high points. Students react by avoiding these 'hard to score points in' subjects[75]. This trend has been given additional impetus by the emergence of 'prestige' university courses[76] that require very high points. This will work to draw students away from science subjects even where there is an inherent attraction for the student towards the sciences.

The Commission on the Points System expressed concern in relation to the extent that students' choices were influenced by the perception that some subjects were more likely than others to lead to higher points because of differences in marking[77]. The NCCA examined this issue in a longitudinal study of results in 1996 and 1997 and concluded that the results suggest that there may be validity

75 The factors determining subject choice at Senior Cycle are complex and not fully understood. A survey carried out on behalf of the Taskforce on the Physical Sciences actually found that 30% of students deliberately choose a science subject in order to maximise their points total.

76 These courses are dotted across all faculties and involve some science related courses such as medicine and pharmacy, but also law and certain business subjects. Usually, the level of points is more a reflection of the supply and demand for places on these courses than of inherent requirements and an unstable market emerges whereby higher points prompts higher demand and so on. This introduces a distortion that can lead to a mis-allocation of talent in the economy. The implications of this have been explored in previous work by Peter Bacon & Associates into training for Pharmacy and the Therapy Professions.

77 Commission on the Points System (1999) *Final Report and Recommendations.*

in these perceptions. This work was re-examined and updated by the Task Force on Physical Sciences[78]. Their analysis indicated that the grades achieved in Physics, Chemistry, French and Mathematics have consistently been lower on average than those achieved in other subjects. The analysis supported the earlier results obtained in the NCCA work and study by other researchers. As a result, the Task Force concluded that 'candidates sitting the physical sciences are generally less likely to perform as well as those sitting other subjects' (page 173). The severity of marking was identified as a key factor giving this result. As a result of these findings, the grading of subjects at Leaving Certificate level is currently being reviewed.

The framework for subject choice at Leaving Certificate level is quite different from what operates at Junior Certificate level. The 31 available subjects are set out in 5 groups:

1. languages;
2. science;
3. business studies;
4. applied science; and
5. social studies.

Students undertaking the established Leaving Certificate must take 5 of these subjects, one of which must be Irish. Apart from a recommendation that each student should take 'at least three subjects from the group of subjects for which he is best fitted, and at least two subjects from outside that group...'[79], the only other requirements relate to certain exceptions. For the Leaving Certificate Vocational Programme, students must take 5 subjects, one of which must be Irish, and must take:

1. two subjects from one of the groups;
2. a modern European Language; and
3. link modules.

In making subject choices, it is likely that the specific requirements of a course that the student may wish to follow at 3rd level will place additional requirements. Most courses require Maths and English, many require a modern language and, since points are calculated over 6 subjects, most students will take at least this number of subjects. The result is that having satisfied the basic requirements (this usually means Irish, English, Maths, a modern language) the choice comes down to either a personal preference or a subject that is of secondary interest but for which there is a perception that it is relatively easy to score points with. Clearly, this structure provides no compulsion to take a science subject unless the student has already identified a science course at 3rd level for which this is a requirement or wishes to keep all options open. In the case of the former, the requirement leads to little additional skills in science – compared to a situation where the minimum requirement was dropped – while there is a clear cost in terms of risk from taking science to keep all options open.

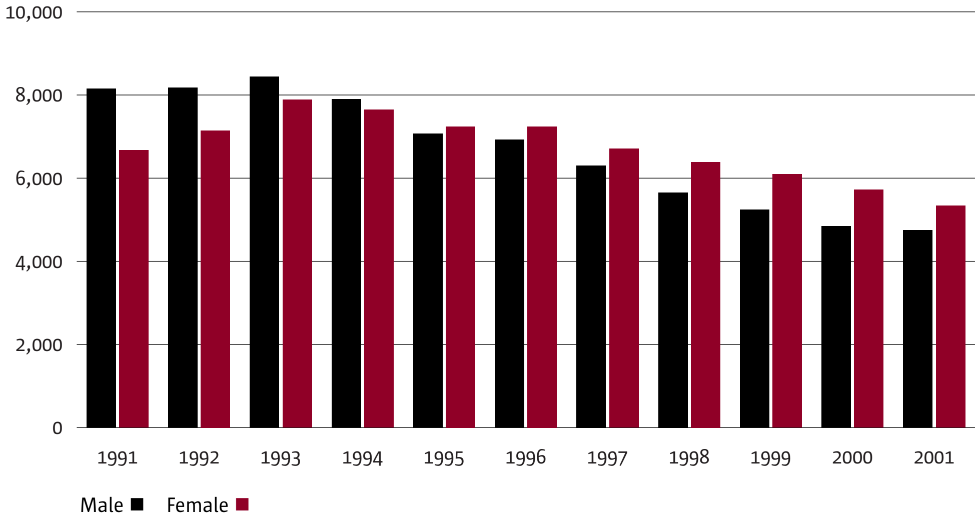
There are also considerable gender differences in the uptake of Leaving Certificate science subjects[80]. Physics, including the physics and chemistry combined option, is still taken by three times more males than females, a reflection to some extent of the reticence of female-only secondary schools to teach this and other maths-related subjects at higher level in the senior cycle. Chemistry is the only subject that has a reasonably equal uptake between boys and girls. However, due to a more rapid decline in the number of males taking chemistry in recent years, females now increasingly out-number males. This is shown in Figure 8.

78 Task Force on the Physical Science (2002) *Report and Recommendations.*

79 Department of Education and Science (2001) section 21 (2) (b).

80 The data in the following charts were sourced from Department of Education and Science. They exclude repeat, vocational and Applied Leaving Certificate programmes.

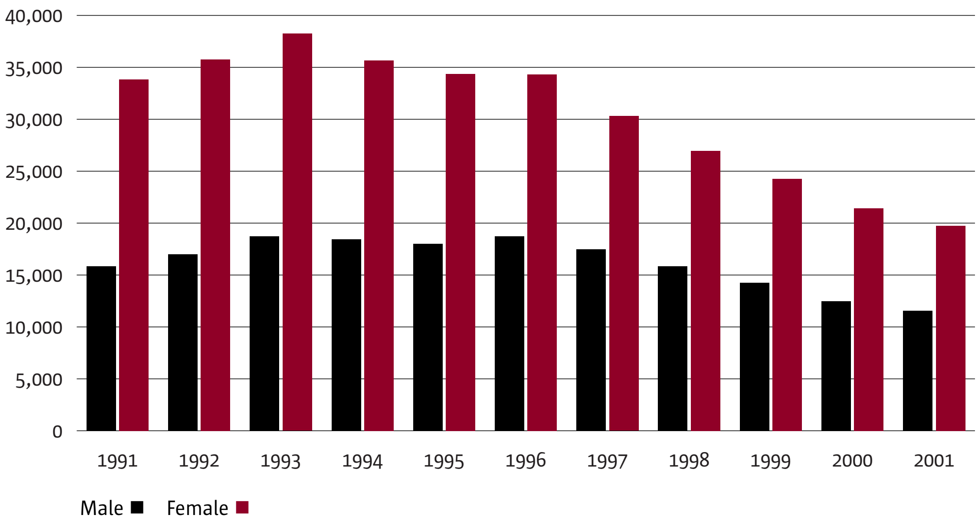
Figure 8: Gender Breakdown of Students Studying Chemistry (1991-2001)



However, the biggest difference emerges with biology. Biology is the most popular science subject at Leaving Certificate and is approximately twice as popular among females as males. This is shown in Figure 9.

This trend has important implications for biotechnology as chemistry and biology are the key science subjects involved. While it cannot be concluded that these trends will be fully reflected at 3rd level, it does appear inevitable that there will be a correlation over time. This means that there will be a decreasing workforce with these skills and that the relevant skills will be increasingly concentrated among females. This phenomenon, when coupled with the lower participation rate of females will exacerbate any skills gaps in the industry.

Figure 9: Gender Breakdown of Students Studying Biology (1991-2001)



The analysis leads to a number of conclusions. First, there is a declining percentage of students taking science at Leaving Certificate level. This is particularly clear for biology and physics. Second, by far the most important reason for this is the changing demographic structure of the population and the fall in the number of students. There is no role for policy to address this directly and, as a result, future planning must proceed on the basis that there will be far fewer emerging entrants to the labour force. However, this should mean that there are available resources that can be directed towards specific aims. The third conclusion is that there has been a decline in the uptake of science relative to the overall student population. This decline is centred on the period just after the Junior Certificate when decisions are being made regarding Leaving Certificate subjects. It is at this point that there may be opportunities to influence student's decisions whether or not to continue with the study of science. For example, if 75% of students took 1 science subject and 40% took 2 subjects then the science subject number would rise to 82,000 on the basis of the number of 2001 LC students. This would be a 46% increase over the actual number of science subjects taken in 2001.

The factors that determine the take-up of science in second-level schools in Ireland have been examined in a recent study[81]. Girls (in contrast to the situation in 3rd level), lower ability students and student in lower classes in streamed schools are less likely to take science at Junior Certificate level. In the senior cycle, science subjects tend to be seen as elite subjects among girls – both in terms of students' abilities and social backgrounds – but, apart from Chemistry, are perceived as more inclusive for boys. A science for all approach would help overcome these barriers to the study of the subject.

The study found that while provision of science subjects is clearly important, it is not the only issue for consideration since there are considerable differences in take-up between students within particular schools and between schools with similar provisions. A particularly important issue is the way in which different ways of teaching science influences student's attitudes towards the subject. A greater emphasis on practical work and student participation has a positive influence on take-up at Leaving Certificate level. Some progress have been made in recent years in capitalising on this correlation by substantially revising the curricula and examination methods for both Junior and Senior Cycle science subjects. In particular, practical work is now formally recognised as a key element of the science curricula. For example, the Junior Certificate science syllabus, scheduled for introduction in Sept. 2003, has provision for the allocation of 35% of the marks to practical work. This increased emphasis on practical work has been reflected in the allocation of extra resources to schools for equipment and facilities and the provision of in-service training for teachers. It is important that these new programmes are implemented in full and as expeditiously as possible.

Students' choice of courses in third-level education is determined to a considerable extent by an on-going process throughout the schooling career. As a result, the subjects that are taken at junior cycle when considered alongside the attitudes and occupational aspirations of students at age 14 are highly predictive of subsequent educational careers. It is clear that considerable resources should be applied to guidance for junior cycle students so as to stream them towards science.

5.2 Tertiary Level

Tertiary graduation rates are an indicator of the current rate of production of people with advanced knowledge by a country's education system. Such rates are influenced both by the degree of access to tertiary programmes as well as by the demand for higher skills in the labour market. OECD research into a wide range of the educational performance indicators, including data on pupil performance and learning, the costs of education, access and participation, and school environment, has shown Ireland to be performing well in many respects[82]. In the 2002 report, Ireland was ranked 7th out of 17 countries surveyed with a tertiary graduation rate (across all programmes) of 31.2 compared to the country mean of 25.9 i.e. the ratio of tertiary graduates to the population at typical graduation age. Tertiary B graduation rates (i.e. those emerging with certificates or diplomas) ranked 4th out of 13 (15.2 compared to 11.2 OECD average) across all programmes. Ireland's survival rate at tertiary type A level for all programmes (2000) was third highest (Ireland = 85, country mean = 70). However the survival rate at Type B diplomas and certificates levels was considerably lower than the country mean (Ireland = 50, country mean = 73). At secondary level, Ireland's measure of scientific literacy among 15 year olds was placed 9th out of 27 countries. Despite Ireland featuring strongly in terms of the percentage increase in expenditure in education (fifth out of 23) in recent years, expenditure per student at primary and secondary levels was well below the country mean (seventh lowest out of 24 primary level expenditure and 9th lowest out of 26 for 2nd level expenditure). Investment in R&D at tertiary level in Ireland brought the expenditure per student to slightly above the country mean.

81 Smyth, E. and C. Hannan (2002) *Who Chooses Science?: Subject Take-up in Second Level Schools.* Dublin: Liffey Press.

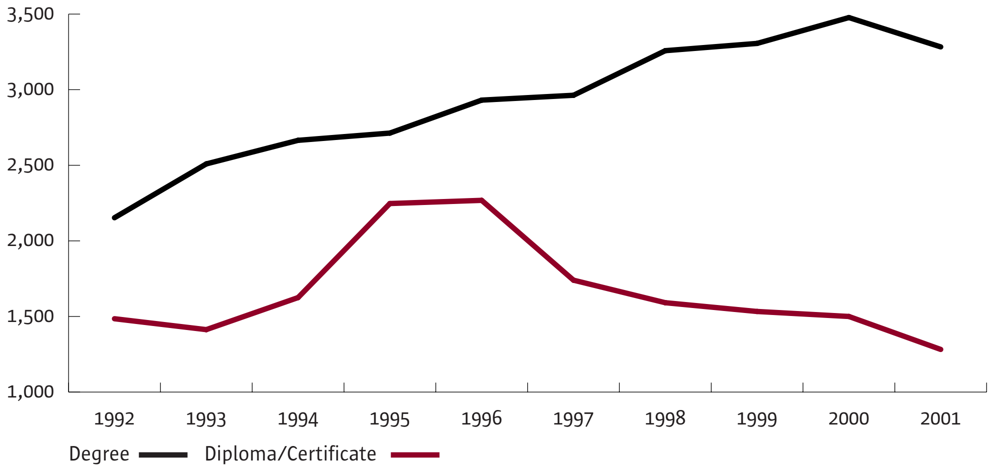
82 OECD (2002) *Education at a Glance.*

5.2.1 Access to University Science

The Department of Education and Science (DES) estimates that there were approximately 120,000 students in full-time tertiary education in 2000-01 in Ireland's 7 universities and 14 Institutes of Technology (ITs). Primarily, the Higher Education Authority (HEA) compiles statistics relating to universities. While the universities are concerned with undergraduate and postgraduate degree programmes together with basic and applied research, the ITs concentrate on providing programmes of education and training in a large range of disciplines leading to qualification at certificate, diploma and degree level. Statistical information on ITs is primarily gathered and processed by the CAO.

Despite more than a 6-fold increase in the number of students in higher education since 1965, with DES projections showing a further rise to 127,000 by 2005/06, there is considerable concern that the number of students enrolling in Science (and Technology & Engineering) subjects is declining. This concern has been the subject of many reports highlighting the importance of sufficient numbers of skilled graduates to meet the demands of the growing technological sectors in Ireland, as discussed earlier in this report. The Third report from the Expert Group on Future Skills Needs stressed the need for a continued supply of science graduates at certificate, diploma and degree levels in the disciplines of chemistry, biology and instrumentation physics. These recommendations were made on the basis of evidence of an emerging decline in science acceptances at degree level in 2000 coupled with an alarming and continuing decline in the number of acceptances at certificate/diploma level science. This decline is shown in Figure 10.

Figure 10: Net Acceptances in Science at Degree and Diploma/Certificate Levels (1992-2001)



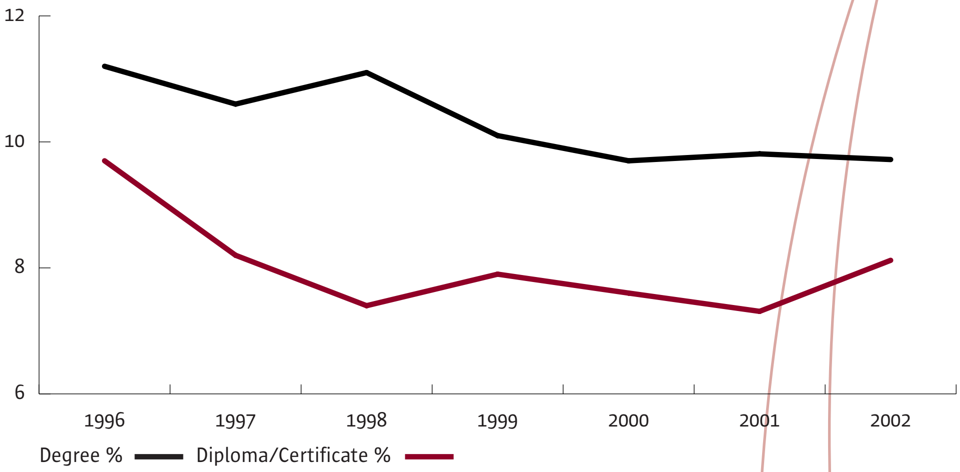
These CAO data show that, in aggregate, acceptances to science degree courses rose steadily to a high of 3,477 in 2000, from 2,153 in 1992, but fell to 3,283 in 2001. However, a somewhat different trend is visible for Certificate and Diploma courses. In this case, the number of acceptances has fallen from 2,268 in 1996 to 1,282 in 2001. This represents a 43% fall in the number of acceptances on Certificate/Diploma degree courses. 2002 data for first preferences onto these courses shows a slight recovery in diploma/certificate acceptances; however no data are available for 2002 actual acceptances[83].

The main cause of this difference is probably the greater influence of the labour market on the certificate and diploma courses. A stated competitive feature of the ITs is to prioritise the supply of the skills that are required by industry and to remain flexible to the needs of industry. Throughout the 1990s, there was a considerable effort among providers of these courses to orientate their offerings towards the rapidly expanding sectors of the economy with a significant increase in the number of places on courses designed to prepare students for employment in IT and business sectors. As shown in Figure 11, there is also a declining trend in stated first preferences among students for

83 First preference data are not a direct measurement of students' enrolment as 5-10% may not become actual registered enrolments.

science. This is a clear indication that, while the orientation of the providers is important, its impact is further strengthened by student choice. Thus, labour market developments in the 1990s may have had a double impact; first through the offerings of institutions and then through the perceptions of students in relation to the relative attributes of the options with which they are presented.

Figure 11: First Preferences for Science at Degree and Diploma/Certificate Levels (percentage of total)



This distinction between the orientation of the providers of degree courses relative to other courses is important, particularly given the type of industry projected to emerge in Ireland as described in Chapter 4 and 6 of this report. It also suggests a further important trend, one which cannot be proven without an in-depth study of decision-making among the providers of non-degree courses. This is that there is evidence of a tendency to follow developments in the economy rather than create the conditions for the economy to develop in certain directions. However, there is a clear contrast with the leading role being played by education policy in Singapore or the collaborative role being provided by the educational establishments – with industry – in the US. Comparison with these regions suggests that the approach being taken in Ireland is likely to be inadequate to stimulate the development of biotechnology where the prior existence of expertise in terms of the skills output of the education institutes, as well as research, would appear to be a prerequisite.

Declining student numbers and lower preferences towards sciences have been accompanied by a lowering of entry level requirements for science certificate/diploma/degree programmes. The marginal decline in acceptances onto science degrees (from 2000) meant that universities accepted students who would previously have selected a certificate/diploma course in the ITs. This trend, if continued, will result in a lowering of demonstrated academic abilities of entrants to science courses and, if entry levels to universities continue to be reasonable indicators of subsequent performance, a fall in the skills levels of science graduates. When placed alongside the onset of the decline in secondary level graduates due to demographic changes, the number of enrolments in science at ITs is likely to continue to decline.

This trend gives rise to a number of further important considerations. The determinants of the level of points required for entry to any course are complex and have not been studied extensively. In an ideal world, the level of points required would be primarily determined by the degree of academic difficulty associated with a course. In reality, however, this is not the case and there are many anomalies if viewed in this light. A much better model to describe the level of points required is given if the number of points required are viewed as the 'price' of gaining entry to the course. As such, like any other price, the level at which this is set may or may not be related to the inherent 'value' of the course; in this case 'value' meaning academic difficulty. The only thing that can be stated with certainty is that the price is the result of the interaction of demand and supply for the course. Thus, courses that may appear to be broadly similar in terms of the prospectus may vary considerably in points as a result of the institution in which they are delivered and other issues, most notably restrictions on supply.

This is important since it can give rise to dynamic effects not all of which might be desirable. In effect, there are instabilities in this market that are not unlike the types of effects that may emerge where a particular area gains a leading role in an industry such as biotechnology. Over time, this leading role means that the area moves further ahead rather than slowing and allowing other areas to catch up. A good example of this in terms of the points system is where a prestige course emerges with particularly high points. This provides a strong signal to students to prefer this course thereby driving up demand and the required points rise even further. There are two factors driving this process. The first is that the number of places may be limited so supply cannot respond to the higher demand. However, a key issue is that the number of points obtained by a student can only be 'spent' on one occasion – they can accept only one course.

The effect of these features of the points system, when viewed as a market, displays *increasing* return to scale. In other words, a course where demand exceeds supply in one period thereby experiencing rising points will, when set against a background of stable or rising aggregate demand for entry to university and stable supply of places – experience even higher points the following years. Therefore, if an anomaly exists, the chances are that it will persist. If overall demand is falling then these courses will be likely to be most resilient to any reduction.

In terms of developments in the level of points for entry to science courses, this has a number of important implications. First, unless science comes back into favour as a course of study due to some external impulse – for example, a big change in the labour market or a successful promotional campaign – then there are features of the system that will work to push it further out of favour. This, in itself, can lower entry requirements if the supply of places remains constant thereby running the risk of lower ability levels. Second, this will be felt first in the less favoured institutions, probably the ITs and on non-degree courses, since the overall lowering of entry requirements means that applicants can now access courses from which they were previously excluded. Third, a policy decision by the authorities to expand the number of places in advance of changes in the labour market would increase supply and reduce 'price' i.e. the number of points required for entry. (This would be the case if a decision were made to gear up for the future growth of biotechnology). This could work to make science less attractive to students wishing to 'spend' all their points in one transaction rather than letting some 'go to waste'. There is a further possible important issue from a process such as this. Lower entry points, if standards are maintained, risk increasing the attrition rate among students who cannot meet the academic standards of the course. Already, science has the second highest non-completion rate among university courses. The HEA, in a study[84] of the progress of students who entered University in 1992/93, showed that less than two thirds (63.4%) of students who commenced science courses in 1992 graduated on time with just over one fifth (22.2%) not completing their course (24.3% male, 20.3% female). The report found that slightly more females (65.2%) than males (61.5%) graduated on time and that 14.5% of females graduated late. This was slightly higher than the percentage of males graduating late (14.1%).

5.2.2 Undergraduate Level

Trends in the total number of science students in universities since 1990 are shown in Table 5.4.

These data show that numbers rose in the first half of the 1990s with a considerable rise in full-time postgraduate science students, over 50% from 1991-96, but this growth has since stagnated. One promising result from this table is that the decline in numbers taking science at Leaving Certificate level, which manifested itself from the mid-1990s on, does not appear to be reflected at third level. One reason might be because the places are available and so they are filled, because students who enjoy science at Leaving Certificate now have the option of continuing to study the subject. However, one clear trend is that the increasing dominance of females in science subjects at LC level is also evident at undergraduate level as shown in Figure 12. This figure also shows that the levelling off in the number taking science at third level that has occurred in recent years, is predominantly a result of decisions by males, with the number of females continuing to increase.

84 HEA (2001) *A Study of Non-completion in Undergraduate University Courses.*

Table 5.4: Total Science Students in Universities (1990-2001)

	Full-time		Part-time		Total
	Undergraduate	Postgraduate	Undergraduate	Postgraduate	
1990-91	5,153	1,393	82	252	**6,880**
1991-92	5,397	1,500	97	262	**7,256**
1992-93	5,719	1,749	41	269	**7,778**
1993-94	5,996	1,926	78	282	**8,282**
1994-95	7,198	2,133	85	283	**9,699**
1995-96	8,126	2,142	209	394	**10,871**
1996-97	7,427	1,918	76	299	**9,720**
1997-98	7,700	1,873	165	302	**10,040**
1998-99	7,899	1,866	157	278	**10,200**
1999-00	7,883	1,916	170	294	**10,263**
2000-01	7,892	2,034	265	386	**10,577**

Source: HEA

Figure 12: Gender Breakdown of Undergraduate Science Students in HEA Institutions (1990-2001)

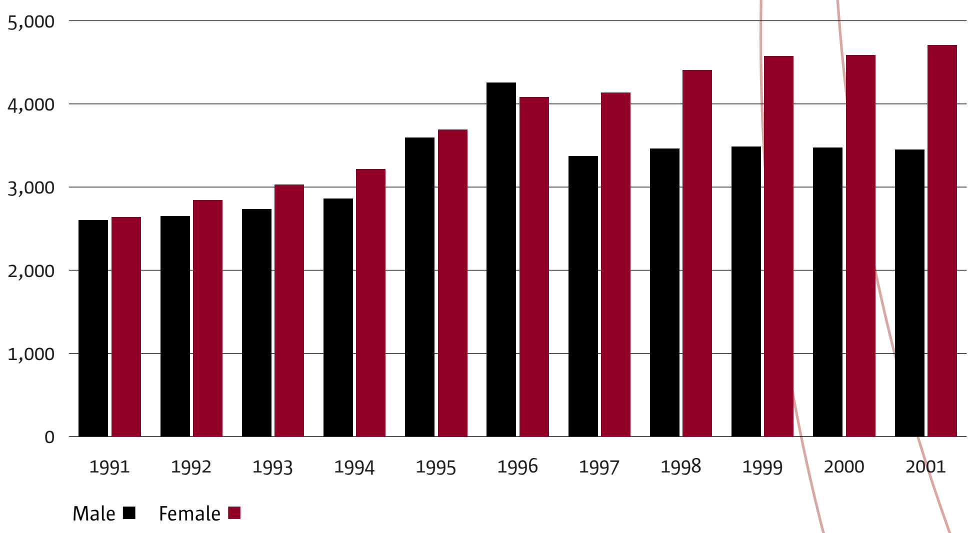


Table 5.5 shows undergraduate awards and enrolments in science in the ITs and the universities[85]. This shows that a total of 1,241 students obtained awards in science from the ITs in 2001. Of these, 402 (32%) received degrees while the remainder received diplomas and certificates. In the universities, almost all students that received awards received degrees. This table also shows that there were 2,966 students enrolled in the first year of undergraduate courses in 2001. Of these, 2,080 were enrolled on degree programmes. However, this is a biased indicator of actual potential progression towards degrees since the IT system allows for progress when the diploma level has been achieved, although the time required to achieve degree level may vary. As a result, only 91 students in ITs registered for degrees from year 1. Thus, forward projections of future degree output require some indication of the student transfer rate between certificate/diploma and degree courses.

85 Courses at undergraduate level are provided under a wide range of names and, with respect to the full assistance offered by the HEA, there have been difficulties in obtaining consistent data on a number of accounts. Furthermore, not all students receive a BSc in Science. Different institutions offer variations, such as, BSc in Biological Science, BSc in Biomedical Science and BSc in Biology. Some, however, offer a 'general' BSc in Science and the student chooses from certain subjects thereby determining that the nature of the final degree can vary. This can occur even where a specialism is indicated in the title, for example, the content of a BSc in Biochemistry will differ in different institutions. On the other hand, one Institution may call their degree a BSc in Biological Science whilst another may call it a BSc in Science (With Biology) although the two courses could be very similar.

Table 5.5: Undergraduate Science Education (Awards and Enrolments)

	Awards			1st Year Enrolments 2001		
	FT	PT	Total	FT	PT	Total
ITs						
Certificates	481	43	**524**	656	23	**679**
Diplomas	315	0	**315**	207	0	**207**
Degrees	377	25	**402**	87	4	**91**
Universities						
Diplomas	0	14	**14**	0	0	**0**
Degrees	2,245	18	**2,263**	1,971	18	**1,989**

Note: Awards are for 2001 for the ITs and 2000 for the universities. Science includes course codes 400,420, 421, 422, 440, 441 and 442 only.

In 2000, 2,263 students obtained primary degrees in science from the universities. Details of the conferring institutions are shown in Table 5.6.

Table 5.6: Undergraduate Study in Science Courses by Institution 2000/01

	UCD	UCC	NUIG	TCD	NUIM	DCU	UL	Total
Degree (PT and FT)	1,613	1,209	1,628	1,508	746	706	538	**7,948**
Other (non-degree and occasional)	14	2	0	34	0	24	135	**209**
Total Enrolment	1,627	1,211	1,628	1,542	746	730	673	**8,157**
Degrees Awarded	482	271	390	539	241	197	143	**2,263**

Note: Degrees awarded in 2000

Males made up 42% of both enrolment and awards. These figures also include about 100 students, mostly male, undertaking part-time science degrees in UCD and UCC.

The ITs provide a range of courses but comparison with the universities is not straightforward. These courses have a variety of names and do not follow standard subject content but are classified by the HEA according to standards developed by international bodies including Eurostat and the OECD. The overall non-completion rate for science subjects (2000) within the ITs has been estimated at 39.7%. The range of 'drop-out' varied greatly among institutes and among study levels as shown in Table 5.7. Although the progression design in the ITs is very flexible compared to the universities, these data clearly indicate that a high proportion of students on some courses do not even achieve the award for which they initially enrolled.

Table 5.7: Non-completion Rates for Science at ITs (%)

Certificate (Range)	21-70
Diploma	12-87
Degree	26-40
Overall non-completion	39.7%

Source: Task Force Report (2002)

These ITs are faced with a choice; they must find a way to enhance their support of student learning and achievement or recruit students who are less likely to drop out. The former is obviously the more appropriate pathway given the need both to help students to achieve their full potential and to ensure that the economy can benefit from students' initial aspirations to engage in third level education.

Table 5.8 shows the output for these courses at diploma, certificate and degree level in 2001 for relevant courses.

In addition, there were 1,336 certificates in computer science, 713 diplomas and 544 degrees from the ITs.

Clearly, projections regarding the number of graduates in the medium-term will depend on current enrolment and completion rates. Output from ITs is difficult to project directly from enrolments due to the flexible articulation between many of the relevant courses. As a result, this section deals with enrolments on university degree courses only.

Table 5.8: Science Awards in ITs in 2001

Field of Education	Certificate	Diploma	Degree
Combined Science, Mathematics and Computing	52	16	131
Combined Life Science	72	27	15
Biology and Biochemistry	206	120	106
Environmental Science	30	22	52
Combined Physical Science	0	9	13
Physics	59	22	8
Chemistry	62	99	52
Total	**481**	**315**	**377**

The total number of first entrants to science courses for the period 1986-2000 and degrees awarded in the universities for 1990-2000 are shown in Table 5.9[86]. These data show the rise in entrants that occurred up to the mid-1990s, the peak in 1995, followed by a levelling off and slight decline in recent years as discussed earlier[87]. However, when these figures are compared with data for degrees awarded four years later it is not possible to discern a definite trend.

When this comparison is done individually for each university the numbers are even more variable. On average, the data show that the number of degrees awarded after four years was 94.2% of the number of entrants four years earlier. This should not be used as an indication of attrition since the rate that this would imply is too low, the problem being caused by the issues discussed in the footnote. Applying this value to the declining number of year 1 entrants in recent years indicates that the number of graduates will fall from about 2,150 in 2002 to 2,040 in 2004.

86 The data available from the HEA for total first entrants differ in some respects from enrolment in first year in the universities. The differences arise due to repeat students, students converting from another course and some part-time students. Thus, the HEA data are effectively the number of school leavers in each year that opt for science in university. This definition provides a consistent series with one further proviso. Up until 1996, computer science was included with science but the figures are now shown separately. While these issues cause some problems in relation to comparison with other data on yearly enrolments, they are sufficiently accurate for the purposes here on the assumption that the number of students repeating, converting and studying part-time does not change greatly from year to year. The indications are that this is a reasonable assumption to make.

87 The distribution of these awards by institution was as follows:

	UCD	UCC	UCG	TCD	NUIM	DCU	UL	% Male
1990	297	267	220	263	103	86	0	54.4
1991	309	200	228	270	128	104	0	50.5
1992	279	209	226	316	115	130	0	51.8
1993	293	248	280	351	121	106	0	47.0
1994	329	242	250	395	128	109	0	45.0
1995	327	299	254	405	149	242	135	46.8
1996	346	255	273	471	152	165	103	46.7
1997	363	247	295	515	146	165	172	42.6
1998	351	229	287	503	188	201	157	44.7
1999	406	241	351	494	217	162	163	43.0
2000	482	271	390	539	241	197	143	42.2

Table 5.9: Enrolment and Awards in Science Degree Courses

First Entrants in Undergraduate Science Degrees (1986-2000) and Number of Degrees Awarded by Universities (1990-2000).

	Number of First Entrants (FT)	Degrees Awarded (FT and PT)	Awards as % of Entrants 4 years earlier
1986	1,361	–	–
1987	1,442	–	–
1988	1,551	–	–
1989	1,467	–	–
1990	1,647	1,236	90.8
1991	1,700	1,239	85.9
1992	1,806	1,275	82.2
1993	1,792	1,399	95.4
1994	1,906	1,453	88.2
1995	2,455	1,811	106.5
1996	2,272	1,765	97.7
1997	2,304	1,903	106.2
1998	2,287	1,916	100.5
1999	2,202	2,034	82.9
2000	2,168	2,263	99.6

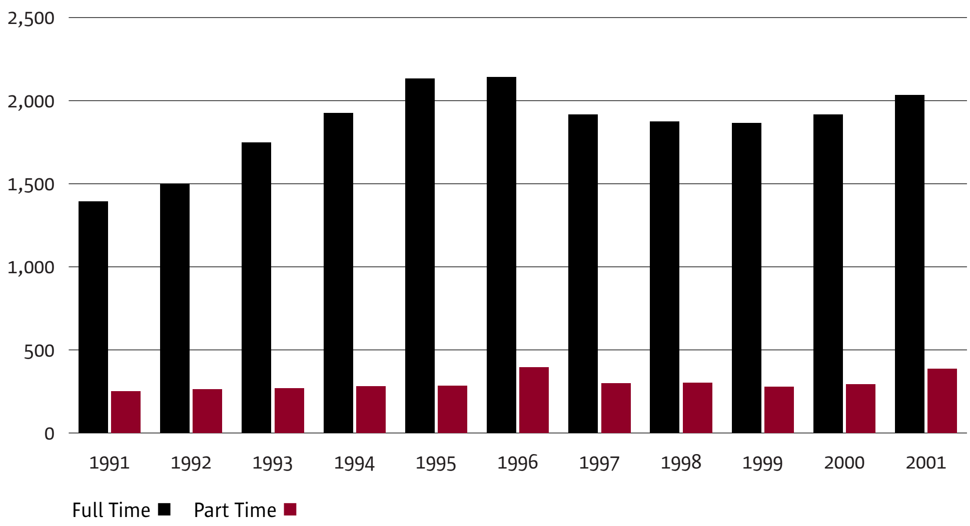
Note: Some figures exceed 100% due to divergence between enrolment numbers and the number of first entrants.

It is clear that these figures should be accepted as indicative of trends only and subject to error intervals. Looking further ahead, the trend in first preferences and the numbers opting for LC science subjects lead to the conclusion that the trend seen in science at second level is likely to assert itself at 3rd level in the next few years.

5.2.3 Postgraduate Study

Although the overall number of science students has levelled off in recent years, there is still growth in the number undertaking postgraduate study in the universities as shown in Figure 13.

Figure 13: Numbers of Postgraduate Science Students in Universities (1991-2001)



This indicates that over 2,400 students were registered to undertake higher degrees in science in these institutions in 2001. Of these, over 2,000 were undertaking full time research. A total of 1,219 were undertaking PhDs while 946 were doing Masters courses. The remainder was undertaking a variety of postgraduate diploma courses in various universities. Details of these enrolments by institution are shown in Table 5.10.

Table 5.10: Enrolment in Postgraduate University Science by Institution 2000/01

	UCD	UCC	NUIG	TCD	NUIM	DCU	UL	Total
Cert/Dip	–	71	46	49	35	26	28	255
Masters	98	191	130	279	22	149	77	946
PhD	367	197	221	237	85	63	49	1,219
Total	**465**	**459**	**397**	**565**	**142**	**238**	**154**	**2,420**

Note: Includes both Full-time and Part-time students. It should also be noted that, due to differences in practices in relation to registration in the various institutions – most notably that some require students to register for an MSc in the first two years of postgraduate study before progressing to the PhD register following assessment of their performance – the breakdown between Masters and PhD in this table may not be an accurate indicator of students' actual intentions when they register, nor the relative emphasis that is placed in the various institutions on each course of study.

The total of 2,420 is divided fairly evenly between males and females but this balance is moving increasingly towards a majority of females at this level, as at other levels. A strong bias in UCD towards PhD rather than MSc programmes means that a greater number are enrolled for PhD overall. With a total of 2,420 students undertaking postgraduate study, mostly fulltime and over 50% doing PhD, progression to this level at almost 30% of undergraduate enrolment in the universities is very high compared to other faculties.

Traditionally this has been the case with science, but it remains to be seen whether the greatly changed labour market in Ireland will have an impact on this trend. It is likely that funding from SFI has been important in the recent growth of the number of postgraduates, particularly since this has happened in a period of a relatively tight labour market which would have been expected to draw students away from pursuing full time postgraduate study.

Postgraduate study is also undertaken in the ITs. Table 5.11 shows that students in ITs obtained 11 Masters degrees and 8 PhDs in 2001. All were undertaken on a full-time basis. However, enrolments on research Masters courses in ITs expanded in 2001. Within the universities, over 100 of the Masters degrees awarded in 2001 were obtained through research. The number of enrolments in 2001 again shows an increase in enrolment for Masters by research but the likelihood is that a sizeable proportion of these will transfer after a period of time to the PhD register in these universities.

Table 5.11: Higher Degree Awards and Enrolments (2001)

	Awards 2000-01					1st Year Enrolments 2001-02				
	Taught		Research		Total	Taught		Research		Total
	FT	PT	FT	PT		FT	PT	FT	PT	
ITs										
Masters	4	0	7	0	**11**	11	0	55	4	**70**
PhD	0	0	8	0	**8**	0	0	3	0	**3**
Universities										
Masters	93	11	61	4	**169**	119	24	166	1	**310**
PhD	0	0	239	6	**245**	0	0	155	0	**155**

Note: Codes 420, 421, 422, 440, 441 and 442 only.

Classifying postgraduate degrees by study area is difficult, particularly where the degree is awarded on the basis of research that has been undertaken. However, some classification into broad areas is possible, to be consistent with the course codes that were identified above. This analysis is shown in Table 5.12.

Table 5.12: Postgraduate Degrees Awarded by Broad Subject Area in 2000/01

	Research	Masters Taught	Total	PhD Total
Combined Life Sciences (420)	1	32	33	30
Biology/Biochemistry (421)	24	24	48	130
Physics (441)	18	5	23	20
Chemistry (442)	14	22	36	50
Other	8	21	29	15
Total	**65**	**104**	**169**	**245**

Note: Universities only; Codes 420, 421, 422, 440, 441 and 442 only.

This shows that the largest numbers of higher degrees were obtained in the key areas of biology and biochemistry with chemistry providing the next highest. Together, these study areas provided 84 Masters – 38 of which were obtained through research – and 180 PhDs. In addition to the courses included in this table, there were also 12 PhDs awarded by universities to students in Combined Sciences (Code 40) and 8 PhDs awarded by ITs. These were 3 PhDs in Life Sciences (Code 42) and 5 in Physical Sciences (Code 44). A total of 30 PhDs were also awarded in the related areas of Mathematics and Statistics (11), and Computing (19) in 2001.

The annual number of science PhDs awarded has risen slightly in recent years from 233 in 1996 reaching a high of 281 in 2000, but falling back to 253 in 2001. The average number of science PhDs awarded by each institution in this period is shown in Table 5.13.

Table 5.13: Average Annual Science PhDs Awarded (1996-2001)

TCD	65
UCD	70
NUI Maynooth*	4
NUI Cork	44
NUI Galway	41
DCU	21
UL	10
ITs	6
Total	**261**

Note: Codes 420, 421, 422, 440, 441 and 442.
**Figure for NUI Maynooth is for 2001 only.*
Source: HEA First Destinations Report

SFI has been provided with a budget of €646 million to support research up to 2006. The creation of this fund is a major innovation and, along with a number of other schemes that have been discussed earlier, provides a structure for the provision of future funding for research. The Third Report of the Expert Group on Future Skills Needs provided early projections in relation to the number of researchers that were to be supported by these schemes. To date, SFI has provided funding of €218 million and additional proposals are being evaluated. However, it is unclear to what extent these researchers would be additional over previous levels of output although some level of additionality is certainly expected. In addition, progress with administering the SFI mandate has been somewhat slower in terms of the dissemination of funds than might have been assumed in the Expert Skills Group report and the available evidence indicates that it would be inappropriate to use these projections to provide an estimate of the impact of SFI currently. This issue is returned to in Section 6.3.2.

Given the potential importance of SFI, the following points should be noted. First, it is important that its impact is made as quickly as possible. Second, for maximum impact, its mandate should be extended beyond 2006 and its funding guaranteed beyond this date. Third, funding allocations should contain a requirement of much more detailed feedback of the use and impact of the funds that are allocated than has been available in this area to date. Finally, the work of SFI should be closely co-ordinated with other agencies in this field to ensure that repetition is minimised while also eliminating any remaining deficiencies in the system.

5.3 Science Skills Output in Northern Ireland

Clearly, demand for science skills in the Republic of Ireland as a result of the development of biotechnology can be supplied from skills available in Northern Ireland. Table 5.14 shows the output of science graduates in Northern Ireland in recent years. The data classifications used are not fully consistent with the coding system that has been adopted elsewhere in this chapter in relation to the Republic. Graduates from biomedical science courses at both universities are included in the 'Subjects Allied to Medicine' category and so are clearly relevant along with biological sciences. However, the large numbers obtaining 'Other Undergraduate Qualifications' in QUB includes the DipHE in Nursing and is not relevant to this study. Furthermore, MSc and PhD obtained through research are not identified separately.

Table 5.14: Science Awards in Northern Ireland (1998-2001)

	Subjects Allied to Medicine		Biological Sciences		Physical Sciences	
	UU	QUB	UU	QUB	UU	QUB
First Degrees (BSc)						
1998	515	184	282	277	129	238
1999	538	263	234	268	94	217
2000	540	200	250	240	110	230
2001	565	375	250	245	105	215
Higher Degree Qualifications (Research Masters and PhDs)						
1998	30	55	45	70	12	59
1999	79	49	32	27	19	33
2000	60	40	20	100	10	70
2001	135	35	50	70	40	55
Other Undergraduate Qualifications						
1998	22	223	37	80	13	77
1999	13	1,113	16	0	8	12
2000	10	910	20	0	<10	<10
2001	20	620	20	0	5	0
Other Postgraduate Qualifications						
1998	97	49	17	31	34	4
1999	60	30	1	1	21	1
2000	90	50	0	30	<10	<10
2001	125	80	5	10	5	0

Note: Other Undergraduate includes qualifications such as Higher National Diploma and Higher National Certificate. Other Postgraduate Qualifications include taught masters, and postgraduate diplomas and certificates.

Source: Higher Education Statistics Agency (NI)

Higher Education Statistics Agency (HESA) also produce an annual first destinations report. However the information it contains is not disaggregated sufficiently to identify the number of NI graduates who go to work in the Republic since the destination category 'other EU countries' is used instead of individual countries. Furthermore, where there is a breakdown by subject area of numbers entering employment, further education etc, these are on a UK-wide basis and are not broken down by institution.

Regulations mean that Biomedical Science graduates from NI who do not go on to further research but instead wish to work as laboratory scientists are restricted to working in the UK so as to gain 'registration'. Since this cannot be obtained by taking up employment in the Republic it can be assumed that very few if any biomedical science graduates enter the Republic's labour pool directly after graduation, although it is likely that they would do so after some period of employment. It is known that some students from the Republic who do their Science BSc in the south come north for postgraduate study and return to the South after completion. However, the annual number involved is very small. What evidence that is available indicates many who obtain science PhDs in Northern Ireland go to the US after graduation to follow their line of research in postdoctoral work. As a result, it appear reasonable to conclude that the number of such graduates who come to the South would also be very small.

This evidence, while incomplete, suggests that, at all levels, the output from the universities in the North would have a minor impact on the labour market in the Republic. This would appear to be particularly the case at higher skill levels. A further point is also important. This report is primarily concerned with examining the impact of new developments in the demand and supply of skills rather than the absolute numbers involved. As a result, even if the flow of skills across the border is greater than the evidence suggests, there is no reason to conclude that this will change much in the future. In other words, this flow is currently leading to tight labour market conditions for scientific skills in the Republic and, with Northern Ireland also engaging in the efforts to develop biotechnology, there is no reason to believe that it will provide a significantly greater labour pool for prospective employers based in the Republic to access in the future.

5.4 First Destinations

The HEA Report entitled 'First Destination of Award Recipients in Higher Education' produced annually since 1982 details the initial employment, further study and training patterns of certificants, diplomates and graduates[88]. The 2002 publication focuses on the year 2000. For that year, 23,000 out of 37,500 award recipients (61%) responded to the HEA's survey. The findings show that, encouragingly, the number of primary and higher degree holders employed in Ireland is increasing with the number seeking employment overseas falling. This enhances the available skilled workforce, but also indicates that a tighter labour market exists than in previous years. Some results from the HEA surveys are shown in Table 5.15.

Table 5.15: First Destination of Graduates (1998-2000)

	1998	1999	2000
Primary Degree			
Engaged in Research Work in Ireland	26.0%	22.4%	22.9%
Engaged in Research Work Overseas	3.9%	4.2%	3.1%
Employed in Ireland	44.5%	44.1%	46.4%
Employed Overseas	7.6%	8.3%	6.9%
Employed in North America (% of O/S)	12.1%	18.4%	22.6%
Higher Degree			
Engaged in Research Work in Ireland	5.9%	5.2%	8.0%
Engaged in Research Work Overseas	3.1%	4.0%	4.5%
Employed in Ireland	56.5%	57.1%	60.7%
Employed Overseas	23.8%	21.6%	19.0%
Employed in North America (% of O/S)	27.4%	22.5%	18.8%

Source: HEA

88 HEA (annually since 1982) *First Destination of Award Recipients in Higher Education.*

Despite an increase in the number of higher degree graduates engaging in research in Ireland, there did not appear to be any significant increase in the number of primary degree graduates entering into research in Ireland. Since these figures are for the year 2000, recent investment by SFI into the number of available postgraduate places in science should have an impact on these figures since then.

Perhaps the most notable feature of this table is the very low number of graduates with higher level degrees who are classified as being engaged in further research. It is likely that this is the result of two factors. The first is that the HEA methodology may not be identifying persons that are employed but that are employed in research. This is not unusual given that the movement of research out of the universities to become a function of commercial ventures is a fairly recent event and is a characteristic of the biotechnology industry in the leading centres. The second explanation however is that there is not a significant amount of research being conducted in Ireland. Certainly, the structure of science related industrial activities in Ireland is heavily weighted towards production, a direct result of the taxation system. This is a key weakness of the Irish economy, very clearly in relation to the leading biotechnology regions but also in comparison with emerging centres in Medicon Valley and Singapore.

5.5 Conclusions

The analysis of student participation in science in Irish universities gives some cause for concern. The numbers of students opting for science in third level are showing signs of decline. The fall in application to science courses reflects developments at second level where a rapid decline in the overall number of students taking the Junior and Leaving Certificates is more than paralleled by the number taking science at Leaving Certificate level. In recent years, the numbers opting for science subjects has fallen faster than the overall numbers undertaking the Leaving Certificate, indicating that science is becoming less attractive to an already declining student population.

The reasons for this are complex but, while policy cannot change the overall demographic factors that are driving the fall in numbers, there are options in terms of intervention to achieve a higher uptake of science. Such intervention is essential as the overall numbers taking science can substantially affect future workforce skills and overall societal knowledge. Therefore, the proportion of students taking science needs to rise within a declining overall total student number. There are opportunities here to increase the take-up of science at Leaving Certificate level by acting to remove any perceptions that may inhibit their uptake, actively promoting interest in the area and revising the requirements to direct students towards science effectively making a science subject a core element of the Leaving Certificate.

The falling numbers enrolled on Diploma and Certificate courses is also a cause for concern since these courses tend to be targeted more than university courses at the immediate and short-term needs of industry and provide opportunities for students with lower academic qualifications to enter science-based industries. This is particularly the case since the type of biotech industry that is likely to emerge in Ireland in the short to medium-term will require a mixture of skills at this level combined with large numbers with higher degrees.

So far, the number of graduates in science has held fairly level but, on the assumption that enrolment in recent years provides an indication of the output of graduates from the institutions over the next few years, the downward trend in science may become more evident. The trends at Junior and Leaving Certificate levels indicate that the pattern of recent years at third level cannot be maintained.

The decline at 2nd level means that the recent outputs from 3rd level will not be maintained. Interventions will need not only to maintain current numbers but to increase them to meet the requirements of biotechnology as suggested by the growth profile indicated in this report. Interventionist policy options must address both the demand for, and supply of, science places. It would be a mistake to increase the number of places available without adequate concentration on making the science option more attractive. To do so would risk driving down the entry requirements particularly for the less attractive courses outside of the top institutions.

A second issue is to observe that a broad range of skill levels will be required by the biotechnology industry. The way in which the industry has developed means that the needs of biotechnology cannot be met through the provision of high numbers of PhD graduates alone, or by graduates that are streamlined according to long established inter-disciplinary boundaries.

Recognition is required of the way in which the industry, as determined from observation of areas with mature biotechnology clusters, responds to the available labour market. A key feature of the industry is that it has tended to develop in areas in which an appropriate learning community is already present. Given the highly competitive arena of many regions vying as host locations for biotechnology, and the imperative that Ireland should not aim to develop simply as a production centre, it is essential that a skill set is available ahead of requirements. However, current course offerings within the educational sector in Ireland do not indicate that the needs can be met sufficiently well to keep pace with global competitors.

A further issue that requires examination is the extent to which the Irish university system is positioned to collaborate with industry in a manner that makes it responsive to its needs. The key issue here is that funding for Irish universities is highly dependent on public funds. Recent research in the UK suggests that over-dependence on public funding for education as distinct from research tends to make universities less responsive in their decision-making to the needs of industry[88]. Universities need to borrow some of the ethos of successful industry by becoming entrepreneurial and enterprising, while yet meeting the needs of the community they serve.

Finally, to allow for the formulation of useful policy, some weaknesses in the collection of data on student numbers need to be addressed. Not only are different systems of classifications used for science in universities and ITs, but a more comprehensive dataset of research and researchers is lacking. It is understood that initiatives currently being implemented will help in overcoming some of the many difficulties that arose in compiling consistent data series for this analysis. However the historical weaknesses cannot be redressed so the determination of future trends will remain difficult for some years to come.

88 See 'The Ruin of Britain's Universities' *Economist*, November 16th 2002 and supporting material.

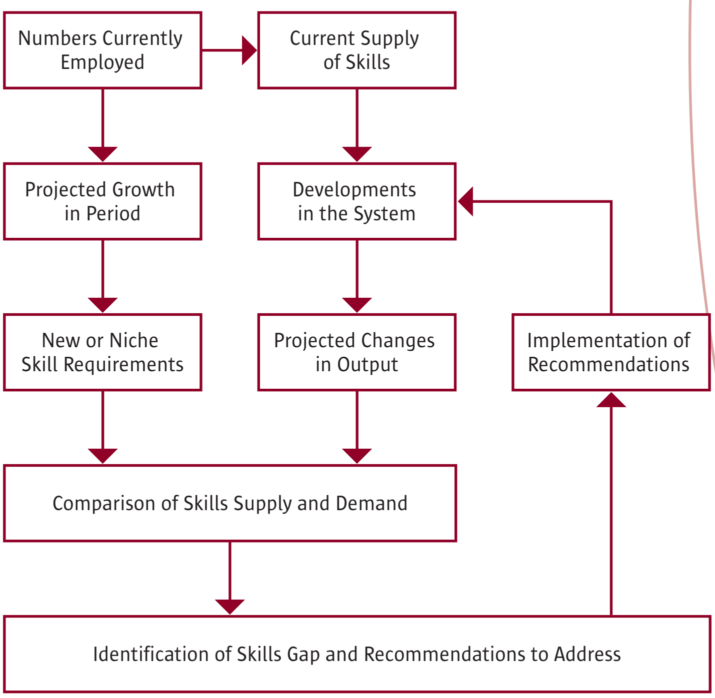
6 Projected Demand and Supply for Skills in Biotechnology

6.1 Future Demand for Skills in Biotechnology: Approaches and Projections

6.1.1 Projecting Skills Requirements

The conceptual approach that usually guides manpower planning exercises is shown in Figure 14. The approach is based on determining projections for skills requirements in the specified sector and comparing these with projected outcomes from the education and training system. Comparison of the two sets of numbers indicates if a skills gap is likely to emerge. This is then to be addressed through the implementation of recommendations, usually specified in terms of additional output from the system that will bring the supply and demand for skills into approximate balance. Generally, it is recognised that projections such as these will inevitably be subject to errors. The implicit argument supporting this approach is that if the exercise is undertaken in a manner that is rigorous then the recommendations will be the best indicator available of the actions that are required, to avoid the emergence of skill deficiencies within the time horizon of the project.

Figure 14 : Standard Approach to Manpower Planning at Sectoral Level



This approach is designed to answer the question:

> *'How many skilled people in each skill category will the development of this industry require over the next planning period?'*

Within the context of this question, and provided adequate recognition is taken of the likely error intervals, this approach provides an indication of what is required to avoid deficiencies that could inhibit the growth of the industry in question. However, this conceptual model is inadequate in a number of respects.

The most important deficiency is that while it is implicitly recognised that the supply of adequately skilled personnel in adequate numbers is required for the development of the sector, this approach does not acknowledge that the supply of skills will determine the type of industry that develops. In terms of Figure 14, there is no explicit link between the demand and supply sides apart from the comparison of the numbers that are projected.

Second, there is no mechanism implied whereby the supply becomes responsive to the needs of industry on an ongoing basis. Projections of this type can never do more than provide broad parameters and identify emerging gaps. This is different from a system whereby the framework is set but the actual supply of skills is made flexible and responsive to the needs of industry as they actually evolve over time. Taking this a step further, the model does not allow for a leading role for the education system to guide the type of industry that emerges. In other words, this approach is incompatible with the idea that for the development of knowledge intensive industries in a particular location, it is necessary for the education and training system to provide that location with a competitive advantage in terms of the skills and experience that is available.

Third, there is no feedback from the exercise to the demand side. Objectives must be based on existing competitive advantages; not every region is going to achieve a full cluster, and niche development will be required. In addition, recommendations in respect of the education system should be both consistent with, and supportive of, other areas of industrial policy.

Finally, this approach does not recognise the risks that are involved in committing significant resources to biotechnology development. There is considerable uncertainty regarding the eventual contribution of this industry in terms of valuable products and more especially, when these might emerge. Furthermore, there is uncertainty regarding the future structure of the industry and the key determinants of profitability. The precise skill sets required are only emerging and will depend in part on the products and structures that evolve. In addition, it should be realised that accurate mapping of the available skills can provide indications to development agencies (Enterprise Ireland, IDA Ireland) of the types of ventures that stand a high chance of success. This is because evidence from elsewhere links the pre-existence of appropriate skills with the subsequent development of biotechnology.

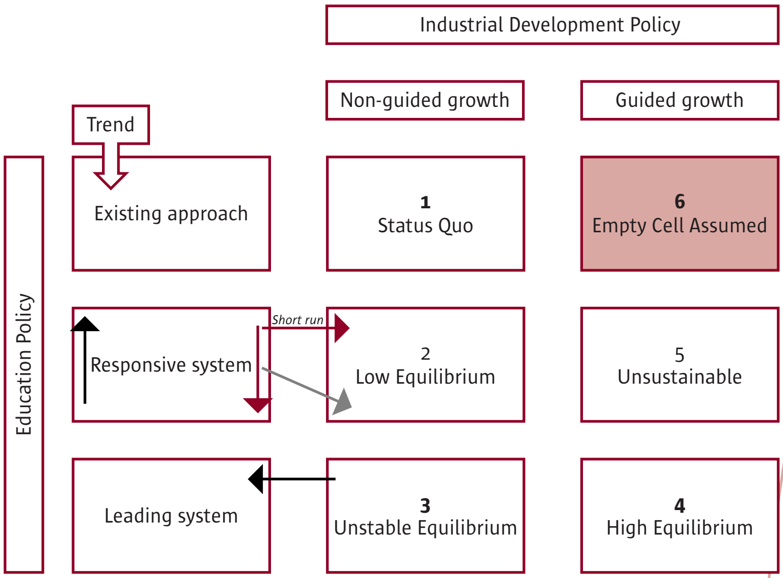
6.1.2 Modelling Dynamics and Outcomes

In light of the foregoing, an approach that recognises the risks, the need to create competitive advantages at an early stage and the vital role of supporting sectors and policies is required, when determining future skills' demand. Clearly, industries such as the biotechnology industry do not develop at random but locate to areas that display competitive advantages. Thus, the correct question for Ireland in approaching manpower planning for the development of this industry is not 'How many skilled personnel?' – although clearly the numbers required in various skill categories are an important secondary question – but, rather:

> What is required of the education and training system, in collaboration with other areas of the economy that are subject to a degree of control by policy makers, to provide Ireland with a competitive advantage in terms of its attractiveness to indigenous and inwardly-locating biotechnology firms?

The key difference between this approach and the previous approach is that it recognises that the education and training systems must play a leading role, rather than aiming to be responsive to needs, in designing the type of industry that emerges. Furthermore, it recognises the importance of ensuring that all policy areas are co-ordinated towards realising the objectives that are set out in advance in respect of the type of industry that is desired. This, in turn, allows for existing competitive advantages to be harnessed. Figure 15 captures these features, not in terms of a flow diagram of the process required to address the requirements but rather in terms of the forces that will determine particular outcomes and the role of policy in determining these outcomes.

Figure 15: Model of Manpower Policy Outcomes



There are a number of alternatives in respect of the type of industry that will emerge and the labour market outcomes produced under different circumstances. Figure 15 shows two possible alternatives for the development of the industry in Ireland. Cells of the outcome matrix on the left, described as non-guided growth, represent the industry outcome if development is allowed to occur without a fully comprehensive and clear industrial policy programme for the development of biotechnology[89]. Those on the right indicate outcomes where effective industrial policy measures are introduced. Thus, the move between the two columns depends on successful industrial policy measures. The three rows of the matrix represent different approaches in terms of the role of education. The top row assumes that education continues to operate much as it did in the past and few innovations are introduced, the numbers produced being determined by the supply structures available. In other words, this is a supply-driven output. The second level represents a move, which has been occurring, towards a demand driven system. This is described as a responsive system since it responds to the needs of industry. A significant change here is the move from discipline-based education to skill development. The final row shows education as a source of competitive advantage with skills being produced in advance of requirement and in areas that are precisely defined according to the needs of the biotechnology industry.

In successful education clusters this move down the matrix occurs as a result of the close interaction of providers with industry representatives and the mutual dependence of the two parts of the economy. However, for a location that wishes to emerge in this industry there are considerable difficulties and risks to be addressed. This can be seen through observation of the various cells of this matrix. Each cell represents a particular outcome for the industry under guidance to various degrees of policy.

The outcomes represented by the numbered cells in Figure 15 can be described as follows:

> **Cell 1.** This represents a situation where the supply of skills continues without further innovations and policy in other areas only promotes biotechnology to the extent that elements of the Irish economy, for example the existing pharmaceutical industry, provide Ireland with sufficient competitive advantages to attract industry. This is a minimalist approach and is not consistent with observed trends. Universities and ITs in particular have introduced innovations, albeit often driven by the need to be able to compete as centres of education. Given that there is much room for further movement in this direction it is likely that the sector will continue to evolve towards a more responsive design. However, the speed at which this occurs is an issue.

89 In respect of Figure 15, industrial policy is treated as all policy areas other than education and training that affect the development of the industry.

Cell 2. This involves development of the biotech industry on the basis of existing strengths in the economy and a continuation of reform in education towards a more responsive system. However, policy is not fully co-ordinated and is akin to an incrementalist approach that allows the economy to evolve rather than be guided. The result is a low equilibrium with some biotech industry, probably restricted to production and education responding over time to the needs of this industry. In many respects, outcome 2 is a fairly comfortable place to be since the educational institutes are responding to needs as observed and graduates are finding employment. In this respect, it constitutes a stable equilibrium[90].

Cell 3. This represents an undesirable outcome and shows the importance of understanding the risks that are involved in developing this industry. To get to Cell 3, the education system responds to policy initiatives and gears up for the biotechnology industry through developing new courses and increasing output in certain skill categories. In addition, experienced workers are attracted away from existing sectors and new skills are developed. Clearly, this is likely to be a very expensive exercise. However, the biotechnology industry fails to develop as expected. This failure may arise for a number of reasons. One obvious issue is that while the skills are produced, the wider policy programme fails to attract biotech in the form expected. This policy risk is accompanied by industry risk – biotech does not deliver as expected – and there is uncertainty over future structure and requirements of the industry. The net effect is that the skills produced are not required or are inappropriate for the type of industry that emerges. This makes Cell 3 an unstable outcome that reverts back to Cell 2 as supply structures re-adjust to requirements and students opt for courses offering better prospects.

Cell 4. A successful biotech cluster begins to emerge in this cell due to availability of the required skills and the success of supporting policies. This represents the high equilibrium and is clearly the desired outcome. Once achieved, this is stable, although clearly not static, and the dynamic, clustering effect occurs. This leads to a strengthening of the systems that have produced these outcomes.

Cell 5. This represents an option in the short-term to develop niche specialities in biotech. Policy initiatives operate in the short-term to attract the industry through the provision of reactor capacity for the production of large molecule proteins. This development would also complement certain existing skills in the labour force, such as experience in process development and pharmaceutical production. However, this is a short-term strategy only since industry investment plans indicate that the deficit in reactor capacity that provides this opportunity will probably be eliminated within five years. This specialism would be primarily for production but would also form the basis for clinical trials since reactor capacity is also required for this activity. This outcome is stable but is unsustainable in the longer-term. This is not to suggest that Ireland would be unable to retain the industry that had been attracted, but it is not a sustainable strategy for success since the competitive basis will be eliminated once the deficit is overcome.

Cell 6. This cell is assumed to be empty since going ahead with attempting to develop the biotechnology industry though a comprehensive policy approach without paying attention to the need to reform the education sector would not be rational. It is arguable, however, that policy could attempt to guide the development of the biotech industry, but that the university system fails to deliver due to its own unwillingness or due to an inability to attract sufficient student numbers thereby undermining any effort at a proactive response.

A considerable debate has taken place between industry and the formal education system over whose role the provision of a skilled workforce actually is. However, this debate is sterile and misses the point that, whatever the balance of the argument, in the absence of a properly trained and prepared workforce and skill-base, biotechnology will not develop in the optimal manner. The role of policy in

90 The concept of equilibrium requires some comment. It should not be understood as a static outcome that represents where the economy is positioned. Rather, it represents a particular outcome of a system, towards which there are forces in the system working to bring it about. Thus, the economy may be always moving towards equilibrium or on an equilibrium path. Furthermore, this understanding of the concept gives it a dynamic aspect that makes the idea of a temporary but unsustainable equilibrium or an unstable equilibrium possible. The former can exist but for a limited period only, while the latter represents an outcome that is produced by the system but that contains within it unresolved imbalances that will quickly alter the outcome towards a more stable outcome.

the future, in both the educational and other spheres, if biotechnology is to develop, is to move the system towards the prior development of a skill-base that pre-empts demand. At the same time it must put in place or facilitate the supporting structures and initiatives that characterise dynamic clusters.

This indicates that there are two equilibria and the role of policy is to move the industry from cell 2 to cell 4. Cell 3 is an unstable outcome and suggests that the system soon begins to revert to something close to Cell 1 or Cell 2. Cell 5 represents a short-term opportunity to achieve some mass but it is not sustainable as a strategy for development. Cell 4, in contrast, is a new equilibrium – in terms of the labour market – with a dynamically growing biotech industry with increasing specialisation in high value-added activities. The difference between Cells 3 and 4 is between success and failure. This is the risk. Creating a leading system and putting in place the supporting policies will be very expensive. The example of Singapore demonstrates this to the extent that policy has been set and is being pursued without overall evaluation along conventional lines. In other words, it is a gamble. The next question to be asked, in the light of the analysis in Chapter 4 and 5 is: what are the numbers of personnel and the specific skills that are required to form the basis for this outcome to emerge?

6.2 Projected Outline for Development

The model of the biotechnology industry outlined earlier distinguishes three areas of activities: research, development and production. The final part, production, can be further divided into bulk production and product finishing. It has been argued that the research function is at the core of the development of a cluster. However, currently Ireland does not have a leading position in terms of its research activities although areas of specific strengths exist. Ireland has competitive advantages in terms of critical mass and strength in related industries like pharmaceutical and medical devices manufacturing. This advantage can be exploited by the biotechnology sector to promote the development of production. Furthermore, this expertise in production could offer opportunities in some product development areas, and the existence of the large cohort of leading pharmaceutical firms in Ireland presents opportunities for the development of R&D activities. The growth of contract development provides niche opportunities. Hence, at least at a theoretical level, it is possible to envisage the emergence of a biotechnology cluster in the sense of Figure 4 (Chapter 4). The question now addressed relates to quantifying the demand for skills that such a model would give rise to in practical terms and assessing what risks would be involved, in terms of the paradigm contained in Figure 15, in seeking to bring this about. This latter aspect, crucially incorporates quantitative assessment of the prospective gaps between demand and supply of skills and the time horizon over which it would be feasible to eliminate these gaps.

In this section we consider the implications of a policy decision to promote a biotechnology cluster in Ireland. It is possible to estimate the demand for skills necessary to provide the competitive edge that is a prerequisite for the emergence of this cluster. To do this requires defining the industrial structure that such a cluster would entail and applying the information on labour requirements that was detailed in Chapter 4 to such a structure.

We consider the creation of employment at three stages on the continuum of activity in biotechnology, namely, *Research*; *Product Development*; and *Production* (bioprocessing).

6.2.1 Research

The development of a competitive research base to form the core for the cluster requires the co-ordination of wider research activities, many of which are currently taking place in Ireland, but also the development of leading centres composed of relatively small numbers of highly skilled personnel assisted by support technicians.

To provide the required profile, the central core of this system would need to involve perhaps 20 'stars', i.e. research scientists who are internationally acknowledged leaders in their fields. These individuals would require a further 100 or so PhDs of varying levels of experience. Many of the central core of 'stars' and some of the other highly skilled personnel undoubtedly would need to come from abroad. It seems reasonable to assume that this would create a demand for an additional 100 PhDs in biology and chemistry, a majority of whom would need to be in biology or with biology-related (e.g. genetics) expertise. In addition, in the region of 100 more skilled personnel would also be required, of whom perhaps 50 would need to be graduates.

6.2.2 Product Development

Firms in the second category are engaged in product development. We assume, for the moment, that these are the result primarily of new FDI, perhaps generated by the emerging collaborations between universities and existing foreign-owned pharmaceuticals. These could also be a result of biotech firms gaining a first presence in Ireland, or existing firms moving towards research activities in Ireland as the economy demonstrates its commitment and emerging competency in research.

For development activity, an appropriate target would be that about five entities would emerge. Examination of leading clusters indicates that these firms would be of medium size, with an average employment of 100. These firms would be engaged in a broad range of functions, but in reality, contract research would appear to offer the most interesting prospects.

This area of activity requires highly skilled personnel as well as individuals of moderate qualifications, with training to prepare them for work in a biotechnology environment. Typically, 20% of employees would have PhD qualifications, with a further 20% with an MSc. A further 20% would have a primary degree in science with another 10% of graduates in other disciplines. Of the remaining 30%, a properly designed sub-degree course would be needed for perhaps half. This means that the total requirement for the emergence of development activity along these lines would be for the following:

100 PhD in science (most of whom need some form of experience);
100 MSc, all of whom would have a background in science but perhaps 50% of whom would have undertaken the MSc in another discipline;
100 BSc;
50 non-science graduates (BA, BComm, ACCA, BL, etc.);
75 Diplomas and Certificates at sub-degree level; and
75 others (operatives etc.).

A key issue for firms in this category is experience, particularly among the PhD and MSc cohort. In this respect, Ireland may have some advantages given the prior existence of the pharmaceutical industry. Among the MSc graduates, particularly those without experience, a range of disciplines would be included. As a result, of the 100 identified, perhaps 50 should have a BSc with a MSc in science while the other 50 would have the MSc in areas including management (optimally an MBA), law or legal affairs, regulation with relevance to biotechnology, and IT. Indeed, the evidence from even the leading centres of biotechnology is that an excess supply of personnel with these types of qualifications, particularly if allied to experience in industry, would be unlikely. As a result, these figures should be treated as the minimum that would be required and the production of greater numbers would provide Ireland with a competitive edge to attract niche service-related activities in the biotechnology sector. Furthermore, the 75 sub-degree qualifications that are required should also be regarded as a minimum since this refers to people with this level of qualification only. Consultations with industry operators indicate that individuals with degrees, even higher degrees, can benefit from sub-degree 'conversion' courses and are eagerly sought by firms.

6.2.3 Production

In relation to the development of production activities, Ireland has a head start in the supply of skills since it has a considerable labour pool in this area, although this is mostly gainfully employed already in other sectors. This implies that the growth of biotechnology would probably mean movement of individuals between the existing pharmaceutical sector and new firms. In addition, it is projected, as discussed below, that employment in the pharmaceutical sector will continue to grow in Ireland. This poses additional issues in relation to the supply of skills given the tight labour market that exists already.

The expectation within the industry is that the production of the main biotech products will take place in firms somewhat similar in structure to the existing pharma firms, although functions and skill sets will vary, that employ 500 to 1,000 personnel. Typically, 5% of employees in these firms would have PhDs, with an additional 5% having a MSc qualification. Approximately 50% of employees would have first graduate qualifications, evenly split between science and other graduates.

The emergence of a successful biotechnology production sector in Ireland would imply the generation of perhaps 3,500 *additional*[91] jobs over the coming 7 years in the cluster. Given the wave of investment internationally in fermentation capacity to meet biopharmaceutical production requirements it is expected that a significant demand for workers will arise in the short to medium-term. IDA Ireland's strategy for the biotechnology and pharmaceutical sectors, envisages the creation of 3,500 jobs. This figure breaks down to reveal the following skill requirements:

175 PhD;
175 MSc;
1050 BSc;
1050 other graduates (BA, BComm, ACCA, BL, etc.);
875 sub-degree Diplomas and Certificates; and
175 others.

These projections for development and production relate to FDI-driven growth, including green-field investments as well as foreign firms collaborating with university-based initiatives in Ireland. However, it is recognised that the development of indigenous biotechnology firms is also an important requirement. In this respect, many of the non-skill issues that are discussed in this report are very important to avoid the emergence of the unstable equilibrium, cell 5 in Figure 15. Some projections for employment in indigenous biotech were contained in the Third Report of the Expert Group on Future Skill Needs. These assume employment of 900 in 2002, and project this to rise to 2,400 in 2006. This projection is somewhat greater than the medium-term objective of Enterprise Ireland. This has recently been stated to be to increase the number of indigenous biotech companies from a current base of 21 to 60 within five years and in the same period to increase the number of people employed in the sector from 400 presently to 1800[92], an increase of 1,400.

Since the higher projection was formulated, the sector, in line with other high-tech industries, has undergone a sharp downturn. This has been felt very sharply in relation to venture capital, which is a crucial link in the chain of development of indigenous firms. As a result, the latter lower projection is assumed as more relevant. In this projection it is assumed that this level of indigenous employment is achieved over the same period as for the cluster that has been described. Many of these indigenous firms would be small and employ a very high proportion of highly skilled individuals along the lines of the development firms. Within the five-year period some should move along the development path and may be engaged in production[93]. However, these are likely to be very small in number and so it appears reasonable to assume skill sets along the lines of the development firms above. One difference is that management qualifications would appear to be more important in these firms, so qualifications such as science with an MBA would be important. Thus, 20% of employees would have a PhD, 20% an MSc, a further 20% would have a primary degree in science with another 10% of graduates in other disciplines, and 15% with an appropriate sub-degree qualification. This gives the following numbers:

280 PhD;
280 MSc;
280 BSc;
140 other graduates;
210 sub-degree Diplomas and Certificates; and
210 others.

---

91 By "additional" we mean an increment on the current rate of FDI-related job creation.

92 An Tánaiste at the launch of the Growcorp European Bioscience Fund I, December 11th, 2002

93 This does not necessarily imply an assumption that drugs emerge as this timeframe is too short for this under typical outcomes. However, alliances and products that are inputs to the industry at various points of the continuum as discussed would be likely and would have impacts on the skill sets required.

6.2.4 Summary Total Demand: Nascent Biotechnology Cluster

In total therefore, these projections suggest that the development of a biotechnology industry in Ireland, along the lines set out, will require in the region of:

- 655 PhD;
- 555 MSc;
- 1,480 BSc;
- 1,160 sub-degree Diplomas and Certificates; and
- 1,700 others.

These projections are based primarily on the requirements of industry with the exception of the research requirement that will be required. It is likely that most of these will, in the medium-term at least, be based in universities and other publicly funded centres.

There are two further areas where high-level skills will be required to support the developments outlined above. The first will stem from the requirement for additional teaching staff and research managers within the universities to accommodate the expansion in research activity. It is likely that this will lead to a demand for 30 PhDs over the next 7 years. Secondly, there will be a requirement for additional technical expertise in government departments and state agencies charged with oversight and regulator responsibilities. It is anticipated that this will generate a demand for 20 MSc graduates over the next 7 years.

In addition, as noted at the outset, the sector will require about 20 stars, some of whom are likely to come from within Ireland. Furthermore, as discussed above, the MSc and sub-degree numbers should be treated as minima, since these personnel are in scarce supply in the industry. Furthermore, the numbers provided for sub-degree qualifications are for people with these qualifications only, but higher skilled individuals with appropriate add-ons of this nature are highly sought by biotechnology firms. This would be particularly true for the 'other graduates'.

In summary, if this total demand were to be generated over a seven-year period, the following additional *annual* requirements would arise[94]:

- 98 PhD;
- 82 MSc;
- 212 BSc;
- 166 sub-degree Diplomas and Certificates; and
- 243 others.

For the purposes of assessing any potential future mismatch between supply and demand it is necessary to establish a baseline employment scenario. We adopt the year 2001 as our frame of reference and assume that the labour market was in equilibrium during that year i.e. we assume that the number of new entrants into the labour market during that period matched exactly the net expansion of the labour force (new jobs created plus replacements for those leaving the labour force). This balance is assumed to hold at all levels of educational attainment.

This assumption is justified by the observation that the Irish economy and labour market reached a stationary/stable point in 2001 prior to the sharp drop in 2002; there was effectively full employment in the economy, while the demand for workers had levelled off. This assumption allows us to isolate the requirements of the biotechnology sector from those of other sectors.

The composition of the demand for skills, based on the foregoing model for future development of the biotechnology sector in Ireland is summarised in Table 6.1.

94 The analysis in this chapter focuses on the *explicit*, or *net*, demand for science skills; there will also be an *implicit* demand for approximately 180 additional BSc graduates per annum to feed into the postgraduate pipeline. This will act to exacerbate any shortfall in skills and consequently the gaps identified by this analysis can be viewed as conservative.

Table 6.1: Projected Increased Skills Demand for Biotechnology Sector (2003-2009)

Additional Needs of Biotech Cluster	PhD	MSc	BSc	Sub-Degree	Other[95]
New Research Centres built around 20 "Stars"	100	–	50	–	–
5 new Product Dev. companies @ 100 each	100	100	100	75	125
Total FDI *additional* jobs (3,500)	175	175	1,050	875	1,225
Total new indigenous jobs (1,400)	280	280	280	210	350
Management and Regulator support	30	20	–	–	–
Total additional needs over 7 years	**685**	**575**	**1,480**	**1,160**	**1,700**
Average demand/year over next 7 year period	98	82	212	166	243

The explanation of Table 6.1 is as follows. The first row indicates the new demand created by the establishment of new research centres, built around world-renowned research scientists or "stars". The second is the demand generated by the new product development centres that it is anticipated will arise based on our study of other biotechnology clusters around the world. The third row relates to the *acceleration* in the rate of FDI-driven job creation. The fourth row reflects the demand generated by expansion in the indigenous biotech sector. The fifth row reflects the once-off demand for high-level skills in the universities for the management of research activities and also in the government sector for oversight and regulation. The sixth row provides the cumulative, additional demand, relative to the assumed equilibrium in 2001. The final row shows the average requirement per year over the next seven years.

Projecting the growth of any industry, particularly when it is an emerging industry, the future structure of which is unknown, is bound to be subject to error. However, the projection provides an indication of the type of skills demand that would need to be satisfied for the emergence of a cluster of biotechnology firms in Ireland in the medium-term. In practice, Ireland's short-term, i.e. less than 5 years, opportunities are likely to be primarily in the location of production activities in Ireland. Developing a world class research capacity of sufficient scale to spawn a biotechnology cluster will almost certainly take longer. However, as argued earlier, the supply of skills should lead development so the demand projections outlined should be considered to be relevant in the short to medium-term.

These figures hide a number of features that should be noted:

- For many of these graduates, the biotechnology industry will share a common labour market with existing industries such as pharmaceuticals and healthcare[96]. New firms will access this labour market to supply some of these skills. At the same time, projections for these associated sectors indicate, that the demand for skills in these industries is also likely to rise;
- Many of the positions require skills that will not be obtained in traditional degree courses. More flexibility will be required and more postgraduate 'conversion' courses, both full-time for new entrants and part-time for existing employees of other industries, to meet the needs of the industry in vital areas such as legislative affairs;
- The non-degree area is vital since this must include specialities such as those outlined in Table 4.3, Chapter 4, which will be required in biotechnology.

95 Includes for example, BA, BComm, ACCA, BL & other non-science qualifications, operatives, etc.

96 Associated industries are defined to be those that draw from a common labour pool with biotechnology. The medical devices sector is highly relevant in this respect. The medical devices sector, while not the primary focus of this report, constitutes a vital sector in its own right (it currently employs 22,000 and produced exports to the value of €3 billion in 2002) and has a symbiotic relationship with the biotechnology sector as it an important application area for biotechnology. For the purposes of this report, we assume that the rate of new job creation in this sector remains at the 2001 in the years ahead. However, any acceleration in the growth in the medical devices sector in the years ahead would generate further demand for science skills and this would accentuate the skills shortage.

6.3 Medium-Term Projection of Skills Supply

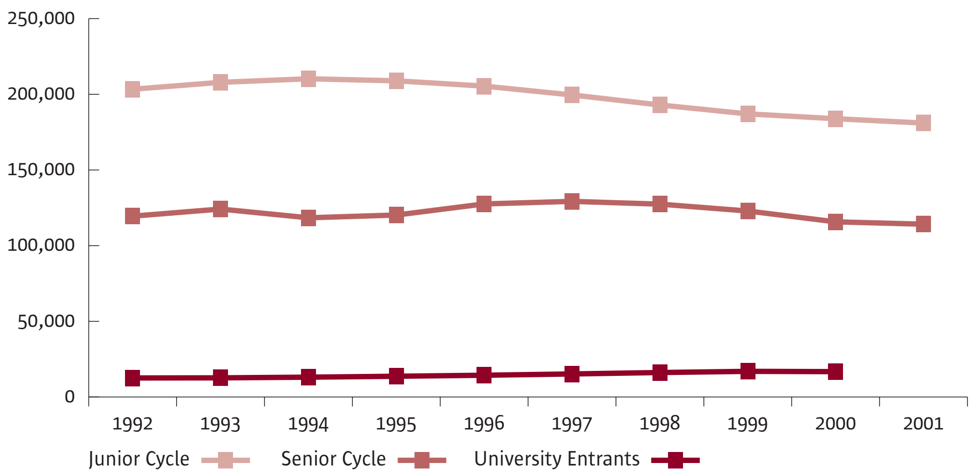
The following sections develop supply projections based on the analysis of current and recent trends described in Chapter 5.

6.3.1 *Cohort Analysis and Projections of Supply of Science Graduates*

The model reviewed in the *Forum of the Expert Group on Future Skills Needs* is reflected in much of the discussion in this report[97]. In terms of projecting the supply of skills, there are a number of key areas of agreement. Firstly, analysis of the supply of skills cannot be undertaken by reference to advanced education levels only but must also look at developments at 2nd level and earlier. There are both qualitative and quantitative issues to be considered in this regard. Secondly, the needs of the biotechnology industry cannot be taken in isolation but must be seen in the context of other sectors. This emphasis is particularly clear as a result of the types of skills that were identified as required earlier. Furthermore, other sectors will both compete for and may supply some of the skills that will be required in the sector. Thirdly, the emphasis on the numbers of skilled individuals that are required must not preclude due attention to the quality of skills demanded. In this regard, the experience of individuals is important. Finally, there is an important time issue to be addressed. While the industry model that has been adopted in this report divides the sector between research, development and production, the time to development of each of these parts of the industry can differ. Thus, for example, it is reasonably clear at this stage what growth in biotechnology manufacturing will occur internationally in the next five years. This time element is also important in relation to the development of courses in universities and the ability to react quickly and flexibly in the design of courses will be an important determinant of Ireland's ability to develop a biotechnology industry.

Demographic trends are a key variable in determining the number of skilled individuals that will be available in the future. The changes that have occurred in the demographic profile of the relevant age groups were identified in Section 5.1. Figure 16 provides a summary of these trends. The number of students enrolled in the Junior Cycle peaked in 1994 at just over 210,000 and has declined since to 181,000 in 2001. This fall of 29,000 (13.8%) is a decline of 2.1% per annum in the number of students. The number of students enrolled in the Senior Cycle peaked at 129,000 in 1997 and has fallen since to 114,000 in 2001. This is a decline of 11.6% and represents an annual fall of 3.1% in the number of students. The faster rate of decline at Leaving Certificate level compared to Junior Certificate may be the result of a number of variables. For example, options other than the traditional Leaving Certificate are increasingly available to 2nd level students and the much-improved labour market in the late 1990s may have provided some incentive to leave school early.

Figure 16: Total Student Trends (1992-2001)

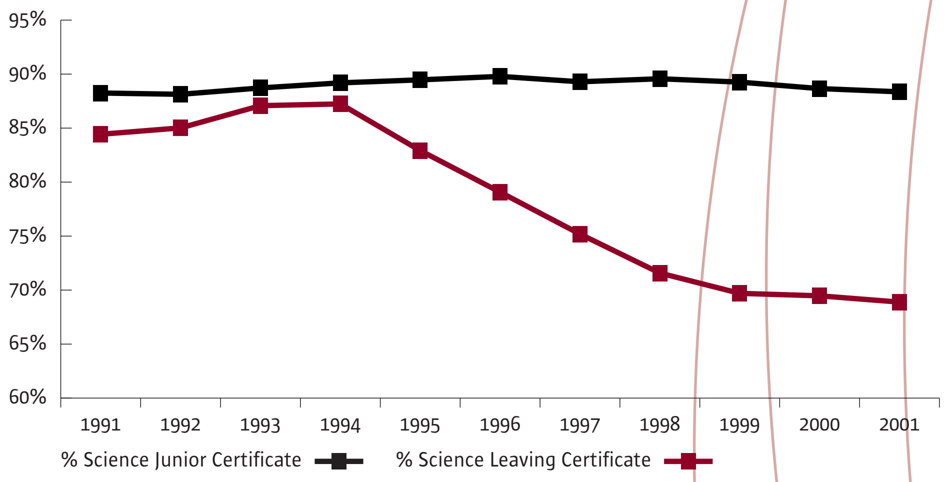


97 Expert Group on Future Skills Needs (2002) *Report on Outputs from Life Sciences Forum on Identification of Issues for Review of Skills Needs,* March 2002

The number of new entrants to universities rose every year until 2000, when a slight decline was observed. This increase from 12,579 in 1992 to 16,757 in 2000 results from much greater participation in university education in this period, a factor that overwhelms the demographic trend of decline to a considerable extent. In this period, new entrants to universities rose from 9.7% of Leaving Certificate numbers in 1992 to 14.5% in 2000. Thus, while demographics are clearly important, participation is also a key variable.

When the number of students opting for science courses is identified separately these relationships are complicated further. The trend at 2nd level is shown in Figure 17.

Figure 17: Science at 2nd Level (1991-2001)



The figures for Junior Certificate level show the number of students taking science. This has remained fairly constant at close to 89% of the total. Thus, changes in student numbers are the key variable governing the study of science at this level. The data for Leaving Certificate level are for the number of science subjects taken. These showed a considerable decline from the mid-1990s on, although this may now have levelled off. The total peaked at 87.3% of student numbers in 1994 and has fallen to just under 69% in 2001.

Trends for university science study are shown in Figure 18. Two important trends are evident. Firstly, acceptances onto science courses at 3rd level, as a percentage of Leaving Certificate students, rose over this period from 3% in 1991 to 4.3% in 2000. However, almost all of this growth occurred in the early 1990s and the percentage actually dropped after 1995 before recovering again in recent years. Second, science as a percentage of university entrants rose in the early 1990s to a peak of 17% in 1995 before declining to about 13% in recent years.

It can be concluded that the expansion of the number of 3rd level places in the 1990s worked to ensure that the number studying science rose, but this has been moderated in recent years by a lower participation in science among those gaining entry. As a result, while the numbers entering university rose over the whole period, the number of new entrants to science courses peaked in 1995 and has since declined from 2,455 to 2,168. However, this comparison may overstate the decline somewhat because the data available for science before the mid-1990s includes computer courses. These courses have been netted out since 1995. As a result, it cannot be inferred that the percentage of new entrants taking science, when computing is excluded, has deviated to the extent that the data suggest.

Figure 18: Science at 3rd Level (1991-2000)

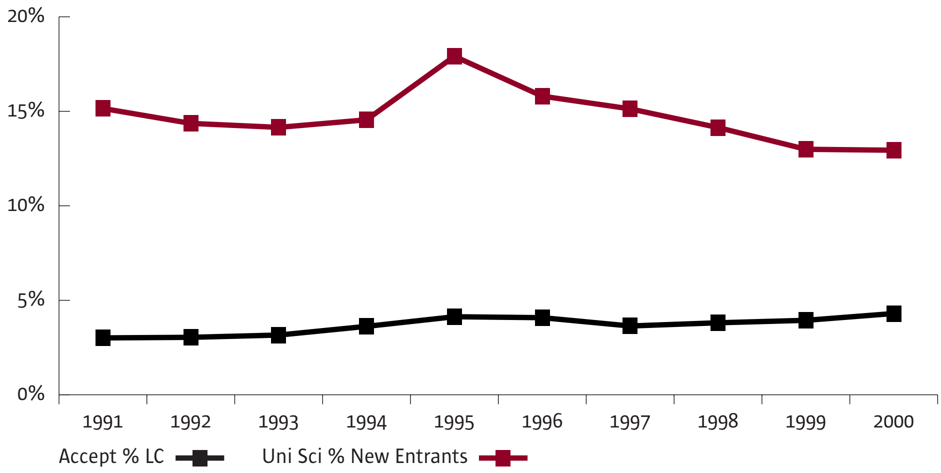


Table 6.2 shows the progression of cohorts of students through the education system at 4-year intervals. The bold figures represent projections based on the observed trends. These projections are linear extrapolations in the sense that they assume a continuation of current policy.

Table 6.2: Cohort Progression and Projections for Science Education

Junior Certificate students 1994	187,545
Leaving Certificate students 1997	129,264
Entry to university degree courses 1997	2,304
Degrees awarded by universities 2001	2,177
Acceptance on Diploma/Certificate 1997	1,533
Diploma/Certificate awarded 1999	846
Degrees from other institutions 2001	402

Junior Certificate students 1998	172,817
Leaving Certificate students 2001	114,186
Entry to university degree courses 2001	**2,134**
Degrees awarded by universities 2005	**2,017**
Acceptance on Diploma/Certificate 2001	1,282
Diploma/Certificate awarded 2003	**713**
Degree from other institutions 2001	**400**

Junior Certificate students 2002	156,977
Leaving Certificate students 2005	**101,060**
Entry to university degree courses 2005	**2,003**
Degrees awarded by universities 2009	**1,893**
Acceptance on Diploma/Certificate 2005	**1,135**
Diploma/Certificate awarded 2007	**631**
Degree from other institutions 2009	**400**

The data for the Junior Certificate are actual student numbers in each case. The estimate for the number of Leaving Certificate students in 2005 assumes that the trend rate of decline of 3.1% per annum is maintained. Over the period 1997-2000, the number of Leaving Certificate students fell by 11.6% while the number of new entrants to degree courses in universities fell by just over half this rate at 6%. It is assumed that this relationship continues so that the number of new entrants to university degree courses falls by 1.6% per annum. It is assumed that the average rate of 94.5% between first entrants and the conferring of science degrees four years later is maintained in the universities. It is assumed that the number of students that opt for non-degree courses, mostly in the ITs, declines in line with the number doing the Leaving Certificate i.e. a decline of 3.1% per annum. However, the more rapid decline in acceptances to these courses in recent years is taken into account. A constant attrition rate is also assumed here. The relationship between those entering degrees and other courses and the final qualifications obtained is complex in the ITs due to the progression system that is available. First registrations for degrees in the ITs are not an indication of the eventual number that receive degrees due to conversion in later years. Furthermore, the trend in registrations for non-degree courses cannot be taken as an indication of the trend in degree numbers and the number of degrees attained has risen in recent years. In the absence of a basis on which to form an alternative projection, it is assumed that the two trends of lower overall acceptance and a higher propensity to progress to the degree level counteract each other and the number of degrees awarded by the ITs remains close to its 2001 level of 400.

The net effect of this is for the total number of science degrees awarded to decline from 2,579 in 2001 to 2,293 by 2009, a fall of 286 or 11%, in the absence of any changes to the observed trends. In addition, the number of students that obtain other qualifications falls from 853 in 2001 to 631 in 2007, and to 594 by 2009, a fall of 259 or 30%. Given that the labour market for these skills is already quite tight, these declines should be seen as gaps in the availability of skills, should they be allowed to emerge, before the requirements implied by growth in the sector are included.

6.3.2 *Projections of Science Graduates with Postgraduate Qualifications*

The trend in postgraduate study in science is poorly correlated with demographic trends and should be more open to being influenced by policy decisions. The provision of funding is a key determinant. In addition, the requirements of the labour market and the provision of appropriate courses will affect the numbers undertaking past-graduate study. Table 6.3 shows total enrolment in science in HEA institutions. It shows that postgraduate enrolment rose in the early to mid-1990s but then declined for a few years. This decline has been reversed in recent years and growth has resumed. That this growth has taken place in a period of relatively tight labour market conditions indicates that postgraduate study has been viewed as a relatively attractive option for science graduates.

Table 6.3 also shows postgraduates as a percentage of undergraduates. This can be interpreted as an indicator of retention in education beyond the initial degree. This shows that retention reached a peak at over 36% in 1993-94 but then declined to below 27% in 1998-99. This has now recovered to close to 30%.

Table 6.3: Science Student Enrolment in HEA Institutions

	Undergraduate	Postgraduate	Postgrad % of Undergrad
1992-1993	5,760	2,018	35.0
1993-1994	6,074	2,208	36.4
1994-1995	7,283	2,416	33.2
1995-1996	8,335	2,536	30.4
1996-1997	7,503	2,217	29.5
1997-1998	7,865	2,375	30.2
1998-1999	8,056	2,144	26.6
1999-2000	8,053	2,210	27.4
2000-2001	8,157	2,420	29.7

Source: HEA

A number of conclusions emerge from these data. The numbers opting for postgraduate study in recent years show an upward trend. The most likely cause of this is probably the greater availability of funding in the universities in recent years. If this is important then the availability of SFI funds in the short to medium-term suggests that the number of postgraduate students will rise. However, the trend in numbers opting for postgraduate study is also likely to be determined in part by the trend in enrolment at undergraduate level. This was determined above to show an annual decline in new entrants of 1.6% per annum in the medium-term. The data in Table 6.3 indicate that this relationship has not been particularly strong over the period shown and the retention rate, as defined, has varied. Indeed, these data indicate that the proportion of postgraduates relative to undergraduates could rise to exceed 35%. When the availability of improved funding is factored in, a retention rate similar to what was achieved in the mid-1990s is not an unrealistic assumption.

The *Third Report of the Expert Group on Future Skills Needs* provided estimates of the potential impact of newly created funds on postgraduate research in Ireland in the next few years. Biotechnology, along with ICT, is set to be a major beneficiary of these awards. The funds are focussed on research as distinct from taught postgraduate courses. For this reason, it is likely that the majority of students benefiting from them will be on PhD programmes, although given the progression system that operates in most cases between research MSc and PhD registers, MSc students are not excluded. However, the numbers were presented in terms of estimated recipients and it is not possible to identify the extent to which these would be additional to the undergraduate cohort that existed before the funds were available. In addition, the allocation of funds under SFI has been slower than assumed in the *Third Report of the Expert Skills Group* and the projections may not be indicative of the actual impact in recent years. To date, SFI have allocated €218 million in research support, but the number of additional postgraduate positions that have been created as a result is unknown. As a result of these unknowns, it is necessary to make certain assumptions regarding the factors that will determine the number of PhD and MSc awards in the future.

Total postgraduate enrolment in 2001 showed a rise of 9.5% above one year earlier. If it is assumed that the impact of additional funding is sufficient to cause the number to rise over the period up to 2005 but at a declining rate i.e. 4% in 2003 and 2% in 2004 and 2005, no growth thereafter, then a total postgraduate enrolment of 3,000 would be achieved. This would be equal to 37.5% of undergraduate enrolment, which has begun to decline due to demographic factors. Because of the fact that, in some institutions, PhD students initially register for MSc courses and then progress, it is not possible to allocate this enrolment directly between the two streams. However, if a simple model is created utilising data on postgraduate awards and enrolments in the 1990s that assumes that MScs are awarded after 2 years on the register and PhDs after 4 years, then the annual growth rate in enrolments, with a 2 years lag for MScs and a 4 year lag for PhDs, provides reasonably accurate estimates of awards when compared to the actual outcome[98]. Applying this model to the estimates for total enrolment and using 2001 as the base year provides projections for total awards. These are shown in Table 6.4. In 2001, a total of 253 PhDs in science were awarded. In addition, 120 taught MSc degrees were awarded and 76 research MScs.

However, the number of taught MScs awarded should be dealt with separately. Here, labour market requirements and the availability of places are the key determinants. It is likely that both of these will have a positive impact on the numbers undertaking this qualification. However, research study has now become relatively attractive to postgraduates for science graduates and the pool from which the students are to be drawn is limited by the number of graduates. It should be recalled that the MSc skills that were identified in Chapter 4 often required science with another discipline, a skill set that requires programmes in the form of taught masters. Indeed, not all students need to have a science degree as their primary degree and not all postgraduate courses should be confined to scientific disciplines if the requirements of industry are to be met. However, this requires a planned expansion of places. At this stage, the best projection is that the output of the base year is maintained.

98 In all cases the error is less than 10% and is much less in many years. Furthermore, deviations above and below the estimate appear to be random.

Table 6.4: Projected Postgraduate Awards in Science (2003-2009)

		Total Output		Additional to 2001 Output	
	PhD	MSc Research	MSc Taught	PhD	MSc
2003	245	101	120	-8	25
2004	252	119	120	-1	43
2005	276	133	120	23	57
2006	298	143	120	45	67
2007	316	149	120	63	73
2008	329	154	120	76	78
2009	335	154	120	82	78

These projections show a gradual increase in the number of PhDs awarded. However, the number of awards in the short-term (in 2003 and 2004) shows no increase over the 2001 output. In relation to research MScs, the increase in recent enrolments has a more rapid impact on the number of awards and the numbers exceed the 2001 output in all years.

The supply side projections are summarised in Table 6.5. Each row of the table contains an estimate of the absolute numbers graduating at each level of qualification by year, as well as an indication of the change in output relative to 2001 (negative values imply a decline in output). The impact of SFI funded projects is manifest in the increasing numbers attaining PhD and MSc qualifications over this period.

Table 6.5: Supply Trends (2003-2009)

Award	2003	2004	2005	2006	2007	2008	2009
PhD	245 (-8)	252 (-1)	276 (+23)	298 (+45)	316 (+63)	329 (+76)	335 (+82)
MSc	221 (+25)	239 (+43)	253 (+57)	263 (+67)	269 (+73)	274 (+78)	274 (+78)
BSc	2,481 (-98)	2,449 (-130)	2,417 (-162)	2,385 (-194)	2,354 (-225)	2,323 (-256)	2,293(-286)
Dip/Cert.	713 (-140)	692 (-161)	671 (-182)	651 (-202)	631 (-222)	612 (-241)	594 (-259)

Estimated output (supply), in absolute terms, at each qualification level by year. Changes relative to 2001 are shown in parentheses; negative values indicate a decline in output.

Table 6.5 indicates that by 2009, the number of diplomas and certificates awarded per annum will have fallen by 259, when compared to 2001, while the number of degrees awarded falls by 286. Assuming that the labour market for these skills was in equilibrium in 2001, these projections show a cumulative deficit of 1,407 for sub-degree qualifications in 2009 and 1,351 for primary degrees. In other words, if the demand for these skills remained at the 2001 level over this period then this number of qualified personnel would have to be supplied from some source. If this is to be supplied through the education system then the number that qualify with diplomas and certificates would have to rise by about 20% over the projected output for 2003, rising to almost 44% over projected output in 2009. The number of personnel required with primary degrees would need to increase by 4% in 2003 over the projected output to meet this demand. This rises to 12.5% in 2009. The changes in postgraduate awards are as in Table 6.4.

6.3.3 Implications of the Projections

These linear projections can be criticised on a number of grounds. As with all projections, the most basic is that they extrapolate observed trends and include assumptions where required. As a result, they are subject to some error and should be treated as such. Firstly, they assume a neutral background in the sense that new interventions do not alter the trend or that the full effect of recent and past interventions is observed. Secondly, they ignore the workings of the system that determine entry to courses, particularly in the universities. An implication of these trends is that fewer people enter university science with the implicit assumption that resources are reallocated to other courses as a consequence. This may not be the case. As pointed out above, the proportion of Leaving Certificate students entering degree courses is small and it may not be correct to infer a trend in a small cohort of the population from a trend in the population as a whole. In other words, the participation rate in science at university in particular, expressed as a percentage of Leaving Certificate students could rise as additional places at university become available. In addition, perceptions among students at this stage of career opportunities could change from those that dominated in the late 1990s. This would cause an increase in the wish to participate and raise the percentage doing science.

Notwithstanding these points, the conclusion is that the number of science graduates in the future, on the basis of current trends, will fall in the absence of intervention. However, changing this prospective trend to maintain current output does not require a major change in the proportion of students taking-up science. Over the period 1995-2001, the number of students accepted onto 3rd level science averaged 4% of the number taking the Leaving Certificate. Achieving a level of 4.65% acceptance onto 3rd level courses would be sufficient to maintain output at the level of recent years. For postgraduate output, the projections for the number of PhDs awarded shows no increase over the 2001 level before 2005.

6.4 Estimates of Potential Skills Gaps

The analysis shows that the prospective deficit in skills has the potential to act as a serious constraint on the development of the Biotechnology sector, in the short to medium-term. Because employment rates in the biotechnology industry are high currently, there is little opportunity for growth to emerge on the basis of employing any surplus supply of existing skills in science. Some opportunities for growth on the basis of slack in the labour market for other graduates may emerge if the current downturn is prolonged, for example from IT. However, this effect is likely to be limited and conversion courses to actively prepare these individuals for employment in biotechnology would need to be developed. As a result, the projected demand for skills represents a net additional requirement to the labour market, which would have to be supplied from the education system or from overseas. The numbers involved are summarised in Table 6.1. These numbers are certainly considerable. In terms of the output of science graduates in 2001, they would indicate increases of the following scale:

PhD	+39%;
MSc	+42%;
BSc	+8%; and
Sub-degree	+19%.

However, as noted in Section 6.3, the projected supply of skills, on current trends, is set to fall at undergraduate level while some growth is likely to occur at postgraduate level.

These figures relate to supply trends only. The projected skills gap must take into account not only these changes but also the additional skills required by the growth of the sector, viz. demand trends. The increased demand identified above was expressed in terms of the requirements to allow a nascent biotech cluster to emerge. It was expressed in terms of an annual average over seven years of the skills' requirements for the described cluster. This requirement can be added to the gap that emerges from the falling supply at sub-degree and degree level, and will be partially offset by projected increases in postgraduate output. This provides the gap estimates shown in Table 6.6.

Table 6.6: Projected Supply/Demand Skills Gaps (2003-2009)

Qualification	2003	2004	2005	2006	2007	2008	2009
PhD	-106	-99	-75	-39	-35	-22	-16
MSc	-57	-39	-25	-15	-9	-4	-4
BSc	-310	-342	-374	-406	-437	-468	-498
Diploma/Certificate	-306	-327	-348	-368	-388	-407	-425
Total	**-779**	**-807**	**-822**	**-828**	**-869**	**-901**	**-943**

Based on an assumed labour market equilibrium in 2001. Negative values indicate a deficit.

The gaps in numerical terms are concentrated most heavily at the primary degree and diploma/certificate levels. However, there is also a consistent shortage of MSc and PhD awards estimated. While the numbers involved here are lower, in percentage terms they are considerable. For example, the estimate for 2003 shows a skills gap for MScs equal to 25% of projected output but practically vanishes in 2009. For PhDs, the gap is 42% of projected output in 2003, falling to 4% of projected output in 2009.

These gaps should not be interpreted as a description of a labour market outcome that will exist. Skills deficits of this magnitude would inevitably have an impact on the rate of development of biotechnology and associated sectors. This means that the projected growth in demand for skills would not occur and the value of this extra employment to the economy would be lost along with the other benefits that accrue from the creation of high value employment.

7 Conclusions and Recommendations

7.1 Main Findings

7.1.1 The Impact of Biotechnology

The biotechnology industry is built upon a set of enabling technologies that have been developed in research centres and that have been commercialised over the past 25 or so years. For a number of reasons it is widely believed that over the course of this century, these technologies and other likely discoveries will revolutionise some of the most important and basic services and products in the economy. The gains to human welfare are likely to be enormous; indeed, at present the potential improvements seem incalculable. Correspondingly, the economic returns to companies, organisations, researchers and employees involved at the cutting edge of developments in these sectors and the economies within which they operate are likely to be very great.

Most of the potential of current developments (let alone future advances) remains to be realised. The sector is only emerging and, to date, the number of available biotechnology products in full-scale commercial production is relatively small. However, all indications are that the process of commercialisation of scientific discovery and associated accumulated knowledge will become more efficient, enabling the full economic potential to be realised into the medium and longer term.

7.1.2 Implications for Ireland

Current developments potentially offer huge scope for further expansion of the Irish economy. In this regard the economy has some significant strengths, most notably critical mass and global presence in the production of pharmaceutical products and medical devices and very recently, significant commitment by Government of financial resources in support of scientific research in Ireland.

However, if Ireland is to develop a competitive and vibrant biotechnology cluster sector it will need to overcome a number of substantial challenges. This report concludes that amongst these is a substantial and widening deficit in required human resource skills that are available or likely to become available to meet the demand of an expanding international biotechnology sector.

The clustering aspect of the industry presents policy makers attempting to develop the industry in new areas with particular challenges and opportunities. It suggests that biotech firms are slow to move – at least in the current stage of development of the industry – while indigenous companies are most likely to emerge successfully in fully functioning clusters. The possible exceptions to this are where specific infrastructure requirements in bioprocessing mean firms locate where this infrastructure is available, and that as biopharmaceuticals move along the development process and become successful products the firms can be induced to relocate part of the value-added process to other centres.

In this context, it is well worth noting that currently, there are about 1,000 biotech drugs in all phases of development with almost 400 in Phase II and III clinical trials. It is estimated that about 25% of all newly launched medicines, devices and diagnostics are derived from biotechnology. Of these, about 150 to 200 are protein therapeutics, a sector that is growing at 15% per annum compared to 7% overall in pharmaceuticals. Due to the high risk that is associated with putting fermentation capacity in place, demand for manufacturing capacity in biologics will exceed current capacity up to 2005 by a factor of four. Currently, there are 250 to 400 monoclonal antibody-based products in the pipeline. In addition, of 133 marketed biopharmaceuticals, 10 approved mAbs (monoclonal antibodies) consume 75% of biologics manufacturing capacity. These products represent 20% of sales of biologics and are growing much more rapidly than biologics in total. In addition, the economics of the sector are skewed due to the presence of a large proportion of ‘orphan’ drugs in this sector that require low volume and flexible manufacturing technologies and processes. As a result, a major round of investment in fermentation capacity is underway at present. This programme has a global dimension and offers the possibility to countries such as Ireland to move towards critical mass, at least in manufacturing of protein drugs. The attraction of investment projects such as Genzyme (fill finishing, County Waterford) and Wyeth (fermentation, Clondalkin) represent a significant first step in securing a foothold in this development.

Current and prospective trends in Ireland's education system in relation to science pose a number of challenges. Closing the skills gap projected in Chapter 6 represents a significant but surmountable challenge. Furthermore, the evidence from the US indicates that a key requirement for the growth of a biotechnology cluster is not that the minimum numbers of required skills are produced, but that sufficient personnel are available, particularly at PhD level, to create competition for places. This provides an incentive for entrepreneurial activity at this level and a stimulus to engage in commercialisation of new research output. If Ireland is to achieve the high equilibrium outcome that was described in Chapter 6, involving the establishment of a self-sustaining biotechnology cluster, then a very considerable commitment needs to be made to the development of relevant human resources. Moreover this commitment would need to be sustained for 15-20 years. Obviously, such a commitment entails opportunity costs, in terms of other choices foregone, with attendant risks to long-term growth if the potential rewards are not secured, or the expected potential of the sector is not realised. Against this, there are opportunities to be realised in the short-term from concentrating on meeting the prospective requirements of bioprocessing while also developing requirements for longer-term growth.

In meeting the skills requirements outlined here, it should be noted that Eastern European countries such as Hungary have many excellent scientists, particularly in areas of weakness in the West. These scientists tend to be mathematically orientated, although often with expertise in biological applications. In general, research institutes and universities in the Central and Eastern European Countries (CEEC) are good and will be a major source of competition following expansion of the EU. In addition, there are many highly skilled people in countries such as India and China. Employment of immigrants from these countries is a potential opportunity to redress skills deficits.

The particular skills that are required by the industry have been identified in Chapter 4. These do not always fit neatly into existing supply structures. A key to achieving a competitive edge here is an education system that observes requirements and is designed to be responsive and to lead development.

Therefore, a new emphasis on flexibility in discipline boundaries in combination with academic excellence is required to produce the skill sets that will be required. There are three key areas in which flexibility is required:

- The design of postgraduate courses, which may be taught MSc or postgraduate diplomas, that cross inter-disciplinary boundaries to produce people prepared for employment in biotechnology and specialist skills;
- A greater breadth of education during the PhD; and
- A range of courses for non-graduates and graduates in other subjects to prepare them for employment in biotechnology. These should include conversion courses and, in particular, specially designed technician courses that closely match the identified requirements of the industry.

The third level sector has made significant strides in recent years in aligning its research activities more closely with the interests of industry. In addition, there is a growing appreciation by the institutions of the commercial value of the intellectual capital present within their research. The institutions are increasingly interested in unlocking this latent value. This trend is being encouraged by the various public policy initiatives attempting to evolve Ireland to a knowledge economy. Major developments within the institutions in recent years include the introduction of senior positions with responsibility for innovation, technology transfer and commercialisation of research, as well as the establishment of business incubators in many institutions. These initiatives have resulted in more strategic approaches to research planning; research (and teaching) is becoming more pan-institution and less department-focused.

Nevertheless, progress along these lines varies considerably between institutions and in many cases, these developments have arisen through the initiative of individual departments or researchers rather than as a result of an institution-wide policy.

It is important that any policy approach emphasises both the demand for and supply of places at third level. An examination is required of the extent to which the Irish university system is positioned to collaborate with industry in a manner that makes it responsive to industry's needs. An example is a requirement for conversion courses and courses that combine study across traditional disciplines.

Furthermore, it should be noted that a broad range of skill levels is required by the industry. An over concentration on producing the skills required to fill high value PhD positions, while important, would not be an adequate response to the biotechnology industry's projected requirements to the end of the decade. It is also important that research activities are co-ordinated and industry focused. This will require close collaboration between all the relevant agencies within an integrated policy environment.

In summary, there is a very widespread belief that the biotechnology industry is in its infancy and will continue to grow for many years, although the growth path remains very uncertain.

7.2 Recommendations on Skills Development and Supply

The key finding of this report is that there is a considerable gap between the demand for skills that would be implied by the development of a biotechnology cluster in Ireland in the medium-term and the projected output of relevant skills over this period. If Ireland is to be successful in developing this industry then this deficiency must be overcome. The recommendations put forwards to achieve this reflect three broad themes:

1. Initiatives to increase interest in the study of science and in careers in science;
2. Measures to improve the capacity of the Irish economy to supply suitably skilled personnel; and
3. Supporting interventions, particularly in the development of Ireland's research competency.

These reflect the arguments that have been put forward: that intervention must increase the demand for training in science as well as the number of available places. In addition, the quality and structure of the skills that are produced must be appropriate.

In summary, the output of relevant skills by the education sector needs to be increased significantly if the biotechnology sector in Ireland is to realise its full potential over the period 2004-2010.

National Research and Government Funding

1. It is clear from international experience that the public provision of funds for research is a key prerequisite for the development of a dynamic and sustainable biotechnology industry. Good progress has been made by *Science Foundation Ireland* in attracting leading, international research scientists to Ireland. However, there is a real danger that these scientists will leave once their initial contracts have expired. It is therefore recommended that, **an unambiguous statement of long-term commitment to the public funding of science in general and biotechnology in particular, should be issued by the Government. This commitment should incorporate *quantified* targets for the level of support to be provided on a multi-annual basis.**

   Such a policy statement would be particularly opportune at this juncture in view of the fact that Ireland is now over half-way through the *National Development Plan* (2000-2006) and that SFI is also half-way through its original remit. It would serve to dispel the growing uncertainty about the future funding of science in Ireland and to retain the confidence of key researchers and investors.

   (Responsibility: Government)

2. **It is further recommended that capital funding under the HEA-operated *Programme for Research in Third Level Institutions* should be restored immediately.**

   (Responsibility: Government)

School System

3. The Biotechnology Sector, like other Science/Technology based sectors, requires a sustained commitment to improving the quality and relevance of the broad school programme. In particular, a strong emphasis on *Science and Mathematics* in school programmes is advocated. **The recommendations of the *Task Force on the Physical Sciences* are strongly endorsed and should be implemented *in full,* with immediate effect.**

   (Responsibility: Government)

4. The transition to the senior cycle merits particular attention. **It is recommended that a quantitative national target should be established in relation to the proportion of students undertaking science at Leaving Certificate.**

   (Responsibility: Government)

Transition Year Programmes

5. It has been observed that the activities undertaken by students during their transition year have a pronounced influence on their subsequent choices of subject at *senior cycle*. Therefore, it is recommended that:

   i. **the forthcoming pilot *awareness campaign* by the *Irish Pharmaceutical & Chemical Manufacturers Federation* (IPCMF), aimed at promoting science in transition year, be extended and expanded;**

      (Responsibility: IPCMF, Forfás)

   ii. **business should sponsor work placement programmes specifically for transition year students to provide them with realistic experience of applications of science and technology in industry; and**

      (Responsibility: IBEC)

   iii. **third level institutions should introduce outreach programmes centred around *active participation* by transition year students in science and technology projects.**

      (Responsibility: Governing Authorities)

Promotion of Science

6. The current efforts to promote Science and Technology based courses and careers should be intensified; business and industry should play a central role in this activity. **The diverse and rewarding career paths (including, in particular, biotechnology) opened by an education in the sciences should be highlighted.**

   (Responsibility: IBEC, Forfás)

7. In the past, the coverage of Science and Technology on RTÉ has been poor, in terms of both news coverage and programming. RTÉ should address this shortcoming by the appointment of a science editor and a higher prioritisation of science and technology in its scheduling.

   (Responsibility: RTÉ)

Technicians/Higher Technicians

8. A new emphasis should be put on the education and professional development of technicians and higher technicians relevant to biotech production by Institutes of Technology and Universities. Further **education/conversion courses should be provided to enable mature life-science technicians to upgrade their skills to incorporate the latest technology and techniques.** This could be done through existing full-time programmes and through a range of industry/Institute collaborative formats. It is imperative that such programmes should be delivered in a *flexible* manner in order to maximise the uptake. This entails part-time courses, weekend tuition, distance learning, in-service development etc.

   Business and industry have a crucial role to play in this matter; they must adopt a more proactive role in promoting and facilitating training and professional development among their employees.

   (Responsibility: VECs, TLI[99])

Tertiary Education

9. Third level institutions should be more cognisant of and responsive to, industry's needs; both parties should actively promote greater communication and closer collaboration in research and technology transfer.

   (Responsibility: Governing Authorities, Academic Councils, HEA, IBEC)

10. While acknowledging that courses are being continually updated in many third level institutions to reflect the rapid advances in this area and indeed that new courses such as MSc in *Bioinformatics* are being introduced, it is recommended that **all institutions should be encouraged to adopt a proactive approach to course development:**

    i. Curricula should be reviewed periodically, in conjunction with industry, to ensure their continued relevance;

    ii. Current trends towards inter-departmental teaching multi-disciplinary research should be accelerated.

    (Responsibility: Governing Authorities, Academic Councils, HEA, IBEC)

11. There should be a strong emphasis in undergraduate, postgraduate and part-time education on the nurturing of **business and enterprise skills** to augment the core scientific skills:

    i. Modules **encompassing non-traditional subjects such as *business, marketing, law and regulatory affairs*** should be included in science curricula. These courses should be tailored to the needs of the biotech sector with, for example, particular emphasis on intellectual property, technology transfer/commercialisation of research and securing venture capital;

    ii. **Third level institutions should encourage and facilitate postgraduate students to take courses taught at other institutions** in order to compensate for the relatively narrow focus of biotech expertise within individual institutions. This would also promote networking and foster collaboration between institutions.

    (Responsibility: Governing Authorities, Academic Councils)

12. **The promotion of associated industries and technologies within the broader life sciences sector should be intensified by the relevant agencies.** Medical Diagnostics, for example, is an important application area for biotechnology. Enabling or supportive technologies such as Bio-informatics are also worthy of consideration in view of Ireland's established strengths in computing, mathematics and physics at third level. The third-level institutions should support this initiative by promoting the appropriate skills in their curricula.

    (Responsibility: Governing Authorities, Academic Councils, HEA, IBEC, IDA Ireland, Enterprise Ireland, SFI)

99 Third Level Institutions

Overseas Talent

13. **It is recommended that national research programmes, in addition to attracting and promoting indigenous talent, should also endeavour to attract high calibre individuals from overseas to undergraduate and postgraduate programmes, post-doctoral and lead research positions, relevant to the Biotechnology Sector.** Ireland should actively promote itself as a desirable location for the pursuit of biotechnology-related study and research. In addition to raising the bar for postgraduate study and research, this would promote international networking by the Irish TLI.

    (Responsibility: HEA)

Gender Balance

14. The gender profile at *entry-level* in the biotech sector is well balanced. However, it becomes progressively more imbalanced the further one looks down the career path. **Obstacles to long-term female participation in industry, ranging from child-care costs to structural issues, should be explored and addressed.**

    (Responsibility: Government, social partners)

Levering the Research Base/Achieving Critical Mass

15. One of the shortcomings of the Irish research system has been the fragmented nature of research effort and the poor co-ordination of research activity among the various research and third level institutions. As a result, it has failed to date to achieve its full potential, *where the whole becomes greater than the sum of the parts.* The Government established a Commission under ICSTI in 2002 to develop proposals for an oversight and review mechanism for the science and technology system in Ireland and this report was submitted to the *Tánaiste* and *Minister for Enterprise, Trade and Employment* in December 2003. **It is recommended that the proposals of the ICSTI Commission be implemented to achieve greater cohesion in the science and technology system. The work of the Inter-Departmental Committee on Science and Technology to develop an Irish Action Plan to respond to the European *Research Area* initiative is also strongly endorsed in this regard.**

    (Responsibility: Department of Enterprise, Trade and Employment)

Appendix 1: List of Consultations

Listed in Alphabetical Order

Cora Beth	Abel	Director of Education, Massachusetts Biotechnology Council, Cambridge, MA 02142
Dr Naseem	Amin	Vice President, Genzyme General, One Kendall Sq. Cambridge MA 02139
Dr John	Atkins	Science Foundation Ireland
Dr Mark	Bamforth	Senior Vice President, Corporate Operations, Genzyme General, One Kendall Sq., Cambridge MA 02139
Mr Kees	Been	Senior Vice President, Oncology Business Unit, Biogen, 14 Cambridge Center, Cambridge MA 02142
Janice T.	Bourque	President and CEO, Massachusetts Biotechnology Council, Cambridge, MA 02142
Mr William	Bullock	International Business Development Manager, Department of Commerce, Raleigh, North Carolina
Mr Steven	Burke	Senior Vice President, North Carolina Biotechnology Center
Ms Barbara	Carr	Executive, Higher Education Authority
Mr Don	Carson	Director of Research, RTP Regional Partnership, NC
Mr Pearse	Cole	Managing Director, Catalyst Genomics
Dr Paul	Coleman	General Manager, Biogen, Denmark
Dr Stephen	Dahms	Chair, Biotechnology Industry Organisation Workforce Committee and Executive Director, California State University Biotechnology Program
Joseph J.	Donovan	Director of Emerging Technology Development, The Commonwealth of Massachusetts, Department of Economic Development, Boston MA 02116
Dr Thomas	Gerteisen	Vice President, Quality Operations Therapeutics Manufacturing & Development, Genzyme
Mr John	Hayden	Chief Executive, Higher Education Authority
Dr John	Irick	Director, Biolex Manufacturing and President, North Carolina Trade Association
Dr Jui	Lim	Director, Biomedical Sciences, EDB, Singapore
Dr Sanford	Madigan	Vice President Corporate Development, Ambit Biosciences, San Diego
Prof David	McConnell	Prof of Genetics, Trinity College, Dublin
Mr Pat	MacGovern	IDA Ireland
Dr Ian	Mehr	Director of Business Development, Paradigm Genetics, Durham, NC
Mr Brian L.	Michaelis	Counsellor at Law, Brown Rudnick Berlack Israels, One Financial Center, Boston MA 02111
Mr Kevin	O'Sullivan	Vice President, Massachusetts Biomedical Initiatives
Mr Joseph	Panetta	Chief Executive, BIOCOM, San Diego
Mr Peter	Pellerito	Managing Director, PMP Consulting, Chapel Hill, NC
Mr Francis	Rottenburg	Director Biotechnology, Scottish Development International
Mr John C	Serio	Counsellor at Law, Brown Rudnick Berlack Israels, One Financial Center, Boston MA 02111
Mr Eamonn	Sheehy	IDA Ireland
Dr John	Stuelpnagel	Senior Vice President and Founder, Illumina Inc., San Diego
Pia J.	Theophiles	Human Resources Representative, Wyeth BioPharma, Andover, MA 01810
Dr Mark	Trusheim	President and CEO, Cantata Pharmaceuticals, Woburn MA 01801
Ms Bonita	Williams	Training Consultant, North Carolina Biotechnology Center
Mr Mark	Wilson	President, BioPhysica Sciences, La Jolla, CA

Appendix 2: Definitions of the Biotechnology Industry

The key technologies involved in biotechnology include:

- Genomics;
- Monoclonal antibodies;
- Gene Therapy;
- Ag-biotech/Transgenic plants;
- Bioinformatics;
- Stem cells;
- Proteomics;
- Pharmacogenomics;
- Age-related biotech;
- Nutraceuticals; and
- Bioreactors (plants/animals).

The main areas of application include:

- Recombinant vaccines;
- Molecular diagnostics;
- Vaccine and drug delivery;
- Bioremediation;
- Pathogen genome sequencing;
- Control of STD;
- GM crops;
- Recombinant drugs; and
- Combinatorial chemistry.

As biotechnology is a relatively new and evolving industry, it is not yet identified by a single separate category in the old Standard Industrial Classification (SIC) code, the EU's NACE system, or the new North American Industry Classification System (NAICS). However, a general consensus about what constitutes the biotechnology industry is emerging as a result of definitions by industry participants, investors, and outside studies of the industry.

People involved in the industry have a clear idea of what their industry is and who is and is not part of it. This is perhaps best demonstrated by the fact that the industry has formed a representative association that defines and represents its interests. In addition, the financial sector has worked on defining the industry so as to be in a position to compile data on metrics such as industry sales, profitability, and investment levels.

The definitions and databases used by different organisations are not fully compatible in all respects but there is broad agreement in relation to the size of the industry, with between 1,000 and 2,000 firms being identified as the biotechnology industry in the US. Two leading industry directories have existed for over 10 years (maintained by the Institute for Biotechnology Information and Ernst and Young) and biotech firms have a strong interest in being listed so as to make themselves visible to potential investors, customers and the pharmaceutical industry.

Researchers from a variety of fields have studied the biotechnology industry and fairly widespread agreement exists on what defines the industry. However, among researchers who have prepared studies of local concentrations of biotechnology-related economic activity, the definition of biotechnology is often tailored to local perceptions and judgments. These generally include biotechnology as defined in the main text of this report, but also expand this to other activities under headings such as "biosciences," "life sciences," "biomedical sciences," and "health care technology." Many of these local studies are used for promotional purposes and comparisons between them are difficult. A meta-study concluded that there was "relatively wide divergence in the production sectors that are included in these classifications" and that the conservative approach would be to adopt the definition favoured by BIO, the industry representative organisation[100]. Table A2.1 provides some examples of definitions that have appeared in the literature.

Table A2.1: Definitions of Biotechnology Appearing in Recent Studies

Source	Definition Adopted
Biotechnology Industry Organisation (BIO)	'the application of biological knowledge and techniques to develop products and services'
Institute for Biotechnology Information (2001)	'firms founded to use new technologies as the basis of their R&D or manufacturing efforts' (Differentiates between pharmaceutical and biotechnology firms)
PriceWaterhouseCoopers (2001)	'developers of technology promoting drug development, disease treatment, and a deeper understanding of living organisms, including biochemicals, cell therapy, genetic engineering systems, drug delivery, and pharmaceuticals' (Treats medical devices, health care services, and medical information systems as separate industries)
Goetz and Morgan (1995)	'any technique that uses living organisms or parts of organisms to make/modify products, improve plants or animals, or develop microorganisms for specific use'
Hall and Bagchi-Sen (2001)	'products and processes for the diagnosis, treatment, and cure of human disease, as well as the development of genetically customised animals, plants, and food'
Paugh and LaFrance (1997)	a set of 'techniques that use organisms or their cellular, sub-cellular, or molecular components to make products or modify plants, animals, and micro-organisms to carry desired traits'

Source: Based on the appendix to Cortright and Mayer (2002)

A number of other studies cited by Cortright and Meyer distinguish between biotechnology firms and pharmaceutical firms but do not adopt specific definitions of what classifies a firm as part of the biotechnology industry.

In conclusion, while an expansive, customised local definition of what constitutes the biotechnology industry may be useful in promoting the industry locally, perhaps by highlighting linkages between biotechnology and other sectors and institutions (like medical device manufacturers, agricultural chemical producers, or medical laboratories), such definitions are not a reasonable basis for wider comparisons. Furthermore, focusing on the core biotechnology industry helps reveal the dynamics of industry growth and location. This is more likely to uncover the processes that will drive growth.

References

Biotechnology Industry Organisation. **www.bio.org**

Institute for Biotechnology Information. 2001. **www.bioability.com**

PriceWaterhouseCoopers (2001) *Money Tree Survey* **www.pwcmoneytree.com**

Goetz, S. J., and R. S. Morgan (1995) 'State Level Locational Determinants of Biotechnology Firms.' *Economic Development Quarterly,* Vol. 9 (2) pp. 174–85.

Hall, L. and S. Bagchi-Sen (2001) 'An Analysis of R&D, Innovation, and Business Performance in the US Biotechnology Industry.' *International Journal of Biotechnology,* Vol. 3 (3) pp. 1–10.

Paugh, J., and J. C. LaFrance (1997) *The US Biotechnology Industry.* Washington, D.C.: US Department of Commerce.

100 Center for Public Policy, Virginia Commonwealth University (1999) *An Analysis of Virginia's Biotechnology Industry,* Richmond.

Appendix 3: Firms' Growth Rates and the 'Sweet Spot'[101]

The medicines industry is composed of two major groups of firms: large drugs companies with market capitalisations in excess of $50 billion and smaller drugs companies and biotech companies with capitalisations of $5 billion or less. In between, there is very little apart from a few weak drugs companies that have suffered in the current stock market downturn. For the larger well established biotech companies, there is a clear question: how can they grow to begin to bridge this huge gap. This is important, because to do so would be to identify oneself to investors as a leading company. This would attract investors, since most small cap funds in the US would regard $5 billion as a low cut-off point, and the company would be able to grow much faster. For this reason, achieving a capitalisation of $5-10 billion has been identified as a key hurdle leading to more rapid growth i.e. the sweet spot of the title.

Research indicates that for the largest biotech companies, a initial public offering (IPO) was made on average, 4 years after incorporation, the first product was marketed 9 years after incorporation and profitability achieved 1 year later. The requirements to achieve the $5 billion capitalisation level have been identified as:

- One product should see capitalisation reach $1 billion but at least two products with over $500 million per annum in sales per product are required for $5 billion;
- A critical mass of R&D spend of at least $100 million per annum quickly rising to over $300 million as the company starts to grow rapidly;
- R&D producing a pipeline of products with the potential to match this level of sales; and
- Rising EPS as a result of increasing sales not cost cutting arising from mergers.

A number of leading biotech firms have found that they fail on one or more of these tests and cannot achieve the hurdle valuation. Indeed the vast majority of products sold by profitable biotech do not achieve annual sales of $500 million. Of 28 such products in 2001, 21 sold less that this level and only 2 sold more than $1 billion. The preferred option then is to merge with a pharmaceutical.

The main benefit for firms achieving these targets is that the stock market places them on a high p/e multiple. But high ratings imply the need for high growth and fund managers look for EPS growth in the region of 20% per annum. Fortunately, for firms that have just qualified for these ratings, this is quite possible. The difficulty is in maintaining this growth rate and few of the large pharmaceutical companies manage to do so. So far, only Amgen need worry about this, but it needs to more than double revenues from the current $5 billion to $10.6 billion in 2006 if it is to maintain 20% growth. As a result, as the firm moves up through the gap in capitalisation between the large and small companies, the rating will start to fall. This raises the question whether this leap is ever possible for the emerging biotech and whether the big pharma model, with one company doing everything from research to marketing, is appropriate for the industry.

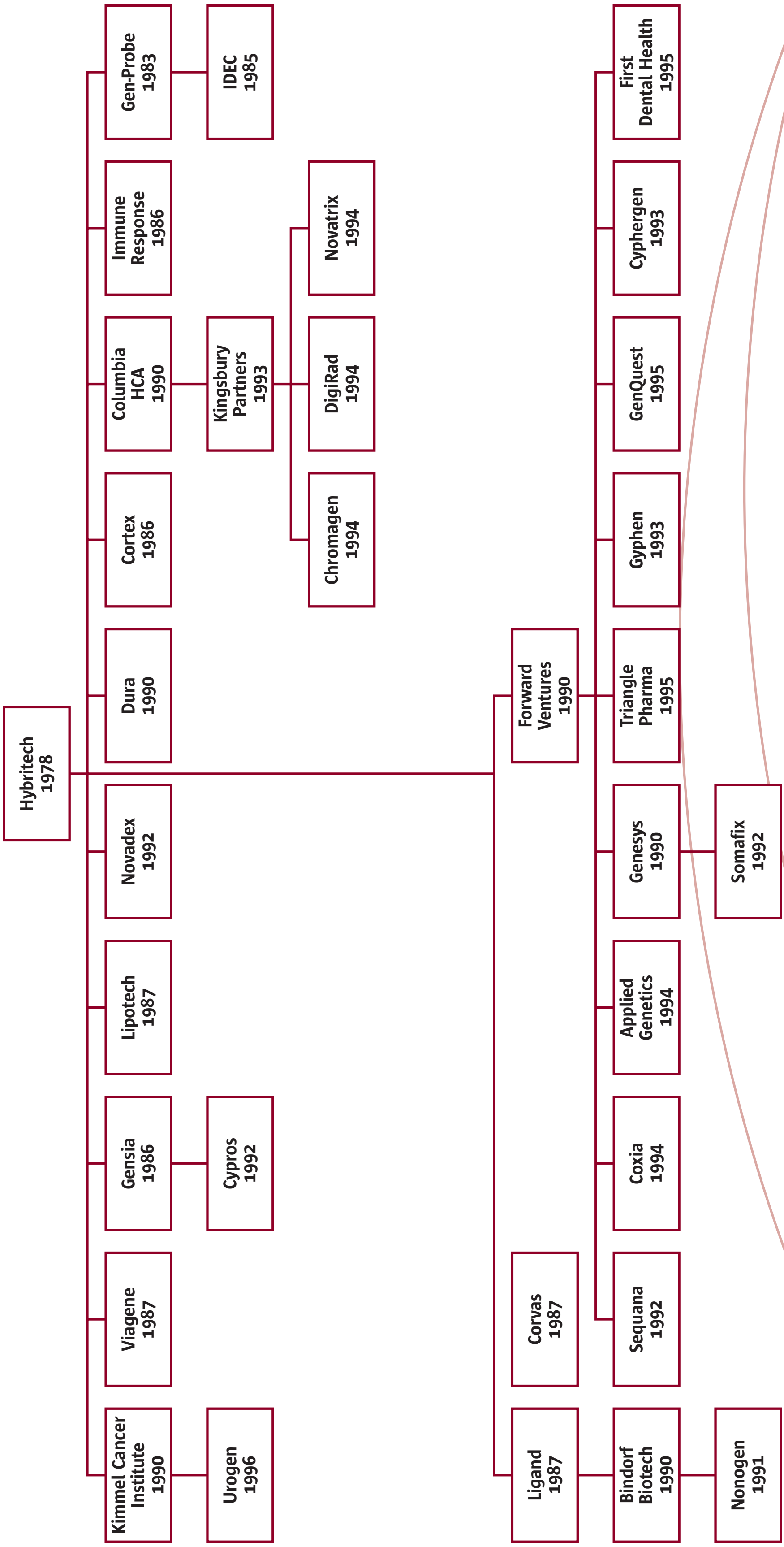
101 The appendix is based on 'The Sweet Spot' *BioCentury: The Bernstein Report on BioBusiness*, Vol. 10 (38) pp 1-11.

Appendix 4: Examples of Biotech Product Pipelines

Company	Product	Indication	Status
Neurocrine	Indiplon GABA inhibitor	Insomnia	Phase III
	IL-4 fusion toxin	Malignant glioma	Phase II
	Altered peptide ligand	Type 1 diabetes	Phase II
	Altered peptide ligand	MS	Phase II
	CRF R1 antagonist	Depression	Phase I
	IL-4 fusion toxin	Cancer	Phase I
	GNRH antagonist	Endometriosis	Phase I
Biogen	Avonex interferon	MS	Awaiting FDA
	Amevive alefacept	Psoriasis	Awaiting FDA
	CDP 571	Crohn's disease	Phase III
	Antegren natalizumab	MS and Crohn's	Phase III
	Adentri adenosine	Heart failure	Phase II
	Lymphotoxin beta	Autoimmune	Phase I
	LFA-1	Psoriasis	Phase I
	Interferon gene therapy	Cancer	Phase I
MedImmune	Synagis palivizumab	RSV	Market
	Ethyol amifostine	Chemoprotection	Market
	CytoGam	CMV	Market
	RespiGam	RSV	Market
	Neutrexin	Pneumonia	Market
	FluMist vaccine	Influenza	Awaiting FDA
	Synagis CHD	Heart disease	Phase III
	FluMist liquid	Influenza	Phase III
	Ethyol	Lung cancer	Phase III
	Siplizumab	Psoriasis	Phase II
	HPV vaccine	Cancer	Phase II
	E. coli UTI	Urinary infection	Phase II
	Epstein Barr vaccine	EBV	Phase II
	Vitaxin	Cancer	Phase I
	CMV Vaccine	CMV	Phase I
Gilead	Ambisome B	Infection	Market
	Tamiflu	Influenza	Market
	DaunoXome	Kaposi's sarcoma	Market
	Vistide	HIV/AIDS	Market
	Hepsera	Hepatitis B	Awaiting FDA
	Cidecin daptomycin	Infection	Phase III
	Tenofovir prodrug	Viral infection	Phase I

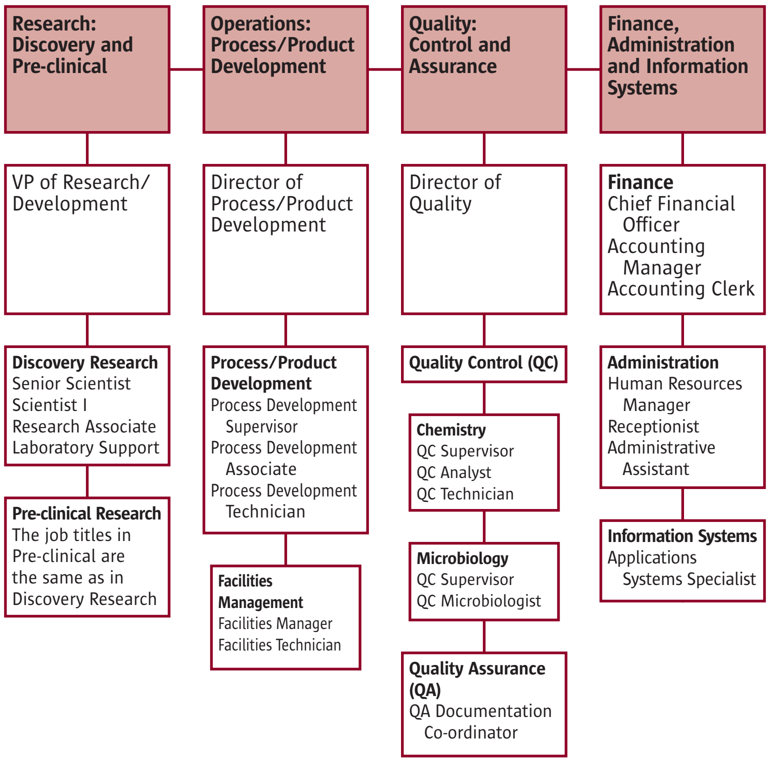
Source: BioCentury (2002)

Appendix 5: Spin-Offs of Hybritech



Appendix 6: Employment Opportunities in Biotechnology Firms

Overview of Jobs in a Small (1-49) Biotechnology Company



Source: Massachusetts Biotechnology Council

Overview of Jobs in a Medium (50-149) Biotechnology Company

Research: Discovery and Pre-clinical
- VP of Research/ Development
- **Discovery Research**
  - Scientific Dir.
  - Assoc. Scientific Dir.
  - Senior Scientist
  - Scientist II
  - Scientist I
  - Sr. Research Associate
  - Research Associate
  - Laboratory Technician
  - Laboratory Support
- **Bioinformatics Software**
  - Software Engineer
  - Scientific Engineer
  - Scientific Programmer
- **Bioinformatics Systems**
  - Database Applications Programmer
  - Database Administration Architect
  - Automated Systems Designer
- **Pre-clinical Research**
  - The job titles in Pre-clinical are the same as in Discovery Research

Operations: Process/Product Development, Manufacturing and Production
- VP of Operations
- **Process/Product Development**
  - Director of Product/Process Development
  - Process Development Supervisor
  - Process Development Associate
  - Process Development Technician
- **Manufacturing**
  - Manuf. Supervisor
  - Manuf. Associate
  - Manuf. Technician
- **Facilities Management**
  - Facilities Manager
  - Facilities Technician

Quality: Control and Assurance
- Director of Quality
- **Quality Control (QC)**
  - **Chemistry**
    - QC Supervisor
    - QC Analyst
    - QC Technician
  - **Microbiology**
    - QC Supervisor
    - QC Microbiologist
- **Quality Assurance (QA)**
  - QA Supervisor
  - QA Documentation Specialist
  - QA Documentation Co-ordinator

Clinical/ Regulatory Affairs
- Medical Director
- **Clinical Research**
  - Clinical Research Manager
- **Regulatory Affairs**
  - Manager of Regulatory Affairs

Finance, Administration and Information Systems
- **Finance**
  - Chief Financial Officer
  - Accounting Manager
  - Accounting Clerk
- **Administration**
  - Manager of Human Resources
  - Human Resources Representative
  - Purchasing Clerk
  - Receptionist
  - Administrative Assistant
- **Information Systems**
  - Manager of Information Systems
  - Applications Systems Specialist
  - Librarian

Source: Massachusetts Biotechnology Council

Overview of Jobs in a Large (150+) Biotechnology Company

Research: Discovery and Pre-clinical

- VP of Research/ Development

Discovery Research
- Scientific Dir.
- Assoc. Scientific Dir.
- Principal Scientist
- Senior Scientist
- Scientist II
- Scientist I
- Principal Research Associate
- Sr. Research Associate
- Research Associate
- Research Assistant
- Laboratory Technician
- Laboratory Support

Bioinformatics Software
- Software Engineer
- Scientific Engineer
- Scientific Programmer

Bioinformatics Systems
- Database Applications Programmer
- Database Administration Architect
- Automated Systems Designer

Pre-clinical Research
The job titles in Pre-clinical are the same as in Discovery Research

Operations: Process/Product Development, Manufacturing and Production

- VP of Operations

Process/Product Development
- Director of Product/Process Development
- Process Development Supervisor
- Process Development Associate
- Process Development Technician

Manufacturing and Production
- Dir. of Manufacturing
- Manuf. Manager
- Manuf. Supervisor
- Manuf. Associate
- Manuf. Technician

Facilities Management
- Manager
- Technician
- Metrology Supervisor
- Metrology Technician

Quality: Control and Assurance

- Director of Quality

Quality Control (QC)

Chemistry
- QC Supervisor
- QC Analyst
- QC Technician

Microbiology
- QC Supervisor
- QC Microbiologist

Quality Assurance (QA)
- QA Supervisor
- QA Documentation Specialist
- QA Documentation Co-ordinator

Validation
- Manager
- Instrumentation Calibration Technician

Clinical/ Regulatory Affairs

- Medical Director

Clinical Trials
- Clinical Research Manager
- Clinical Research Associate
- Biostatistician
- Clinical Data Associate
- Clinical Database Programmer/ Analyst

Regulatory Affairs
- Director/Manager of Regulatory Affairs
- Senior Regulatory Affairs Associate
- Scientific Writer
- Documentation Assistant

Finance, Administration and Information Systems

Finance
- Chief Financial Officer
- Accounting Manager
- Accounting Clerk
- Payroll Clerk

Administration
- Public/Investor Relations Manager
- Government Relations Manager
- Director of Human Resources
- Human Resources Representative
- Security Manager
- Buyer
- Receptionist
- Administrative Assistant

Information Systems
- Manager of Information Systems
- Applications Systems Specialist
- Librarian

Business Development/ Marketing and Sales

Business Development
- Director of Business Development
- Manager of Corporate Planning
- Business Development Research Analyst

Marketing and Sales
- Vice President of Marketing
- Marketing Research Analyst
- Product Marketing Manager
- National/ International Sales Manager

Source: Massachusetts Biotechnology Council

Reports Published by the Expert Group on Future Skills Needs

Report	Date of Publication
The First Report of the Expert Group on Future Skills Needs Responding to Ireland's Growing Skills Needs	December 1998
Business Education and Training Partnership Report on the Inaugural Forum, Royal Hospital Kilmainham	March 1999
The Second Report of the Expert Group on Future Skills Needs Responding to Ireland's Growing Skills Needs	March 2000
Business Education and Training Partnership 2nd Forum, Dublin	March 2000
Report on E-Business Skills	August 2000
Report on In-Company Training	August 2000
Benchmarking Mechanisms and Strategies to Attract Researchers to Ireland	July 2001
The Third Report of the Expert Group on Future Skills Needs Responding to Ireland's Growing Skills Needs	August 2001
Labour Participation Rates of the over 55s in Ireland	December 2001
National Survey of Vacancies in the Private Non-Agricultural Sector 2001/2002	March 2003
National Survey of Vacancies in the Public Sector 2001/2002	March 2003
The Demand and Supply of Skills in the Food Processing Sector	April 2003
The Demand and Supply of Engineers and Engineering Technicians	July 2003

Members of the Expert Group on Future Skills Needs

Member	Organisation
Dr. Danny O'Hare (Chairperson)	President Emeritus, Dublin City University
David Barry	Department of Enterprise, Trade and Employment
Brian Cogan	Forfás
Enda Connolly	IDA Ireland
Roger Fox	FÁS
Jack Golden	Cement Roadstone Holdings/Institution of Engineers of Ireland
Una Halligan	Hewlett Packard
Fergal Costello	Higher Education Authority
David Lowe	Goodbody Stockbrokers
Joe McCarthy	Arkaon
Kevin McCarthy	Department of Education & Science
Dr. Sean McDonagh	Skills Initiative Unit
Eugene O'Sullivan	Department of Finance
Peter Rigney	Irish Congress of Trade Unions
Dr Catherine Kavanagh	Forfás
Aisling Penrose (Secretary)	Forfás

Secretariat

Forfás, Wilton Park House, Wilton Place, Dublin 2.

Tel: 01-607 3000   Fax: 01-607 3030

E-Mail: info@forfas.ie   Website: www.forfas.ie

The Supply and Demand for Skills in the *Biotechnology Sector*