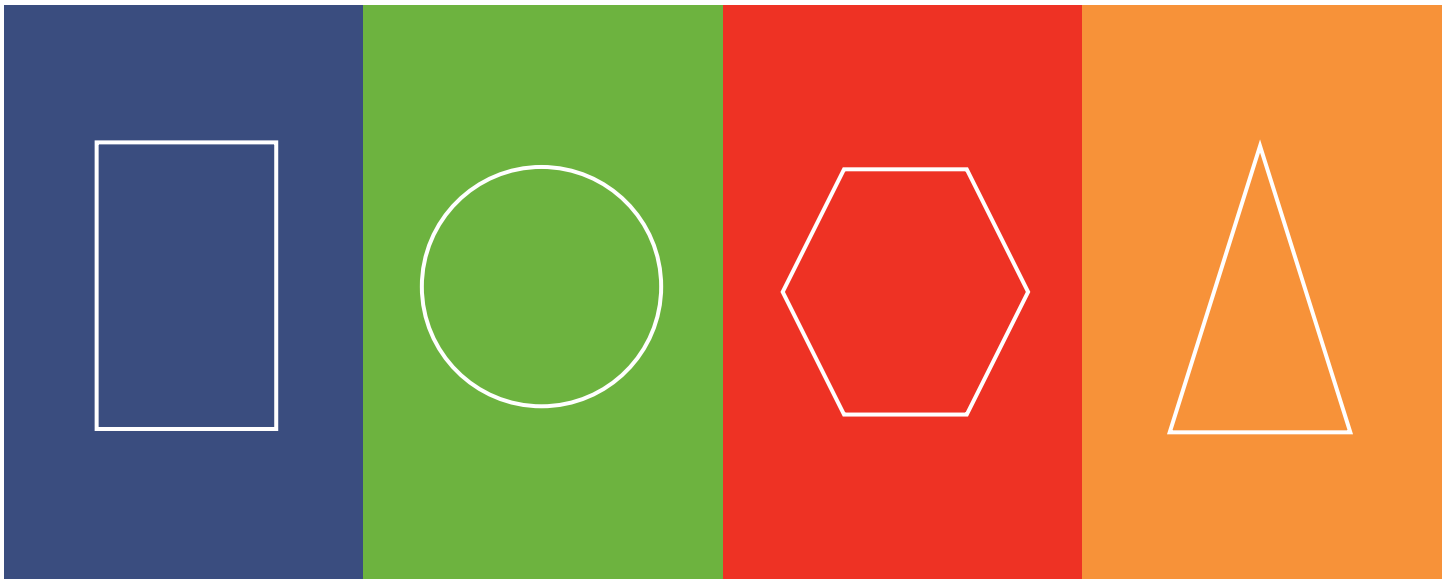


Future Skills Needs of the Irish Medical Devices Sector

Expert Group on
Future Skills Needs

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

2008

Table of Contents

Acknowledgments

The report is substantially based on research carried out by Publica Consulting and McIver Consulting on behalf of the Expert Group on Future Skill Needs and Forfás. Forfás would like to fully acknowledge the quality of their work.

Forfás is grateful to the many industry executives, academics and staff at expert organisations in Ireland who gave interviews as part of the study. In particular Forfás would like to acknowledge the substantial contribution made at various stages of the report by the Irish medical devices association.

Thanks are also due to the industry executives, academics, state government officials, executives of industry organisations met during study visits to the US, and to the leading US serial-entrepreneur-physician-engineer-academic, lawyer-counsellor-of start-ups and venture capital executives who were so generous with their experience and expertise. Forfás is grateful to Enterprise Ireland and IDA Ireland for their considerable assistance in arranging and carrying out the three study visits. Thanks are due to Mr. Ken McDonnell, a member of Enterprise Ireland's Medical Devices Advisory Board, who arranged interviews with some of the leading lights in medical devices in Silicon Valley. Thanks are also due to other members of the Advisory Board for their advice and assistance. Minnesota State Colleges and Universities were also particularly helpful, for which we are grateful.

Forfás would like to record its appreciation to Dr. Sean Mc Donagh, Chairperson of the Steering Group responsible for overseeing the work of the report and to each member of the group for their commitment and contribution.

Foreword

On behalf of the Expert Group on Future Skills Needs, I am very pleased to introduce this report *Future Skills Needs of the Irish Medical Devices Sector*.

The medical devices sector is very important for Ireland. The sector produces a great variety of high value-added products and it provides significant high skilled employment here. The industry has grown significantly over the last decade and Ireland is now one of the leading global medical devices industry centres. While the sector faces challenges – as do other industries – there are many reasons to be confident of its future success. Inward investment into the medical devices sector in Ireland is continuing. The 'Made in Ireland' brand is highly valued for medical devices products and the industry is making greater use of R&D leading both to greater product and process innovation. A continuous focus on ongoing innovation is key for the industry to thrive and renew itself into the future. As technological convergence progresses, there will be an opportunity to position Ireland as a location that is well equipped to undertake R&D and production operations in bio-convergence products.

The aim of this report is to examine trends and drivers of change in the industry which will have the greatest impact over the period 2007-2013; to determine the implications of these changes for the skills requirements of the sector; and to put forward specific recommendations for ensuring that skills will underpin the future development and growth of the industry. I am very pleased that the study has fully done this. It is recognition of the successful collaboration and commitment given by the many interested stakeholders involved – in industry, academia, state bodies and expert organisations.

I would like to thank everyone who contributed to the production of this report. This includes all those, in Ireland and the US from industry, academia and expert organisations who participated in interviews and discussions, all of which were invaluable in producing this report. I would like to record my fullest appreciation to members of IDA Ireland and Enterprise Ireland for their excellent support and sharing of expertise. I would like to express my gratitude to Dr. Sean Mc Donagh who chaired the Steering Group that oversaw the completion of the report, and to each member of the group for their full commitment and support. Finally, I would like to thank the team at Forfás for leading this project to a successful conclusion.

Anne Heraty
Chairperson, Expert Group on Future Skills Needs

Executive Summary

Scope of Study

This study was commissioned by Forfás on behalf of the Expert Group on Future Skills Needs, at the request of Enterprise Ireland and the Irish Medical Technologies Council. The overarching objective of the study was to assess the skills requirements at all levels of the medical devices sector in Ireland, over the period 2007-2013.

The terms of reference of the study were as follows:

1. Identify the structural trends and drivers of change in the industry which will have the greatest impact on skills requirements;
2. Determine the implications of these trends/drivers of change for the skills requirements of the sector;
3. Deduce the implications for education and training provision; and
4. In the light of the foregoing analysis, put forward specific recommendations for ensuring that skills can be a spur to further development of the industry.

Methodology

The methodology had the following main components:

- Secondary research;
- Analysis of data on students and higher education courses;
- Interviews with medical devices companies – both Irish and foreign-owned;
- Interviews within the higher education sector;
- Study visits to Massachusetts, Minnesota and Northern California; and
- Interviews with industry, professional organisations and State Agencies.

Industry Profile

Ireland is one of the leading global medical devices industry centres. Inward investment from overseas has grown rapidly, particularly in manufacturing, but also in world-class research and development. The major medical devices industries here are in relatively high growth and high value-added activities such as the manufacture of medical and surgical instruments, and surgical appliances and supplies. There are also significant R&D operations. Employment in the sector here has risen rapidly over the decade and now stands at nearly 24,000. Foreign-owned companies account for over 90% of employment. Even so, employment in Irish-owned companies is rising somewhat faster than in foreign-owned companies. Sales by medical devices companies in Ireland are worth about €6 billion per annum – with exports accounting for over 95% of sales. "Made in Ireland" is considered one of the best labels a medical device can have. Challenges facing the sector are rising costs, unfavourable exchange rate trends, and improving

manufacturing capabilities of competing low cost economies. Globally the sector is in the early stages of what is likely to rapid convergence between technologies, with devices combining biomechanical, electronic and biologically active components.

Skills Strategy for Sector

The study presents two future employment scenarios for the sector, one based on a continuation of the level of growth seen since 2000, and the other based on slower growth. Projections are based on the view that the share of employment in operative level occupations is likely to fall, while that in engineering, scientific, technician, sales and purchasing occupations will rise. Aside from the possibility of strong competing demand from other sectors, the supply of engineers and scientists appears likely to be sufficient in numbers, although there is an issue with the supply of electronic engineers. Technological convergence will deepen over time. There will be an opportunity to position Ireland as a location well equipped to undertake R&D and production operations in a range of bio-convergence products. The essence of a skills strategy for the medical devices sector must be on:

Building Operational Excellence

Building excellence in medical devices operations requires progress on three closely integrated fronts, all of which have significant skills implications.

- Automation, to address the high costs associated with manual assembly;
- Lean manufacturing, to eliminate waste and speed logistics; and
- Improving quality and eliminating waste.

Driving Innovation

A focus on ongoing innovation is essential for the industry to renew itself into the future. Key skill-related areas where action is required are on providing the medical devices industry with the high-level engineering and scientific skills it requires for innovation; and achieving a greater involvement by Irish clinicians in medical device innovation.

Developing High-level Engineering and Scientific Skills

The main opportunity to differentiate Ireland on the basis of skills is in the supply of high quality engineers. Key areas where action is required to underpin the future supply of high-level engineering and scientific skills include:

- Ensuring a supply of PhD graduates in relevant disciplines who are well prepared to enter the industry;
- Better preparation for undergraduate biomedical and mechanical engineers to work as practical engineering designers; and
- Greater involvement by electronic engineering departments in biomedical electronics, to produce a largely new flow of engineers.

Increasing Involvement by Clinicians in Medical Device Innovation

Attaining greater involvement by clinicians in medical device innovation is not just a matter of developing and translating clinical research, although this is a significant part of what is required. Significant medical devices innovations frequently emerge informally from the application of engineering principles to clinician insights as much as from formal clinical research. Initiatives should be undertaken in a number of areas to develop the supply of people with combinations of clinical and engineering skills, as such people are particularly well suited to innovating in medical devices.

Increasing Entrepreneural and Intrapreneural Activity

Innovation resulting in entrepreneurship or intrapreneurship is crucial to the future of the medical devices sector in Ireland. It will lead to the development of a significant entrepreneurial indigenous sector, and underpin the future of the foreign-owned sector in Ireland. This will require a significant increase in entrepreneurial activity, developing new businesses, whether stand-alone or within existing companies. The evidence of the study visits to the US is that skills-type interventions can do much to boost entrepreneurial and intrapreneurial activity.

Developing Professional and Specialist Skills

Two broad types of professional development intervention are required. Firstly, a need for managers and professionals working in the medical devices sector to develop a broad working knowledge of a range of topics that are important and specific to the medical devices sector. Secondly, a need for a small number of managers and professionals to have a deep specialist knowledge in areas such as regulatory affairs and clinical trials management.

Meeting Opportunities of Deepening Technological Convergence

Technological convergence in medical devices will become deeper over time. It will impact on skills requirements in a number of ways. It will broaden the range of disciplines that are core to the medical devices sector, from mechanical engineering, biomedical engineering, materials engineering and medicine, to also include biological sciences, electronic engineering, pharmacology and chemistry. It is likely that technologies will emerge that are core to areas of convergence, and which will have to be understood by significant numbers of people from different disciplines.

Industry Networks

Interaction and networking between professionals and managers with interests in medical devices will be crucial for developing processes for innovation – reflecting what can be seen in California and Massachusetts.

The recommendations from the study are outlined as follows. Chapter 8 of the report puts each recommendation into more detailed context.

Recommendations

Recommendation 1: Centre for Medical Device Manufacturing Excellence

A Centre for Medical Device Manufacturing Excellence should be established in the higher education sector to assist industry in developing the skills required for automation, lean manufacturing and quality management.

The Centre is likely to operate in a number of modes, including: provision of short duration courses, on site or on-campus; provision of masters level courses, part-time and possibly full-time; contributing to undergraduate courses in relevant disciplines; and applied research with industry partners making high-level expertise available to smaller operations etc.

The Centre should be modest in scale and be established for a limited period, renewable while its services continue to be required. It would make use of existing facilities in the higher education sector. It is envisaged that the Centre would be established on the basis of proposals from higher education institutions (possibly from consortia) to IDA Ireland and Enterprise Ireland, which would provide core funding. While actual costs would depend on the detailed arrangements for the Centre, it is estimated that core funding of the order of €5m capital and €1m recurring would be required.

Recommendation 2: Upskilling Operators and Technicians

Interested parties from Irish Medical Devices Association, FÁS, Skillnets and other organisations should, as appropriate, cooperate in the following.

- Rolling out by companies of training leading to the award of the Level 5 FETAC Medical and Allied Devices Production Certificate.
- The development of a course in biomedical technology leading to a special purpose Level 6 qualification. Participation should be paid for by companies, with some support from FÁS, Skillnets and other public providers of funding for training.
- In-company and part-time courses to train technicians to work with automated medical device production systems. Participation should be paid for by companies with some support from FÁS, Skillnets and other public providers.
- Institutes of Technology and medical devices companies should continue to cooperate in providing bioscience technician courses at Levels 6 and 7 to upskill operators, or in reskilling technically qualified people from other disciplines.

It is envisaged that approximately 5,000 assemblers, operators and technicians would require upskilling training in the next three years.

Recommendation 3: High-level Engineering and Scientific Skills

Higher education institutions involved in graduate studies in biomedical engineering should continue to work towards establishing a Fourth Level Graduate Education Institute, so as to prepare graduates to contribute effectively to medical devices sector innovation and to strengthen the network of relationships among future key players in Irish medical devices innovation. The Expert Group supports the need for such an institute. The EGFSN also acknowledges the need for excellence in proposals for such an institute. The Stanford Biodesign Programme, described in the body of this report would form a useful model for the Irish graduate school.

Institutions providing Level 8 to 10 programmes in biomedical engineering, and in mechanical engineering should identify ways in which they can better prepare their students to work in engineering design. Electronic engineering departments with interests in bioelectronic engineering should examine the scope to add biomedical content to their programmes, or to place additional emphasis on medical technologies in their research.

Recommendation 4: Engaging Irish Clinicians in Medical Devices Innovation

Entry into the new graduate programmes in medicine by engineering graduates has the potential to produce a supply of graduates qualified both in medicine and engineering. Medical and engineering schools should jointly create more opportunities for clinicians in training to undertake studies and/or research in medical technology and biomedical engineering. Medical schools should feature career paths involving participation in medical technology innovation.

The Irish Medical Technologies Council should sponsor initiatives to raise the profile of innovation among clinicians, particularly those still in training. Industry and Enterprise Ireland should provide funding to support these interventions.

Recommendation 5: Developing Entrepreneurs and Intrapreneurs

Enterprise Ireland should continue to develop its range of training and coaching supports for medical devices entrepreneurs, and for prospective entrepreneurs. Enterprise Ireland should also consult with Irish higher education institutions interested in medical technologies with a view to the development of a programme to boost the supply of effective entrepreneurs and intrapreneurs. The Stanford Biodesign Fellowship Programme is one possible model to consider. The Irish programme should draw on leading US expertise in creating medical devices business.

Recommendation 6: Professional Development

A part-time professional development course targeted at medical devices sector managers and professionals should be developed by a higher education institution, covering topics including: regulatory affairs; quality and product development in the medical devices regulatory environment; healthcare economics and reimbursement; clinical trials; intellectual property; sales and marketing; and organisational leadership.

Enterprise Ireland, in cooperation with the Irish Medical Devices Association and other interested parties, should consider commissioning the development of part-time professional education courses in:

- Healthcare Economics and Reimbursement;
- Intellectual Property in medical devices;
- Sales Management and Marketing for Medical Devices; and
- Venture Financing of Medical Devices Start-ups.

These courses should be targeted on industry professionals who are working in the area. It is envisaged that one iteration of each course would be run initially, with additional courses being run if demand is apparent. Part of the cost of the above provision(s) would be recovered from participants through fees.

Recommendation 7: Postgraduate Taught Courses

A Masters Course in Regulatory Affairs should be introduced by a higher education institution, either targeted specifically on the medical devices sector, or targeted jointly on medical devices and pharmaceuticals sectors, but with a medical devices specialisation. It should be developed in collaboration with the industry in order to ensure relevance and encourage uptake. The course will be delivered in a number of different formats.

It is recommended that higher education institutions should consider the creation of a graduate diploma or masters degree in the design, management and conduct of clinical trials. It is envisaged that the cost of provision would be recovered from participants, as with other part-time postgraduate courses.

Recommendation 8: Technological Convergence

Technological convergence in medical devices will deepen over time. It will impact on skill requirements in a number of different ways.

As technological convergence in medical devices progresses the following should be introduced:

- Courses in important convergence topics into undergraduate biomedical engineering courses;
- Masters programmes in important convergence topics to facilitate graduates in specialising in key areas of skills demand, targeted on graduates both from relevant scientific and engineering disciplines; and
- Specialist or cross-disciplinary undergraduate degrees, where clear industry demand exists.

Recommendation 9: Medical Devices Industry Networks

Interaction and networking between professionals and managers will be crucial to developing processes for innovation in the medical devices sector. The Irish Medical Technologies Council has significant potential to promote this interaction.

The Irish Medical Technologies Council should actively promote communication and networking between industry leaders, entrepreneurs, leading scientists and engineers, academics, clinicians and industry development agencies involved in medical technologies.

Chapter 1: Introduction

1.1 Introduction

This study was commissioned by Forfás on behalf of the Expert Group on Future Skills Needs, at the request of Enterprise Ireland and the Irish Medical Technologies Council.

The overarching objective of the study was to assess the skills requirements, at all levels from operatives through to post-doctoral researchers, of the medical devices sector in Ireland, over the period 2007-2013.

1.2 Objectives

The objectives of the study were as follows:

- Identify the structural trends and drivers of change in the industry which will have the greatest impact on skills requirements over this timeframe;
- Determine the implications of these trends/drivers of change for the skills requirements of the sector. These may stem from the changing occupational composition of the sector as well as changes in the nature of particular occupations;
- Deduce the implications for education and training provision in Ireland. Specifically, the study should:
  - Map the range of education and training provision in Ireland for the Sector;
  - Assess the adequacy of the current skills supply pipeline, both quantitatively and qualitatively, for the medical devices sector's future requirements;
  - Assess the need for upskilling of the current workforce in the sector in the light of the likely industry trajectory and the current educational profile of the workforce;
  - Assess the requirements for conversion courses, post-graduate courses and professional development etc; and
  - Consider the requirement for certification and accreditation in recommendations for new education and training programmes;
- In the light of the foregoing analysis, put forward specific recommendations for ensuring that skills can be a spur to the further development of the industry in Ireland.

1.3 Methodology

The methodology had the following main components:

- Secondary research;
- Analysis of data on students and higher education courses;
- Interviews with companies – both Irish and foreign-owned – from a range of areas within the sector;
- Interviews within the higher education sector, covering academics responsible for teaching courses relevant to the sector, engineering and medical academics involved in higher education based research institutes relevant to the sector and other academics involved in research relevant to the sector;
- Three study visits to the US – to Massachusetts, Minnesota and Northern California; and
- Interviews with interested expert organisations, including industry and professional organisations and State Agencies.

1.4 Report Structure

Chapter 2 describes how the Irish medical devices industry has grown, and examines how it is structured. It reports on employment growth, firm ownership and regional distribution. It describes medical devices sales and exports and value-added.

Chapter 3 examines trends in the US/international medical devices industry, particularly important for Ireland as the US is the main source of medical devices inward investment. It provides an important model for innovation and entrepreneurship and is a significant export market.

Chapter 4 profiles the medical device industry skills starting with a review of occupational data for the Irish and US medical devices sectors. It then examines skills requirements in more detail, focusing on each major stage of the sector's value chain.

Chapter 5 examines specific trends for the Irish medical devices sector in terms of clinical specialism, type of product, company, technology, research and development; higher education research; outsourcing and supply chains; and education and training developments.

Chapter 6 explores patterns of innovation and entrepreneurship in the medical devices sector. New product development, and incremental improvements to products, are centrally important to the future of both foreign-owned and Irish-owned medical devices companies in Ireland.

Chapter 7 looks at likely future demand for new recruits into the medical devices sector at all levels. It presents two employment scenarios and makes projections of demand based on these, and on assumptions about future patterns of upskilling in the sector. It then looks in more detail at skills requirements and assesses the adequacy of the available supply in both quantitative and qualitative terms. It comments on measures that may be required to address the skills needs identified.

Chapter 8 outlines the main conclusions and recommendations of the report.

Chapter 2: Trends in Irish Medical Devices Industry

2.1 Introduction

Ireland is one of the leading global medical devices industry centres, with an industry comparable in scale to those of Massachusetts and Minnesota, two of the main centres of medical devices in the US. This chapter describes how the industry has grown, and examines how it is structured.

Relevance of Chapter to Skills Analysis

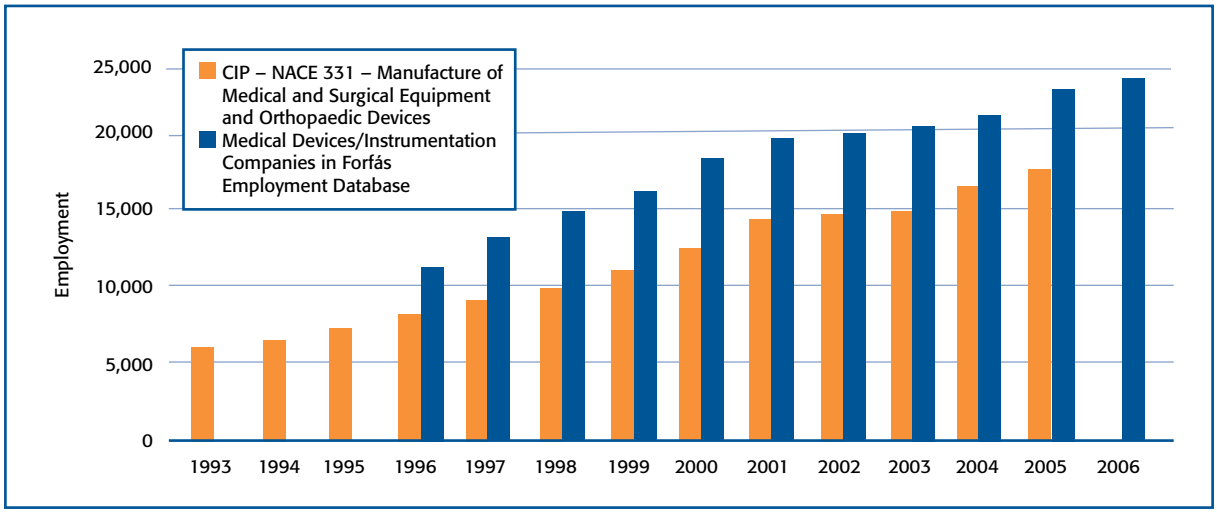
The requirement for skills in any sector is influenced by employment trends in the sector. All other things being equal, a sector in which employment is growing rapidly will have a greater requirement for skills than a sector that is growing slowly. In order to understand likely future skills needs, it is important to have an understanding of trends in competitiveness, which are likely to influence future employment patterns and skills requirements.

Skills needs often also vary between different types of companies. For example, a company with manually intensive production operations has different skills requirements to one with automated operations. In many industries, including the medical devices sector, there are differences in profile between foreign-owned and Irish-owned companies that drive differences in skills requirements.

2.2 Employment in Irish Medical Devices Sector

Employment in the Irish medical devices sector has risen rapidly since the early 1990s, as can be seen in Figure 2.1.

Figure 2.1: Employment in Irish Medical Devices Sector 1993 to 2006



Source: Census of Industrial Production, CSO, and analysis of Forfás Employment Database.

Most of the Irish sector is focused on the manufacture of medical and surgical instruments, and on surgical appliances and supplies. While the sector produces a great variety of products, there is a strong focus on technologies for minimally invasive surgery, particularly in cardiovascular surgery. The leading product categories produced by the industry are:

- Stents (tubular devices inserted into constricted vessels and channels in the body to hold them open, generally using minimally invasive techniques); and
- Instruments and delivery systems for minimally invasive surgery.

Within the area of surgical appliances, there is also significant activity in the manufacture of orthopaedic devices.

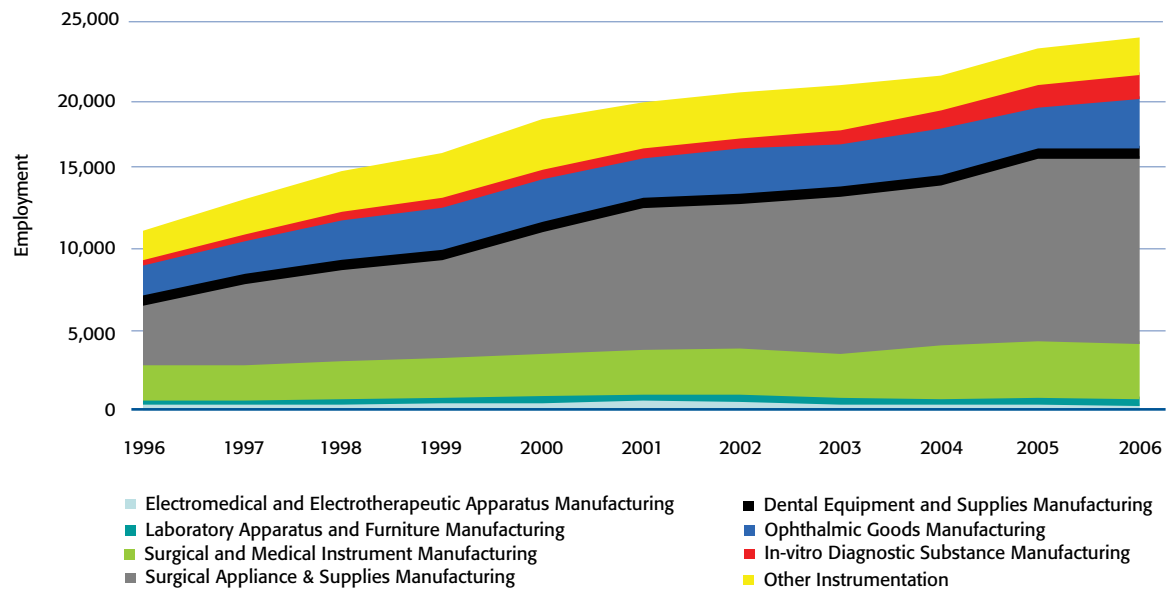
There is significant activity in the manufacture of ophthalmic goods (including contact lenses) and in diagnostic test kits.

While medical devices based on electronics and information technology form a major part of the sector globally, companies producing such devices form only a small part of the sector in Ireland.

Activity in dental-related manufacture is also very limited, mainly addressing the needs of the domestic market.

Figure 2.2 disaggregates employment growth in the sector between different subsectors from 1996 to 2006, showing that most of the growth has come from surgical appliances at an average rate of 11% per annum. The percentage rate of employment growth in ophthalmic goods and in diagnostics has also been high, at approximately 15% per annum and 24% per annum respectively, although starting from a low base. The analysis in Figure 2.2 follows the medical devices categories in the North American Industry Classification System (NAICS), to facilitate comparisons with the US.

Figure 2.2: Employment in Irish Medical Devices Sector, Disaggregated by NAICS Subsector



Note: Dental Laboratories approx. 25 employees (2006).

Source: Based on analysis of Forfás Employment Database.

The main medical and surgical specialisms in which medical devices manufactured in Ireland are used are:

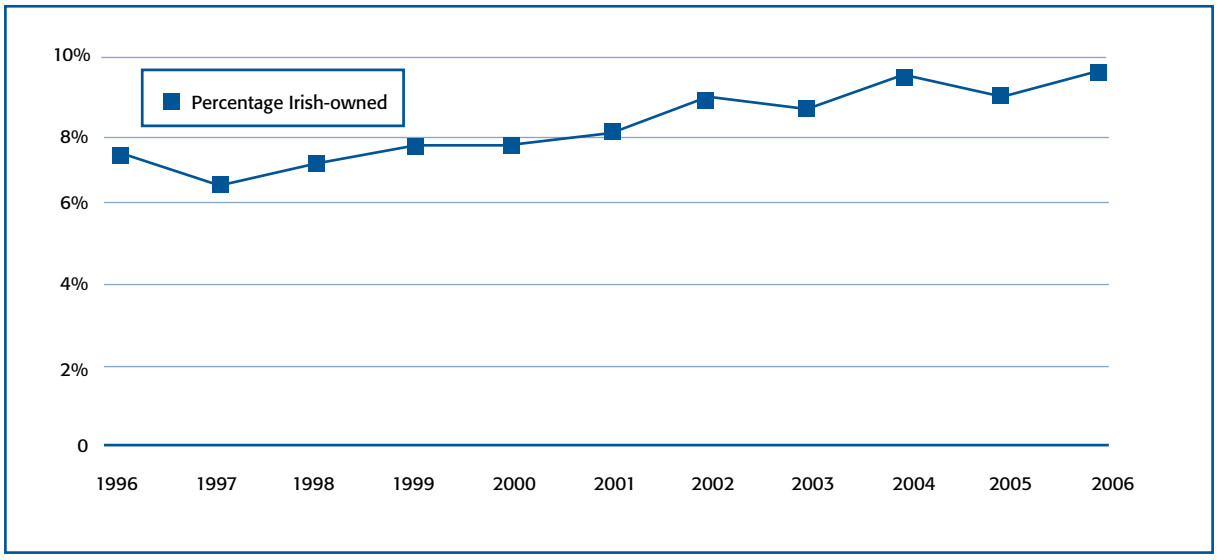
- Cardiovascular;
- Peripheral vascular;
- Ophthalmics;
- Orthopaedics;
- Urology;
- Imaging; and
- Respiratory.

Diagnostic products are used in a wide range of medical (and even veterinary) specialisms.

2.3 Employment by Firm Ownership

Foreign-owned companies account for over 90% of employment. Even so, employment in Irish-owned companies is rising somewhat faster than in foreign-owned companies, gradually raising the share of employment accounted for by the domestically-owned industry.

Figure 2.3: Medical Devices Employment in Ireland by Irish-owned Companies



Source: Based on analysis of Forfás Employment Database.

Most foreign-owned companies produce finished products. In some cases, production is from raw materials. In other cases, production involves final assembly and test from components sourced externally, whether from subsuppliers or from other operations in their group.

Most significant Irish-owned companies in the sector are engaged in subsupply, addressing various points in the value adding chain, including:

- Assembly;
- Production of components;
- Production of packaging;
- Testing;
- Engineering development services; and
- Consultancy.

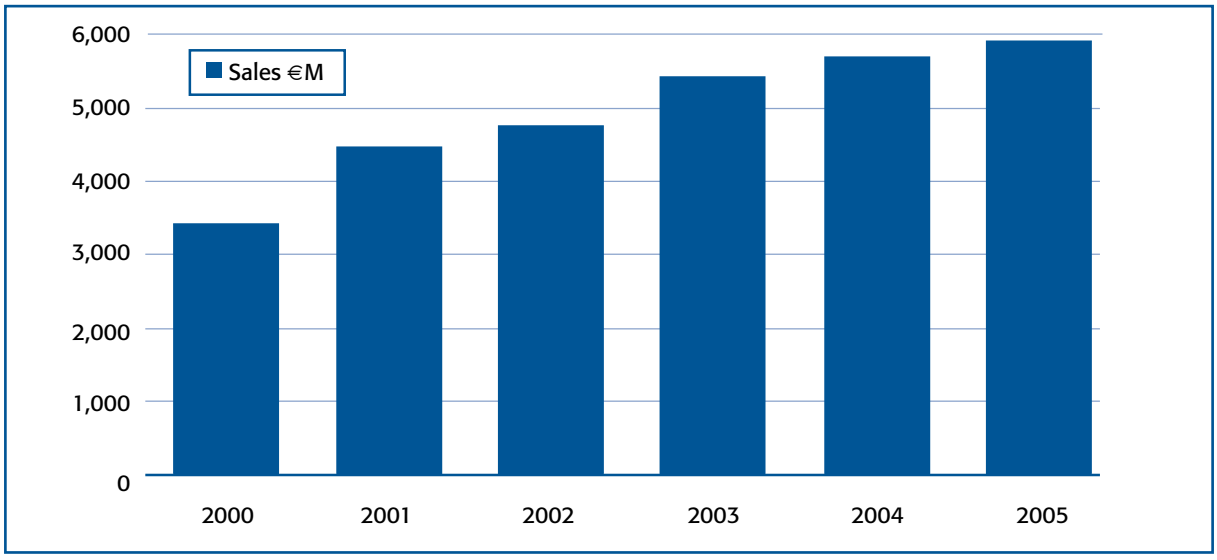
In many cases, companies are involved in subsupply at a number of complementary points in the value adding chain. For example, a subsupply company that solves a manufacturing challenge is sometimes in a good position to also manufacture the product.

A small number of Irish companies are involved in developing and marketing finished products of their own.

2.4 Medical Devices Sales

Sales by foreign-owned medical devices companies have risen significantly since 2000, although the rate of growth appears to have slowed down, as can be seen in Figure 2.4. Even so, average annual sales growth between 2000 and 2005 for these companies was 11.7% – representing substantially faster growth than for foreign-owned companies in any other Irish manufacturing or internationally traded services sector over the same period[1].

Figure 2.4: Sales by Foreign-owned Medical Devices and Instruments Companies in Ireland

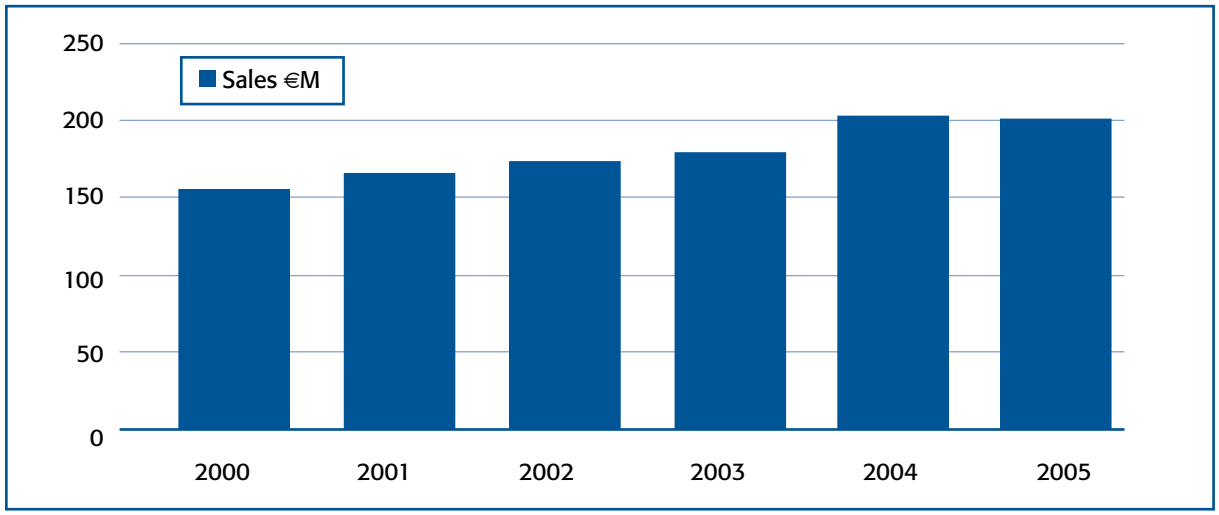


Source: Annual Business Survey of Economic Impact, 2005, Forfás.

1 *Annual Business Survey of Economic Impact, 2005, Forfás, Table C1.*

Sales by Irish-owned companies have also increased significantly, although with a fall between 2004 and 2005, as can be seen in Figure 2.5.

Figure 2.5: Sales by Irish-owned Medical Devices and Instruments Companies



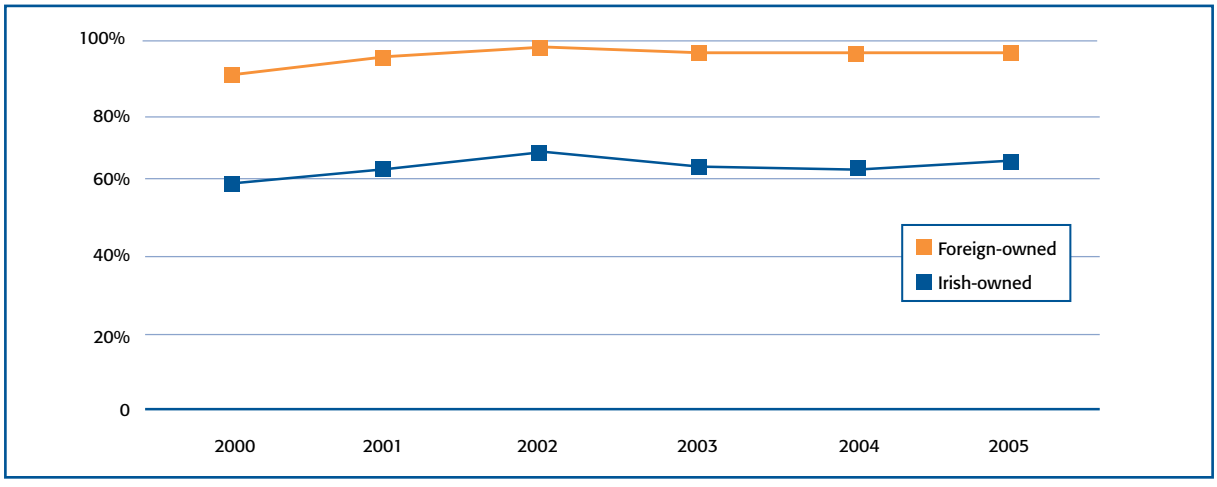
Source: Annual Business Survey of Economic Impact, 2005, Forfás.

Most of output from the medical devices sector is exported, either directly or after incorporation into the products of other medical devices companies.

As can be seen in Figure 2.6, direct exports from foreign-owned companies account for 96% of sales. With some foreign-owned subsupply activity, the actual percentage destined for foreign markets is even higher.

The share of sales by Irish-owned companies accounted for by direct exports is lower, reflecting mainly the fact that many are engaged in subsupply to the Irish operations of foreign-owned companies. Sales of finished products by Irish-owned companies to the domestic market also account for the lower proportion of exports as a percentage of sales.

Figure 2.6: Exports as Percentage of Sales of Medical Devices and Instruments Companies



Source: Annual Business Survey of Economic Impact, 2005, Forfás.

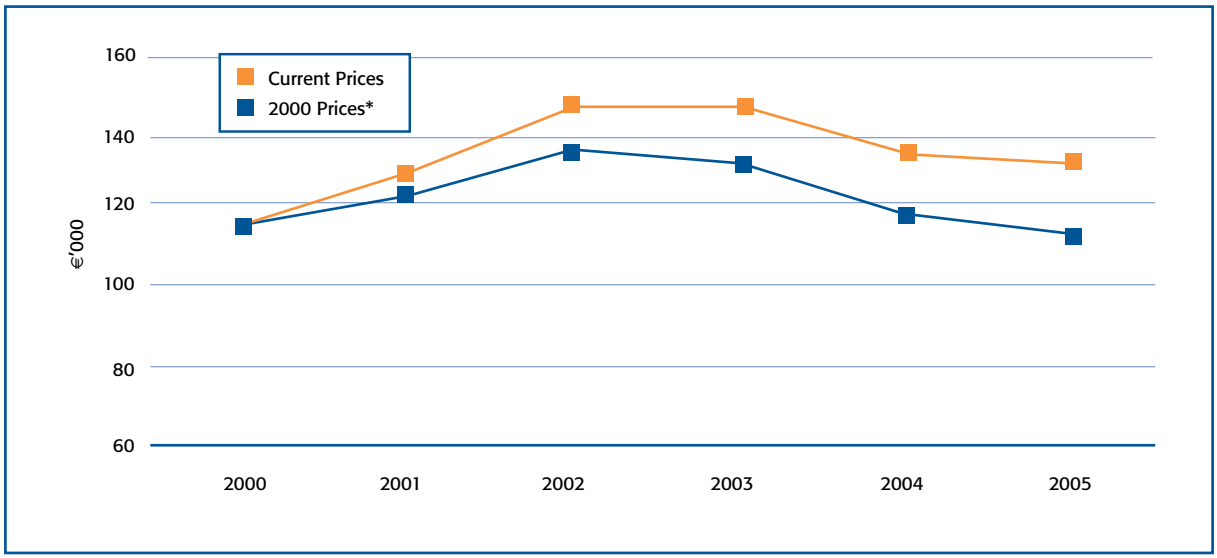
2.5 Medical Devices Value-added

In real terms, value-added per employee in foreign-owned medical devices companies peaked in 2002, and then fell up to 2005, the most recent year for which data are available, as may be seen in Figure 2.7.

Given the very high-level of exports and the fact that much of the trade was with countries outside the European Union, it seems likely that much of this fall was driven by the strengthening of the euro, and that the trend looks somewhat more positive when viewed in dollar denominated terms by the US corporations that account for the majority of the industry. The value of the euro rose by 21% between mid-2000 and mid-2005, relative to the US dollar.

Even so, if this trend in value-added per employee continued over a significant period, it would indicate a progressive loss of competitiveness that could threaten the sector's future. It points towards a need for the foreign-owned companies in the sector to pay particular attention to productivity improvement over the period addressed by this report.

Figure 2.7: Value-added per Employee in Foreign-owned Medical Devices and Instruments Companies (€'000)

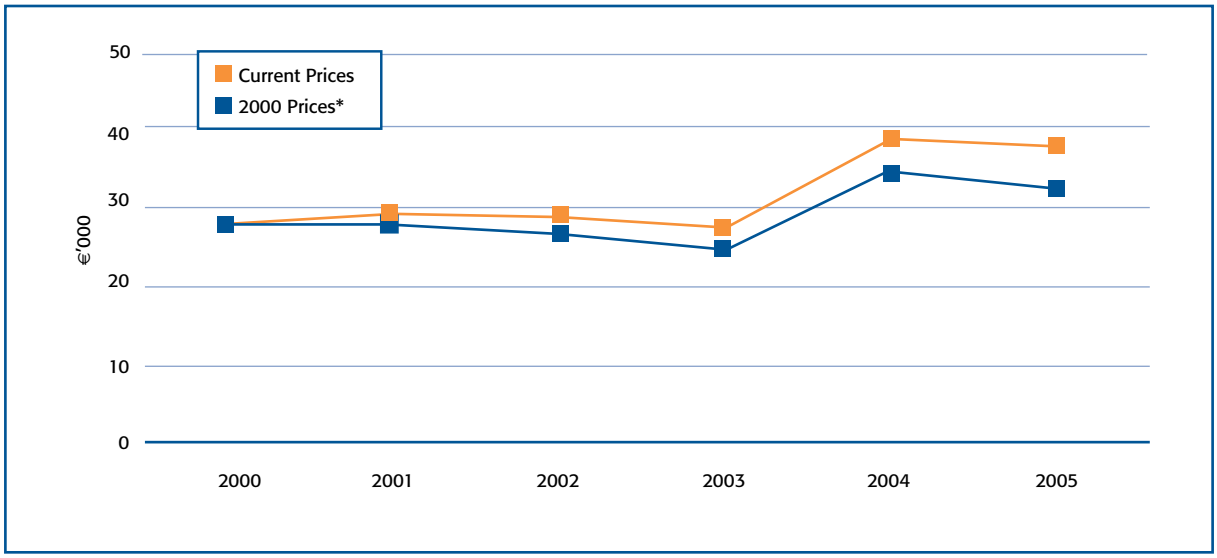


** Deflated by Consumer Price Index.*

Source: Annual Business Survey of Economic Impact, 2005, Forfás.

Value-added per employee has developed more positively for Irish-owned companies since 2000, as can be seen in Figure 2.8. While it has been somewhat volatile, real growth in value-added per employee rose by 2.8% compound per annum between 2000 and 2005.

Figure 2.8: Value-added per Employee in Irish-owned Medical Devices and Instruments Companies (€'000)



** Deflated by Consumer Price Index.*

Source: Annual Business Survey of Economic Impact, 2005, Forfás.

2.6 Regional Distribution of Medical Devices Companies

The main centre of the Irish medical devices sector is around Galway, with almost 40% of employment in the sector being in the West region, and 31% in Galway City and County. As well as being the leading centre of activity by foreign-owned medical devices companies, Galway is also the main centre of activity for indigenous start-ups.

Elsewhere, operations are widely spread across the country, but with just 8.7% of employment being in Dublin and the Mid-East.

A number of major companies have operations in more than one region, apparently partly to ensure that they do not outgrow the capacity of local labour markets to supply their needs.

Figure 2.9: Regional Distribution of Medical Devices Companies

Region	Share of Employment
Border	9.0%
Dublin	3.8%
Mid-East	4.9%
Midlands	10.2%
Mid-West	10.8%
South-East	11.4%
South-West	10.9%
West	39.1%
Total	**100.0%**

Sources: Analysis of Forfás Employment Database.

Figure 2.9 provides data on the regional distribution of medical devices companies.

2.7 Conclusions

The Irish medical devices sector has a strong history of growth. It is predominantly foreign-owned, although the Irish-owned component is growing. It is overwhelmingly an export industry, either directly, or through subsupply to exporting companies.

Value-added in foreign-owned companies has dipped since 2002, which may have been driven by exchange rate trends. Value-added in Irish-owned companies has risen.

The sector's main centre is in Galway, but there are operations in all regions of the country. Activity in Dublin and the Mid-East region is very limited.

Chapter 3: United States/ International Medical Devices Industry Trends

3.1 Introduction

While medical devices industries are present in many countries, the behaviour of the US industry is particularly important to Ireland.

- It is the source of most medical devices inward investment into Ireland, and leads globally in medical devices exports.
- It provides an important model for innovation and entrepreneurship in medical devices.
- The US domestic market is a significant market for both foreign and Irish-owned companies operating in Ireland.

Relevance of Chapter to Skills Analysis

The Irish medical devices sector is primarily an export sector. Most employment in the sector is in the Irish operations of US medical devices companies. Most employment in Irish-owned medical devices companies arises from servicing the needs of US-owned medical devices companies.

These factors make an understanding of US trends critical to any assessment of the sector's future, whether the assessment is focused on skills or on other priorities. Trends in US employment, and in employment by US based companies in international locations, are particularly important to developing an understanding of current and future skills needs of the medical devices sector in Ireland.

3.2 Shipments by US Medical Devices Sector

Figure 3.1 presents data on shipments by each of the main industries that form part of the US medical devices sector, with the following qualifications:

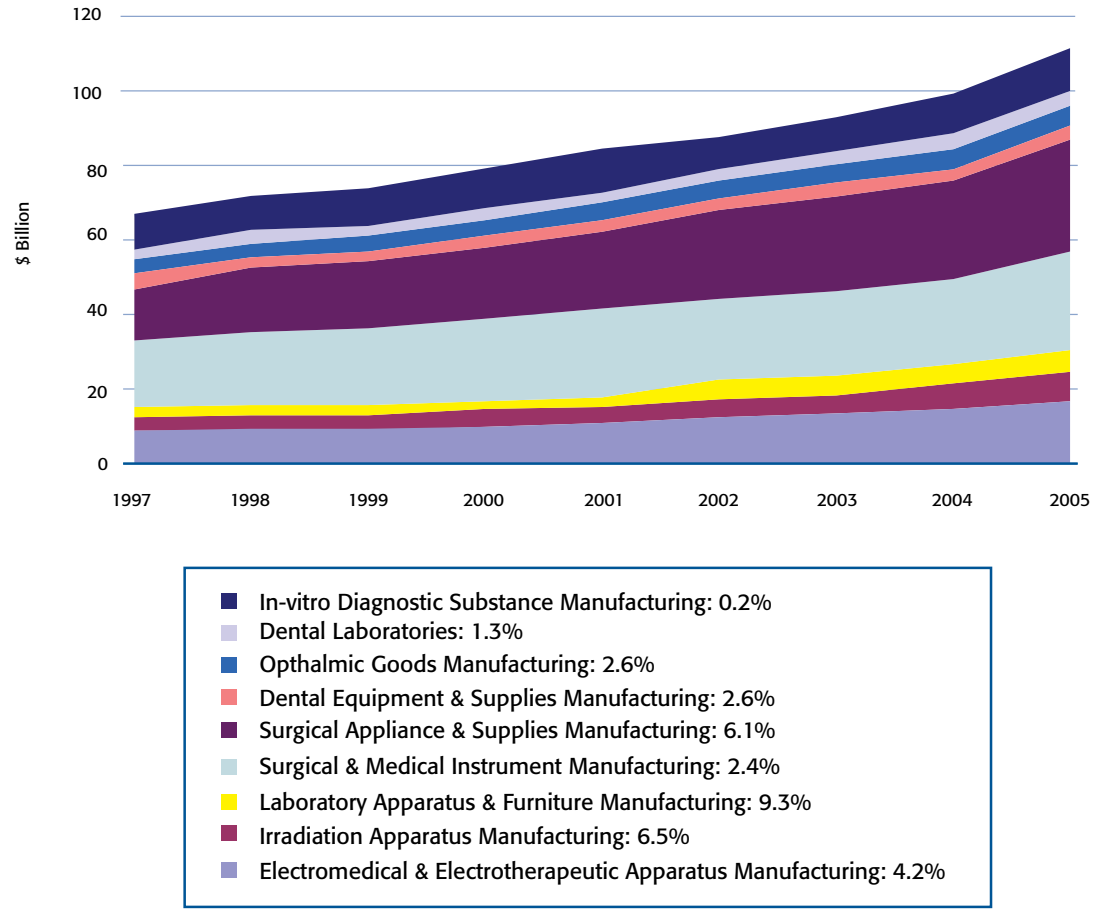
- "Irradiation apparatus manufacturing" encompasses a range of medical and surgical products, including many medical imaging products, but also includes products with non-medical applications in areas such as security imaging; and
- Definitions of the medical devices sector differ as to whether diagnostic products are included. "Diagnostic substances" are frequently encapsulated in a device, as in for example a pregnancy test.

The sector's shipments grew strongly between 1997 and 2005, although the rate of growth varied between industries.

- The value of shipments from "laboratory apparatus and furniture" manufacturing grew by a strong 9.3% per annum compound.

- Shipments from "surgical appliance and supplies manufacturing" also grew strongly, by 6.1% per annum compound.
- Shipments from "irradiation apparatus manufacturing" similarly grew strongly by 6.5% per annum compound, although it seems likely that the growth was boosted by increased sales of security imaging equipment following 9/11, more than by organic growth in demand for medical and surgical imaging equipment.
- Shipments from "electromedical and electrotherapeutic apparatus manufacturing" grew modestly, by 4.2% per annum compound.
- Shipments from other industries grew more slowly, at 2.6% per annum or less.

Figure 3.1: Value of Shipments by US Medical Devices Sector (US$ Billion)



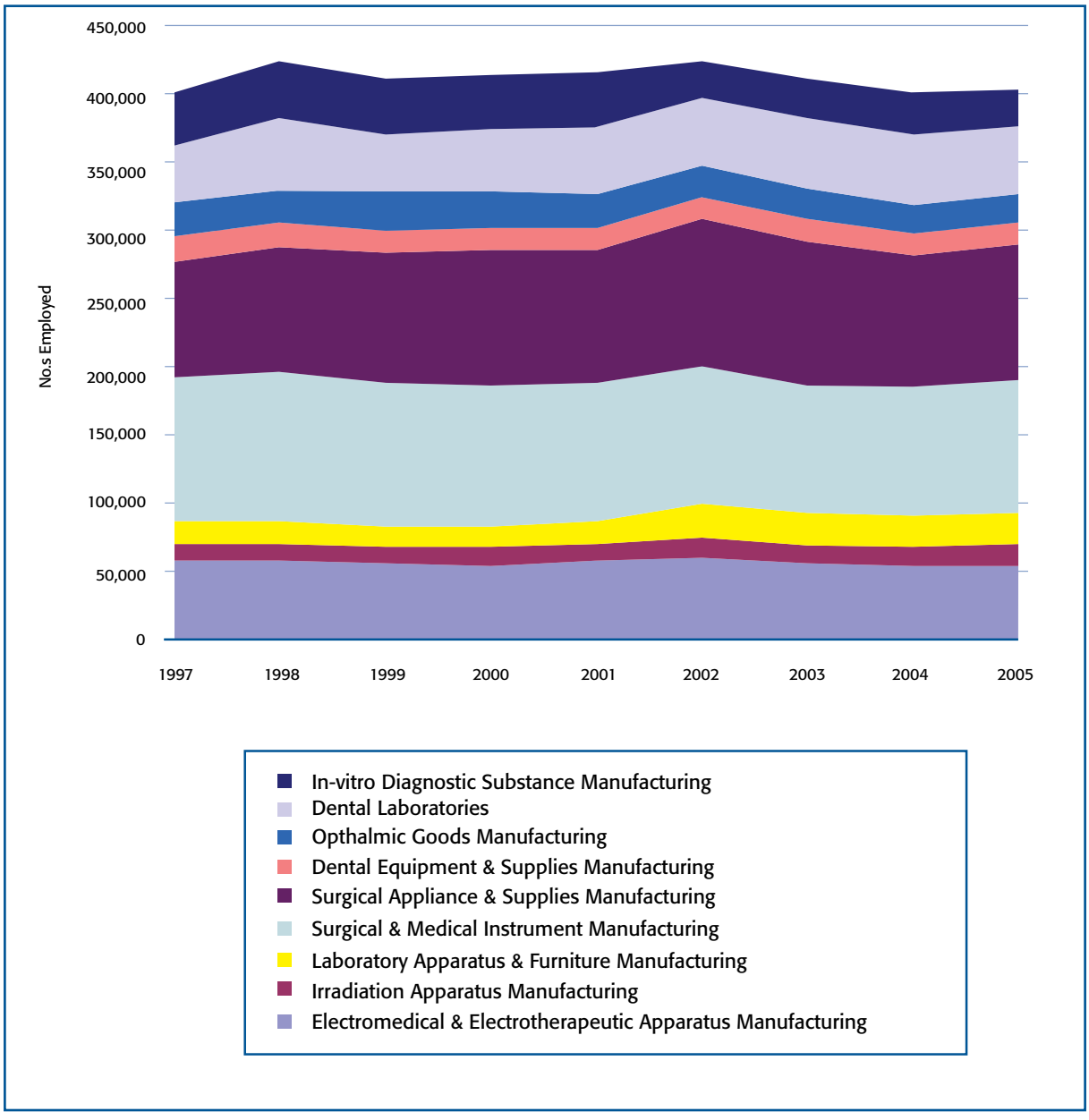
Percentages quoted represent the compound annual rate of growth between 1997 and 2005.

Source: Data from US Annual Survey of Manufactures.

3.3 Employment in US Medical Devices Sector

Figure 3.2 presents data on employment in each of the main industries that form part of the US medical devices sector. Employment in the sector as a whole is approximately flat over time.

Figure 3.2: Employment in US Medical Devices Sector

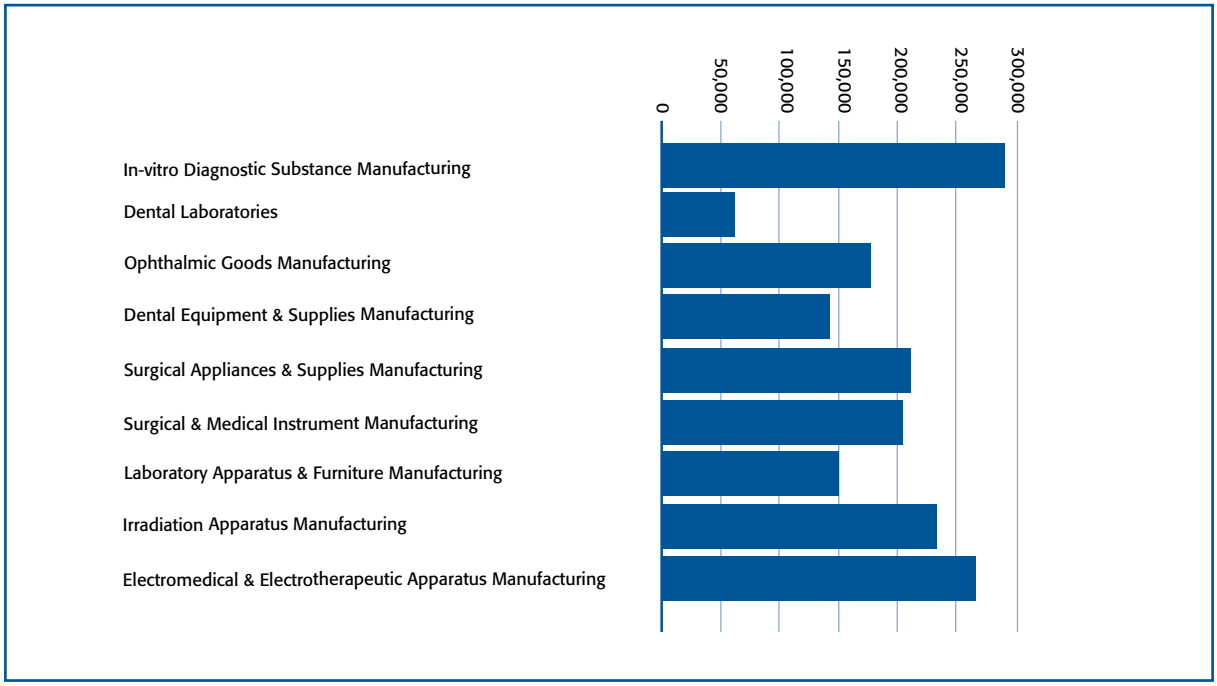


Source: Data from US Annual Survey of Manufactures.

3.4 Value-added per Employee in US Medical Devices Sector

Value-added per employee in the sector varies sharply between industries, being relatively low for dental-related industries, and for "laboratory apparatus manufacturing", as can be seen in Figure 3.3.

Figure 3.3: Value-added per Employee in US Medical Devices Sector (US$)



Source: US Bureau of Labor Statistics.

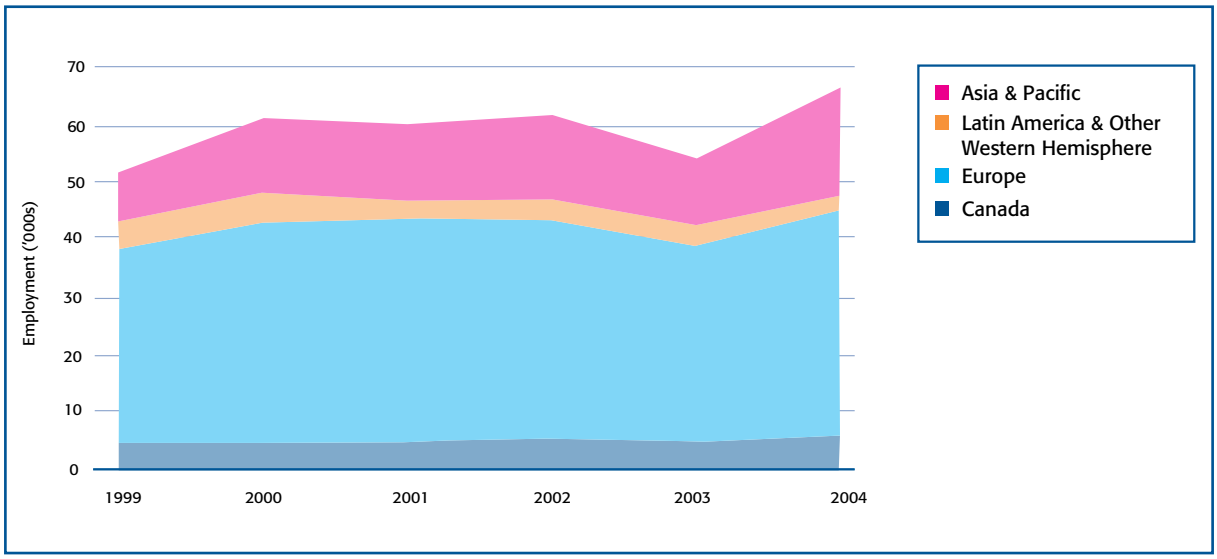
3.5 US Mobile Investment Trends

US medical devices companies have substantial operations in other countries – mainly in Europe, Latin America, Canada and Asia. In contrast with many other manufacturing industries, however, the rate at which manufacturing has migrated to locations with low labour costs has been quite slow.

Figures 3.4 and 3.5 present data on employment in international affiliates in NAICS 33451, which includes Electromedical and Electrotherapeutic Apparatus Manufacturing and Irradiation Apparatus Manufacturing, and NAICS 339, which includes all of the other medical devices sectors with the exception of In-Vitro Diagnostic Substance Manufacturing. As the trends in the data are consistent with qualitative information gathered specifically for the medical devices sector, and as medical devices companies account for a substantial part of the US employment in these NAICS industry codes, it is likely that the trends seen in these Figures broadly reflect medical devices trends.

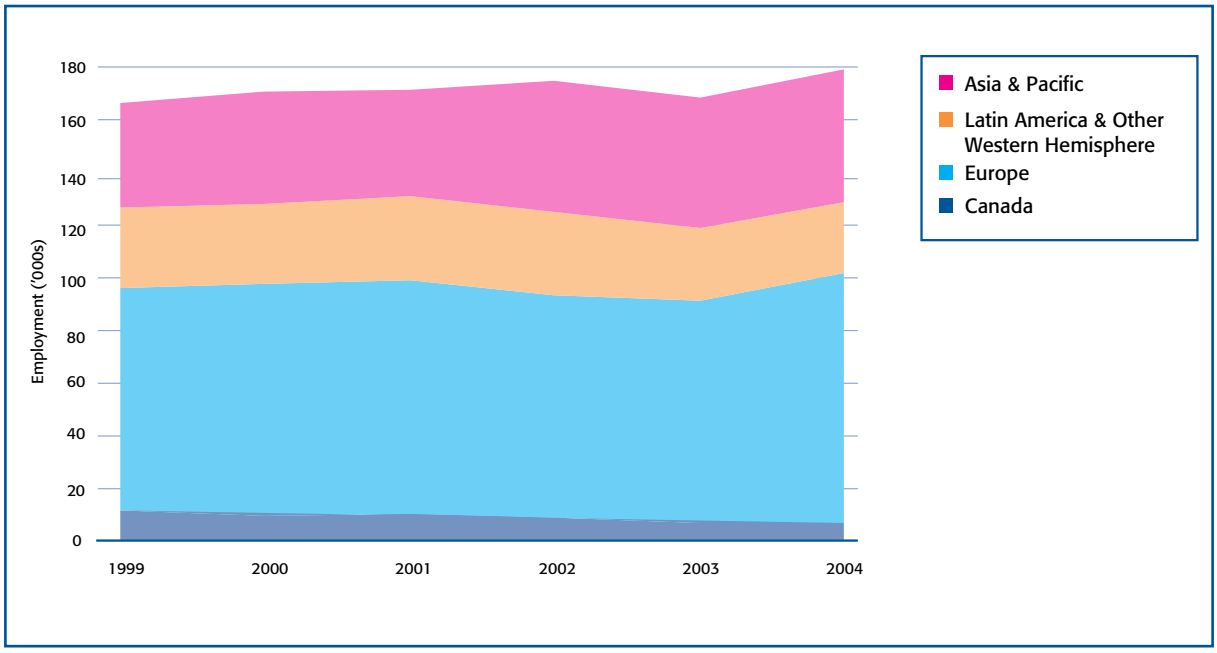
The Figures show employment outside the US in US affiliates growing at a modest rate, with gradual growth in Europe being consistent with continuing growth in the Irish medical devices sector. Growth in Asia has been faster (7.1% compound per annum between 1999 and 2004 for the two NAICS sectors depicted), but is still much less than for many other sectors of manufacturing industry.

Figure 3.4: Employment in Majority Owned Affiliates of US Companies – NAICS 33451 – Navigational, Measuring & Other Instruments ('000s)



Source: Data from US Bureau of Economic Analysis.
Note: Approx. 500 employed in Middle East and 100 in African continent.

Figure 3.5: Employment in Majority Owned Affiliates of US Companies – NAICS 339 – Miscellaneous Manufacturing ('000s)



Source: Data from US Bureau of Economic Analysis.
Note: Approx. 1,600 employed in African continent.

The growth in Asia appears to be partly at the expense of US neighbours, with overall employment in Latin America and Canada falling.

Falling employment in Latin America is significant, as many US medical devices companies have operations in Mexico, many of them supplying components for final assembly and test in the US, Canada or Ireland. It suggests that component manufacture may be more vulnerable than other activities to being moved to Asia. This is consistent with interview evidence that the country of origin is important to underpinning customer confidence in a source of medical devices, with the US, Canada, Ireland and Japan being countries that inspire particular confidence. The stated country of origin of an assembled product is typically determined by the location of final assembly and test, so the location in which components are manufactured is usually not visible to customers.

Issues of confidence drive medical devices companies to locate even manually intensive manufacturing in locations that inspire confidence. A substantial part of US (and Irish) employment in medical devices is still in labour-intensive manual assembly operations. The reputation of a medical devices company and its products can be damaged badly if a problem arises with a product, and the damage can be exacerbated greatly if it is not seen to have manufactured the product in a responsible way. Choices about the location of operations can affect both the reality and the external appearance of manufacturing risks, quite aside from country-of-origin labelling considerations.

Even so, medical devices companies are sensitive to cost. Even within the US, decisions on the location of operations are affected by labour costs, with new manufacturing operations often being established in lower cost regions. And although migration of manufacturing to Asia is relatively slow, it is happening. Companies are working hard on reducing costs, through reorganising supply chains, and through improving their own operations with automation, lean manufacturing and improved quality management.

3.6 Conclusions

While the value of shipments by the US medical devices industry is growing, total US medical devices employment is flat.

Employment is growing in foreign affiliates of US companies, notably in Europe and Asia. The growth in Europe is consistent with the growth seen in the Irish medical devices sector. Up to 2004, at least, the rate of growth in employment of US affiliates in Asia has been quite modest compared to that seen in most other manufacturing industries. This is consistent with the interview evidence which indicated that so far medical devices companies are being cautious about moving to locations with lower labour costs, and are continuing to develop manufacturing operations in developed countries.

Chapter 4: Medical Devices Skills

4.1 Introduction

This chapter profiles medical device industry skills. It starts with a review of occupational data for the Irish and US medical devices sectors. It then examines skills requirements in more detail, focusing on each major stage of the sector's value chain in turn.

Relevance of Chapter to Skills Analysis

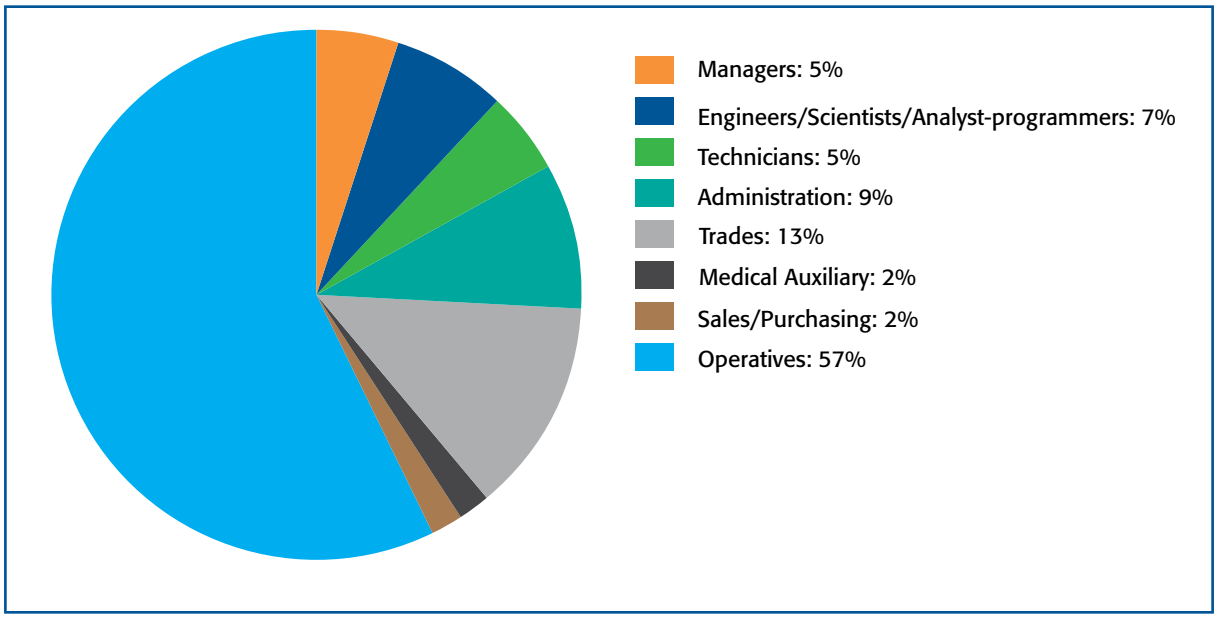
This chapter sets out the description of medical devices sector skills on which the remainder of the report is based.

The chapter provides both statistical information on the skills mix, and a description of the main skills required in the sector. Both types of information on skills are required to underpin the analysis. Statistical information is required to underpin quantitative aspects of the analysis. An understanding of the complexities of skills in the sector is required to underpin qualitative aspects of the analysis.

4.2 Occupational Mix – Irish Sector

Figure 4.1 presents data on the mix of occupations in NACE 33. As the medical devices sector (NACE 331) accounts for approximately 77% of the employment in NACE 33, the occupational mix in this wider sector should well reflect the mix of occupations in medical devices.

Figure 4.1: Mix of Occupations in Ireland in NACE 33



Source: CSO QNHS data provided by SLMRU FÁS[2].

2 *The way in which occupations are grouped in this chart is partly driven by the need to comply with requirements regarding minimum numbers that can be published based on Quarterly National Household Survey data.*

Employment is dominated by manufacturing operations. Operatives and similar roles account for more than half of employment. Technicians and trades such as fitters and electricians, most of whom work in manufacturing, account for almost another 20%. Based on interview evidence, a significant proportion of those medical devices employees classified in national statistics as operatives, are termed technicians by their employers.

Engineers, scientists and computing professionals, who may work in R&D or operations, and who are central to the sector's capability to innovate, account for just 6.7% of employment in NACE 33.

The sector also employs a small but significant number of people in medical auxiliary roles, such as nurses, reflecting companies' contact with clinicians and involvement with clinical trials, as well as their own occupational health needs.

As with other sectors, significant numbers are employed in management, administration sales and purchasing – a total of 16%.

4.3 Occupational Mix – US Sector

The level of precision and detail that is possible in the Irish data is limited by the fact that the data source – the Quarterly National Household Survey is a sample survey that is not designed to produce accurate data on groups that are small in number. For this reason, it is useful also to look at US data for the sector.

Figure 4.2 provides data on the mix of occupations for NAICS 33451 (Navigational, Measuring & Other Instruments, which includes but is not limited to the electromedical/electrotherapeutic and irradiation industries) and for NAICS 3391 (Medical Equipment and Supplies Manufacturing). As most Irish medical devices operations would be classified under NAICS 3391, its occupational mix is the most relevant to the Irish industry.

Figure 4.2: Mix of Occupations in NAICS 33451 and 3391

Occupational Group	% Share in NAICS 33451	% Share in NAICS 3391
Management Occupations	9.55	6.37
Business and Financial Operations Occupations	7.29	3.28
Computer and Mathematical Science Occupations	8.36	1.50
Architecture and Engineering Occupations	23.66	5.70
Life, Physical, and Social Science Occupations	1.36	1.23
Legal Occupations	0.10	0.09
Education, Training, and Library Occupations	0.05	0.00
Arts, Design, Entertainment, Sports, and Media Occupations	0.82	0.57
Healthcare Practitioner and Technical Occupations	0.11	1.20
Healthcare Support Occupations	0.00	0.12
Food Preparation and Serving Related Occupations	0.02	0.03
Building and Grounds Cleaning and Maintenance Occupations	0.39	0.57
Sales and Related Occupations	3.57	3.53
Office and Administrative Support Occupations	11.16	14.10
Construction and Extraction Occupations	0.20	0.08
Installation, Maintenance, and Repair Occupations	3.22	2.20
Production Occupations	28.49	54.01
Transportation and Material Moving Occupations	1.42	5.35
All Occupations	**100**	**100**

Source: Bureau of US Labor Statistics.

Points to note when interpreting the above Figure are that:

- "Architecture and Engineering Occupations" and "Life, Physical and Social Science Occupations" include both professional level and technician occupations;
- "Construction and Extraction Occupations" includes occupations such as electricians that are also commonly present in manufacturing environments; and
- Between them, the "Production Occupations" and "Transportation and Moving Occupations" categories are roughly equivalent to the "Operatives" category in Figure 4.1. Most of those classified as being in "Transportation and Moving Occupations" are involved in movement of materials within the manufacturing plant, although some truck drivers are also included.

At this high-level of classification, the mix of occupations in the US in NAICS 3391 is quite similar to that seen for the Irish sector in Figure 4.1. The most significant difference is that the Irish sector appears to have a somewhat larger share of engineers, scientists, and technicians and computing professionals – 12% in the Irish data versus a total of 8.4% for "Architecture and Engineering", "Life, Physical and Social Science" and "Computer and Mathematical Science" Occupations in the US data. This difference is probably a function of the Irish sector being concentrated in some of the more knowledge intensive medical devices industries, and also of the significant levels of R&D undertaken in Ireland.

Figure 4.3 provides more detailed US data on the key engineering and scientific occupations for NAICS 3391.

Figure 4.3: Employment in Engineering and Scientific Occupations in NAICS 3391 (2006)

Engineering Occupations	No.s Employed	% Total Employment
Biomedical Engineers	2,160*	0.71
Chemical Engineers	100	0.03
Computer Hardware Engineers	50	0.02
Electrical Engineers	410	0.13
Electronics Engineers, Except Computer	130	0.04
Health and Safety Engineers, Except Mining Safety Engineers and Inspectors	70	0.02
Industrial Engineers	4,560	1.49
Materials Engineers	260	0.09
Mechanical Engineers	3,360	1.10
Engineers, All Other	790	0.26
Electrical and Electronics Drafters	50	0.02
Mechanical Drafters	410	0.13
Drafters, All Other	120	0.04
Electrical and Electronic Engineering Technicians	460	0.15
Electro-Mechanical Technicians	270	0.09
Industrial Engineering Technicians	1,670*	0.55
Mechanical Engineering Technicians	840	0.27
Engineering Technicians, Except Drafters, All Other	570*	0.19
Life, Physical, and Social Science Occupations		
Biochemists and Biophysicists	50	0.02
Microbiologists	160	0.05
Biological Scientists, All Other	420*	0.14
Medical Scientists, Except Epidemiologists	320	0.10
Chemists	480	0.16
Materials Scientists	50**	0.02
Market Research Analysts	870	0.28
Social Scientists and Related Workers, All Other	80	0.03
Biological Technicians	170	0.06
Chemical Technicians	450	0.15
Environmental Science and Protection Technicians, Including Health	30	0.01
Life, Physical, and Social Science Technicians, All Other	90	0.03

** Data for 2005 (not available for 2006).* *** Data for 2004 (not available for 2005 or 2006).*

Source: US Bureau of Labor Statistics.

Some key points to note are:

- The absolute number of engineers and scientists employed in medical devices in the US is small compared to many other technology industries;
- While biological scientists, chemists, biological technicians and chemical technicians are present in the sector, they are heavily outnumbered by engineers and engineering technicians;
- The sector employs more mechanical engineers than biomedical engineers, which probably reflects the fact that strong mechanical engineering design is very important to the sector. There is considerable overlap between the two disciplines, making graduates in either of these disciplines good candidates for many engineering roles. Strong mechanical engineering design skills are important to the sector;
- The sector has relatively large numbers of industrial engineers, reflecting its strong manufacturing focus; and
- The number of specialist materials engineers is low, despite the importance of specialist biocompatible materials in the sector, and the number of materials scientists is much lower again.

4.4 Skills and the Medical Devices Value Chain

4.4.1 Introduction

This section outlines the main elements of the medical devices value chain, and describes the main areas of skill in each.

4.4.2 Medical Device Innovation

Classical Innovation Process

Traditionally, most medical device innovation comes from interaction between clinicians and engineers. It is based on the sound application of existing mechanical or electronic engineering technologies – often mature technologies – to clinical problems[3].

Most medical devices start with a clinical insight, that a new or modified device might allow clinicians to achieve:

- Better clinical outcomes;
- Reduced costs, often through less time in theatre or shortened patient stays; or
- Greater patient comfort.

3 *Bio-compatible materials, and the challenges of making devices thin or small, with the right mechanical properties, make materials science and materials engineering important to medical devices innovation. However, the statistical evidence (seen earlier) is that this does not result in large numbers of materials scientists and engineers being employed. In many cases, mechanical and biomedical engineers know enough materials science to be able to innovate effectively, particularly when they have access to expert advice and support from materials suppliers and from specialist engineering consultancy services.*

The more fundamental innovations typically come from leading **clinicians** seeking to innovate in clinical practice, which may or may not be in the context of formal research activity.

More incremental innovations may be initiated by clinicians, or by **engineers** seeking improved engineering solutions. Engineers still rely on the clinical insights of leading clinicians to validate their ideas. The main engineering disciplines for medical devices innovation are mechanical, electronic and biomedical. Biomedical engineering combines mechanical (sometimes electronic) engineering with biomedical sciences and biocompatible materials science.

The innovation process typically goes through a succession of prototypes, leading to the production of functioning prototypes that can be used in clinical trials. The prototypes are typically produced by highly skilled **technicians**.

In addition to clinical and engineering skills, innovators must have a good understanding of **regulatory affairs**, as they impact on innovation, or at very least, access to good regulatory affairs advice.

Skills that allow innovators to assess market opportunities are also important, including **market analytic** and **strategic skills** similar to those required in many other industries, to allow innovators to assess the size and viability of markets, and to develop sound business strategies.

Access to good expertise in **healthcare economics** and **reimbursement** is also important, as even a good product will only be successful if healthcare providers can get the costs of using it reimbursed at an economic level by healthcare funders. Companies targeting the US market often decide whether or not to proceed with a device on the basis of whether they expect it to be reimbursable at an economic level by Medicare and Medicaid, the major government sources of reimbursement. These account for a large part of the market in their own right, and their decisions on reimbursement are frequently reflected by private healthcare insurers.

Other skills to which innovating companies need access are in:

- Professional skills in **intellectual property**;
- Skills relating to **funding**, including specialist medical devices skills among **venture capital firms**, and among **law firms** advising medical devices companies engaged in fundraising; and
- Capability to efficiently identify **and introduce innovators to the right partners** that they need at each stage in innovation. A wide range of experts consulted in the US study visits highlighted capabilities in this area as critical to the success of new medical devices businesses, and highlighted the strong web of relationships required to facilitate it as a key factor determining the success of any region in building and retaining an innovative medical devices industry.

Depending on the innovator's own engineering skills, and on the specific character of the device under development, access to first class **contract engineering and prototyping services** can be important.

Innovation and Convergence

Technological convergence is increasingly bringing biologically active substances into the medical device sector's products, both small molecule substances and the large molecule, and even cellular, products of biotechnology. This trend is making skills in **biological sciences, chemistry and pharmacology** increasingly important to innovation in medical devices, alongside the clinical and engineering skills that have traditionally dominated innovation.

Technological convergence is also bringing new patterns of innovation to the fore. Fundamental medical device innovations have traditionally started from a clinical insight, partly because mechanical engineering technology, and significant parts of electronic engineering technology, are relatively mature.

However, when technologies are changing rapidly, this can inspire innovations in products in which they are used. Rapid developments in **biotechnology**, and areas of **electronic engineering** technology such as sensors and telemetry, are creating opportunities for technology-led innovation in medical devices that did not exist before. Clinical insight remains core to the innovation process, but it will not always be the starting point for major innovations into the future.

One consequence is that formal research leading to the development of platform technologies with a range of possible applications is likely to become more important to medical devices innovation. The traditional approach to medical devices innovation focuses tightly on developing a solution to a specific clinical problem, usually with a belief that there is a fairly high probability that a working solution can be developed. With less mature technologies, it is typically much less certain that the outcome of an R&D effort will solve any single specific problem. It is necessary that the effort try to produce a platform technology with a slate of possible applications, to maximise the likelihood that at least one will work.

Innovation in Diagnostics

Traditionally, innovation skills in diagnostics have differed from those in other medical devices industries, being primarily about high-level **biological sciences** skills, supported by **technician** level skills. Skills in regulatory affairs, marketing, healthcare economics and reimbursement are as important as in other medical devices industries, as are skills in intellectual property, funding and identifying partners.

However, convergence is bringing **engineering** skills into diagnostics innovation. Traditional diagnostic kits requiring limited engineering innovation will continue to form a major part of the diagnostics industry, but products combining biological components with electronics and ICT components are rapidly becoming significant[4].

4.4.3 Clinical Trials

In order to confirm their effectiveness and safety, medical devices undergo clinical trials before they are brought to market.

Two main medical devices regulatory systems are important to the sector – those of the US Food and Drug Administration (FDA) and the European Union. On the whole, clinical trials requirements that they impose for medical devices are much more limited than those for pharmaceuticals, allowing medical devices to be brought to market more quickly than drugs, and at much lower cost.

The extent of the regulatory requirement for clinical trials varies depending on factors such as, for example, the risks in normal use, how invasive the product is, how long it will be in contact with the patient and whether it is life-supporting or life-sustaining.

4 *One key emerging area is that of diagnostic arrays capable of undertaking large numbers of diagnostic tests on a single sample simultaneously. These arrays are devices similar to electronic integrated circuits, featuring an array of many cells, each containing a different biological analytic substance to undertake a different test. A key emerging application is in genetic analysis, to assist in diagnosing genetically-influenced diseases, or to facilitate personalised medicine. Personalised medicine will respond to a person's individual genetic profile by identifying individuals at elevated risk of specific diseases, and by guiding clinicians as to what treatments will be most effective given a person's individual genetic make-up. In many cases, for example, the effectiveness of a pharmaceutical in treating a condition varies depending on the individual's genetic make-up.*

It can also depend on the extent to which the product is similar to other devices already in use. The US FDA's 510K approval process allows medical devices deemed substantially similar to those already in use to be approved with a greatly reduced requirement for trials. Interviewees suggest that the majority of new devices requiring approval are approved for US use under this process.

A pharmaceutical component to a device generally increases the extent of the requirement for clinical trials substantially, even though the drug has typically already been approved for other applications. If the drug is deemed to be the main component of the device, or if it has not been approved for other purposes, this can cause the product to be classified as pharmaceutical for regulatory purposes, greatly increasing the clinical trials requirement.

Clinical trials require skills in the following main areas:

- The clinicians that have contributed to bringing a new medical device to the level of a trialable product have a critical role to play in clinical trials. They often carry out the first trials themselves, and their confidence in the device is important to recruiting other clinicians to take part later trial phases. They may also take a wider role in a clinical trial, for example in training other clinicians to use the device clinically;
- Skills in design and management of clinical trials are required to produce reliable evidence that meets regulatory requirements;
- The conduct of clinical trials is regulated, and regulatory affairs skills are required to ensure and demonstrate compliance; and
- Front line skills in conducting clinical trials are required.

Internationally, many clinical trials specialists come from nursing backgrounds, after taking further qualifications in the design, management and conduct of clinical trials.

4.4.4 Production

Biomechanical and Bioelectronic Devices

There is considerable diversity among medical devices production processes.

Common machine processes include, among others:

- Injection moulding of polymers;
- Extrusion of polymers;
- Drawing of wires;
- Braiding of wires;
- A wide range of coating processes;
- Automated assembly of electronic components; and
- Heat sealing of polymers.

While production of some medical devices products is heavily automated, many devices are assembled, tested and packaged manually.

This diversity means that there are considerable variations in the mix of skills required between different medical devices production operations.

Key occupational areas involved in day-to-day operations include the following.

- **Manual Assembly Operative**s – Manual assembly operatives account for a substantial share of medical devices production employment in Ireland and the US. The main skills required are manual dexterity, the ability to conscientiously comply with formal working procedures, sufficient awareness to identify visible problems with components and assemblies, and the flexibility to move between assembling different products. They are typically qualified to Leaving Certificate level or equivalent, and may have taken a medical devices qualification at Level 5 in the National Framework of Qualifications.
- **Machine Operator**s (sometimes termed "technicians", depending on the company and on their level of responsibility) – Machine operators operate machines, loading raw materials, watching for problems, and in many cases setting the machine up and undertaking basic troubleshooting and maintenance. Skill requirements are generally increasing over time, as operators take more responsibility in areas such as troubleshooting, maintenance and quality assurance. They are typically qualified to Leaving Certificate level or equivalent, and may have taken a medical devices qualification at Level 5 in the National Framework of Qualifications.
- **Technicians** – Technicians working in production can have a wide variety of roles, in areas such as toolmaking, machine set-up, troubleshooting, maintenance, monitoring the operation of automated systems, and technical testing for quality assurance. They are typically qualified to around Level 6 (Craft Certificate or Higher Certificate) or Level 7 (Ordinary Bachelor Degree or (legacy qualification) National Diploma) in the National Framework of Qualifications, or have technical training or qualifications of some other sort. Some are qualified to a higher level.
- **Quality Control and Quality Assurance Staff** – Depending on the level of automation, manual and visual inspection can play a major role in medical devices quality control. These roles are often filled by very experienced operatives and operators, typically with additional training in quality control, quality assurance and sometimes quality improvement.
- **Operations Managers and Supervisors** – These roles are similar to those in other industries, except that they need strong skills relating to operating in a highly regulated environment.

A number of roles concerned with the design, improvement and management of production processes are also important in the sector, including the following:

- **Production Engineers/Industrial Engineers/Automation Engineers/High-level Technicians** – These are engineering roles concerned primarily with bringing products into production, with optimising production processes, with keeping production processes in control, and with technical troubleshooting beyond the comfort zone of those concerned with day-to-day operations. They are mostly undertaken by people with Honours Bachelor or masters degrees in engineering disciplines such as production engineering, manufacturing engineering, mechatronic engineering or mechanical engineering. Highly skilled technicians, typically with qualifications around Level 7 in the National Framework of Qualifications also have a significant role in this.

- **Process Design Engineers** – Process design engineers play a critical role where companies are designing automated production systems, particularly where the automation is end-to-end rather than in islands connected by manual operations. This is increasingly important as companies automate to increase efficiency and improve quality. They are distinguished from other engineering roles here because the core of these roles is about process design rather than incremental improvement, and because this has been identified as an area of skill that is particularly important to the future viability of the sector in Ireland or any other high cost location.
- **Validation Engineers** – The medical devices sector employs significant numbers of validation engineers to validate the compliance of production processes with the specifications that have been approved by, or notified to, regulators. These typically have an Honours Bachelor Degree in a relevant engineering or science discipline. The role is traditionally paperwork intensive, but the increasing incidence of complex automated production systems is making it more technically challenging in many cases.
- **Regulatory Affairs** – Regulatory affairs staff track compliance of operations with regulatory requirements, advise other staff on regulatory matters, report on compliance and manage relationships with regulatory authorities.

Bio-convergence Devices and Diagnostics

Where devices include significant biologically active components, companies employ scientists, science technicians and processing operatives with skills similar to those of the small molecule pharmaceutical or bio-pharmaceutical industries. They undertake roles parallel to those of engineers, technicians and machine operators in manufacturing biomechanical and bioelectronic devices.

Qualifications of scientists are generally between primary degree and PhD level. The term “technician” can cover a wide range of levels of skill and qualification, and can encompass process operative-type roles. Qualifications can range from a certificate at the equivalent of around Level 6 in the National Framework of Qualifications up to masters level (Level 9) for very highly skilled roles.

The trend is for operative level workers to have specialist qualifications, whether obtained full-time in a training scheme or in college, or part-time after recruitment through certified training sourced by their employer.

In diagnostics, technicians are generally qualified to at least Level 6 in the National Framework of Qualifications in an appropriate discipline.

Where the biologically active material plays an significant active role in the product, it can be necessary for regulatory affairs staff to be expert in pharmaceutical regulation, as well as medical devices regulation.

4.4.5 Sales and Marketing

The main markets for most medical devices are with healthcare providers. For the high added value parts of the sector that are of most relevance to Ireland, the key influencers in these markets are leading clinicians.

The most important initial steps in bringing a new device to market are as follows.

- It is necessary to convince thought leaders in the specialism or subspecialism that will use the device that it presents an opportunity to significantly improve clinical outcomes, reduce costs or improve patient comfort for at least some group of patients. The number of thought leaders in any subspecialism is typically small, and if the benefit to changing is clear-cut and significant, a switch in practice can happen quite quickly.
- It is necessary to establish a reimbursement framework for the device and associated procedures that will allow healthcare providers to benefit (or at least not suffer) financially from adopting it. This is simplest where the innovation saves money (e.g. by reducing the incidence of complications or shortening the duration of a procedure) while fitting within an existing reimbursement category[5], but it can involve seeking agreement for higher levels of reimbursement where the product enables better patient outcomes.

The key players in achieving these steps are:

- The **clinicians** involved in the development of the product, and those who have been involved in clinical trials; and
- **Healthcare economists**, who have a leading role in establishing the benefits of a device quantitatively, and communicating these benefits to healthcare providers, health insurers and other reimbursement organisations.

As the product is brought to market, the role of the sales organisation is central. Indeed, the economics of selling do much to shape the structure of medical device industries, favouring companies that focus on particular clinical specialisms, with broad portfolios of products targeted on those specialisms.

An established company launching a new medical device typically has a sales force that has established relationships with clinicians and healthcare organisations involved in the specialism for which the device is intended. Individual **sales people** have good access to decision-makers.

As in other industries where selling processes are relationship-based, **sales managers** have a key role in directing and developing sales people.

Entrepreneurial companies established bring a new product to market generally either:

- Recruit established sales people, to take advantage of their access to decision-makers; or
- Leverage existing sales forces by partnering with an existing company or (only feasible in some specialisms) working with a distributor.

There is a trend underway to establish training services to train clinicians in innovative procedures that rely on new medical devices. This is partly driven by regulatory requirements. Some major companies have established training centres, with skills much like those in hospitals, and with the involvement of clinicians in providing training.

5 *In the US, reimbursement is generally structured by Diagnosis-Related Group (DRG). Insurers and other funders agree to pay healthcare providers a flat amount for each case according to the DRG under which it has been classified, giving them a clear incentive to reduce costs.*

4.5 Conclusions

Employment in the medical devices sector in Ireland is dominated by manufacturing operations, and operatives account for more than half of all employment. There are also significant R&D operations in Ireland.

The sector also employs technicians, some working in R&D, and the majority in production. The term technician tends be used in a way that includes anyone with significant hands-on technical skills, encompassing graduates of courses in engineering at Level 6 and 7, but also those with trade qualifications and those with other technical training or qualifications. In the diagnostics sector, technicians are generally qualified to at least Level 6 in an appropriate discipline.

Engineers play a major role in the sector, in areas including working with clinicians to develop medical devices solutions to clinical problems, and a wide range of roles in production, including manufacturing engineering, design of automated processes and validation engineering.

Reflecting the highly regulated nature of the sector, it is important for employees at all levels to have an appropriate understanding of regulatory affairs. There are also specialist regulatory affairs professionals.

Other areas of skills that are important to the sector include:

- Sales management and marketing;
- Clinical trials management; and
- Healthcare economists/reimbursement experts.

Biological scientists and pharmacologists/chemists, along with bio- and pharma-technicians and bio- and pharma processing operatives play a significant role in parts of the sector, and their presence is likely to grow as medical devices and biosciences technologies increasingly converge.

Chapter 5: Major Trends in the Medical Devices Space

5.1 Introduction

This chapter starts by outlining how medical devices can be analysed and disaggregated in a number of different ways, by clinical specialism, type of product, type of company or by technology.

It goes on to look at trends in the sector under three headings:

- Cross-cutting trends that affect many parts of the sector simultaneously;
- The major trend of technology convergence, under which different technologies are increasingly coming together within medical devices; and
- Trends that are specific to the Irish medical devices sector.

Relevance of Chapter to Skills Analysis

Innovation plays a major role in the medical devices sector. The direction of that innovation, and the mechanisms behind it, both have major implications for skills requirements. Trends in the technologies used in medical devices will affect the engineering and scientific skills required to develop and produce new products. The balance between product development and production work in the sector will affect the share of employment accounted for by people with scientific and engineering qualifications, and the level of those qualifications.

A greater focus on product development will boost demand for complementary skills in areas such as regulatory affairs and intellectual property.

Existing trends in education and training affect the supply of skills, and the way in which they are upgraded and updated over time, and also form an important part of the context to new measures that might be taken to improve skills for the sector.

5.2 Medical Devices Space

The medical devices space is a complex one, with several important dimensions. For this reason, different ways of analysing the sector can be relevant under different circumstances.

- The **market** for medical devices is primarily structured by **clinical specialism**. Typically, established medical devices product companies focus on particular specialisms, building portfolios of products, often based on diverse technologies that meet the needs of those specialisms.
- The sector produces a **range of general types of product**, including for example (not a complete list) implants, delivery systems for implants, instruments, imaging products, hospital supplies and diagnostic products.

- There are several main **types of company**, including:
  - Established product companies, typically with a portfolio of products marketed to particular specialisms;
  - Start-up product companies, typically bringing a new product to address a specific clinical need to market; and
  - Subsupply and services companies, that provide product companies with components, contract manufacturing services, and other services in areas such as testing, engineering consultancy and product development.
- The sector uses a wide range of different **technologies**.
  - At a high-level of aggregation, these technologies can mostly be classified under the following areas: mechanical engineering; electronic engineering; materials science; and increasingly biological sciences and pharmacology/chemistry. There is often a substantial software content to devices involving electronic engineering, and there can be substantial software-based modelling associated with mechanical engineering technologies.
  - At a lower levels of aggregation, a great variety of technologies is used. Examples of mechanical engineering technologies commonly used in the sector include injection moulding, polymer extrusion, drawing of wires, braiding of wires, coating and textile technologies among others.

5.3 Cross-cutting Trends

5.3.1 Introduction

New developments in medical devices are generally targeted on one of more of the following:

- Achieving better health outcomes for patients;
- Lower cost; and/or
- Greater patient comfort.

A number of trends cut across industry's pursuit of these goals.

5.3.2 Increasing use of Minimally Invasive and Non-invasive Techniques

Clinical practice increasingly favours interventions that do a minimum of damage during surgery, or even avoid surgery.

Minimally invasive surgery can improve the health outcomes for patients. It can also greatly reduce the cost of treatment, by reducing time in surgery, steeply reducing the recovery period during which the patient has to remain in hospital, and reducing the risk of complications that will extend time in surgery and recovery time. With much smaller incisions, it can greatly improve patient comfort.

Devices for minimally invasive surgery – particularly cardiac surgery – form a large part of the Irish medical devices sector's output.

Innovation in this area continues, with surgeons progressively expanding the range of conditions that can be operated upon minimally invasively, often working with medical devices companies to develop new devices to enable this.

Exactly the same drivers also favour non-invasive techniques replacing traditional and minimally invasive techniques. For example, if it becomes possible for a condition to be treated safely and effectively with pharmaceuticals, this in turn may replace minimally invasive surgery for that condition.

The benefits of new minimally invasive and non-invasive techniques can be so great that they drive quite rapid adoption, causing older techniques, and the medical devices they use, to be discontinued over a short period of time.

5.3.3 Data Collection and Responsive Devices

The medical devices industry is early in the process of creating implantable devices that collect, record and transmit data about:

- Their own operation; and
- Measurements made on the body using integrated sensors.

Improved external diagnostic devices, in areas such as imaging, are also rapidly increasing the volume of data available. Healthcare information systems are improving how the data is handled and made available to clinicians.

The industry is also early in the process of creating implantable devices that can respond:

- Directly to measurements they have made on the body; and
- New instructions or reprogramming transmitted from outside the body.

The large amount of additional data that these developments will make available should enable physicians to improve the quality of treatment, driving better health outcomes, which should in turn lower costs and improve patient comfort. By providing early warning of imminent problems, it may allow health crises to be avoided with limited intervention, again improving outcomes and reducing costs.

Some devices will perform better if they respond appropriately to measurements of factors such as variations in the heart rate.

The capability to modify the behaviour of an implanted device without the need for new surgery will reduce the need to replace existing implants, and will allow the performance of implants to be adjusted more easily in line with clinical indications. This applies both to devices that are primarily bio-mechanical and bio-electronic in nature, and also to devices in which a biologically active component is important, such as in drug delivery implants.

Again, this should lead to better health outcomes and lower costs.

5.3.4 Better Fit

Better and more available imaging technology, and modelling software, are together improving capability to fit implants to the body dimensions of individual patients.

5.3.5 Personalised Medicine

Personalised medicine – medicine tailored to the individual's genome – is gradually making an impact in healthcare:

- In many cases, the risk of developing a condition is linked to genetic factors; and
- In many cases, genetic factors influence the effectiveness of a pharmaceutical in treating a condition, and potentially also the pharmaceutical's toxicity.

There is an expectation that, as tools for analysis of the individual genome improve, it will become increasingly possible to personalise medicine, based on individual genomic analysis. This is expected to greatly improve patient outcomes, by:

- Treating people at elevated risk of a condition; and
- Choosing pharmaceuticals with a very much greater certainty that they will be effective and not excessively toxic.

This is directly relevant to the medical devices sector, as much of the genomic analysis will be done using diagnostic devices. While the overall diagnostics industry has grown relatively slowly in recent years, personalised medicine has the potential to boost its growth. Interviews in the study visit to California highlighted the emergence of companies producing diagnostic arrays to analyse samples for large numbers of genetic variations at once. Aside from the development and production skills involved, they highlighted an emerging need to employ significant numbers of medical laboratory scientists and technicians to undertake the tests as a service for healthcare providers.

Personalised medicine is also likely to be relevant to the development of drug delivery devices into the future. They also contribute to maximising pharmaceutical effectiveness while limiting toxicity by delivering the drug where it is needed, when it is needed.

5.3.6 Integrated Therapy Providers

Most established medical devices companies focus on one or more medical or surgical specialisms, providing a portfolio of products to meet the needs of each. Companies try to provide a range of products that meets the needs of each specialism as fully as possible.

While the origins of the sector are in providing clinicians with the tools and appliances they need, medical devices innovation is increasingly intertwined with clinical innovation. Significant medical devices innovations are designed to provide the equipment to exploit significant new clinical insights. In some cases, the innovation in clinical practice is sufficiently fundamental to revolutionise the treatment of a specific ailment.

In these cases, medical devices companies increasingly seek to provide an integrated package of products and services, including:

- The new medical device or devices;
- Training for clinicians; and
- Complementary equipment and supplies.

5.3.7 Geographic Differentiation in Medical Devices Operations

As in many other industry sectors, there is an increasing tendency to establish production operations in locations with low pay costs and good labour availability, while locating key corporate roles and roles relating to innovation in higher cost areas with an established base of expertise, which are often more attractive to high skilled professionals. In the US, while California, Massachusetts and Minnesota are recognised as the industry's leading centres, much of the sector's employment is in production operations in lower cost areas such as Indiana, Utah or Puerto Rico. Even within the leading states, there is a tendency to locate labour intensive production operations in areas where they can access relatively low cost labour, while locating higher skilled work in higher cost areas.

5.3.8 Commoditisation of Medical Devices

Many of those interviewed for this study felt that it was likely that medical devices would continue to be high added value products, with continuing innovation renewing the capability of the sector to operate in high labour cost locations, and with brands and country of origin labelling continuing to be of great importance in the market.

Others, however, talked about commoditisation, with competition from low cost producers increasing, and progressively less premium being placed on brands and countries of origin of products. They suggested that this would transform the industry over time. Manufacturing, engineering and innovation in medical devices would migrate to locations such as India and China, taking advantage of what would become a strong supply of skills and of easy access to the clinicians serving a large population.

It is too early to say how big a threat commoditisation poses to the Irish medical devices industry.

5.4 Technology Convergence

One of the key trends affecting the medical devices sector is that of technological convergence. Historically, mechanical devices have accounted for the largest part of the medical devices sector, with devices based on electronics and information technology accounting for the next largest part. Biological and pharmaceutical technologies have historically featured mainly in diagnostics.

However, the areas of overlap between technologies have been growing. The following are some examples of convergence:

- While coatings designed to retard infection have long been a feature of mechanical and electronic implants, coatings designed to release drugs have moved into the mainstream, particularly with drug eluting stents[6];
- More complex devices, based on electronic and mechanical engineering, are being integrated with biotechnology products in diagnostic devices such as diagnostic arrays;
- Drug delivery devices are bringing mechanical and electronic technologies together with pharmaceutical and biosciences technologies in the same device;
- Many therapies based on the delivery of cells, such as stem cell treatments, will require specialist delivery devices;

6 *A stent is a tubular device that is inserted into a vessel in the body to prevent or treat a flow constriction. The most common use is in coronary arteries, although versions are also used in the peripheral vascular system, in the urinary tract and in other vessels. Drug eluting stents have a polymer coating diffused with a drug intended to counteract restenosis – the return of the constriction despite the presence of the stent.*

- There is considerable work being done at the interface between mechanical and materials engineering, and biosciences, in developing materials and devices that will support tissue regrowth, such as bone scaffolds and products that facilitate the regrowth of epithelial layers;
- Innovations in sensors and telemetry will increasingly allow devices to be more responsive to conditions in the body, whether the main features of the underlying device are primarily mechanical, electronic or biological in nature; and
- Imaging technologies, which are primarily based on electronic technologies, are increasingly frequently being used with other device technologies, for example to assist in guiding minimally invasive surgery, or to assist in choosing the best fit from a range of orthopaedic implants.

Figure 5.1 maps out the main broad technological areas within the international medical devices industry. It highlights the fact that the main technologies in the sector at present are mechanical, with electronic/IT technologies also being important, and with biologically active substances being core to diagnostic kits. It highlights the fact that some convergence products already exist, bringing together two or even three of mechanical, electronic and biosciences technologies, but that considerable growth is expected in these convergence areas into the future.

The Figure illustrates the importance of materials science as an important existing cross-cutting technology, and nanotechnology as an important emerging cross-cutting technology. Some applications of nanotechnology are already present in the sector, in areas such as coatings, and the likelihood is that they will become more significant over time. Indeed, many of the applications commonly quoted in the foresight literature for nanotechnology are directly relevant to medical devices, with drug delivery devices, biosensors, biotelemetry devices, repair nanobots, and biocompatible and biofunctional nanocoatings featuring prominently.

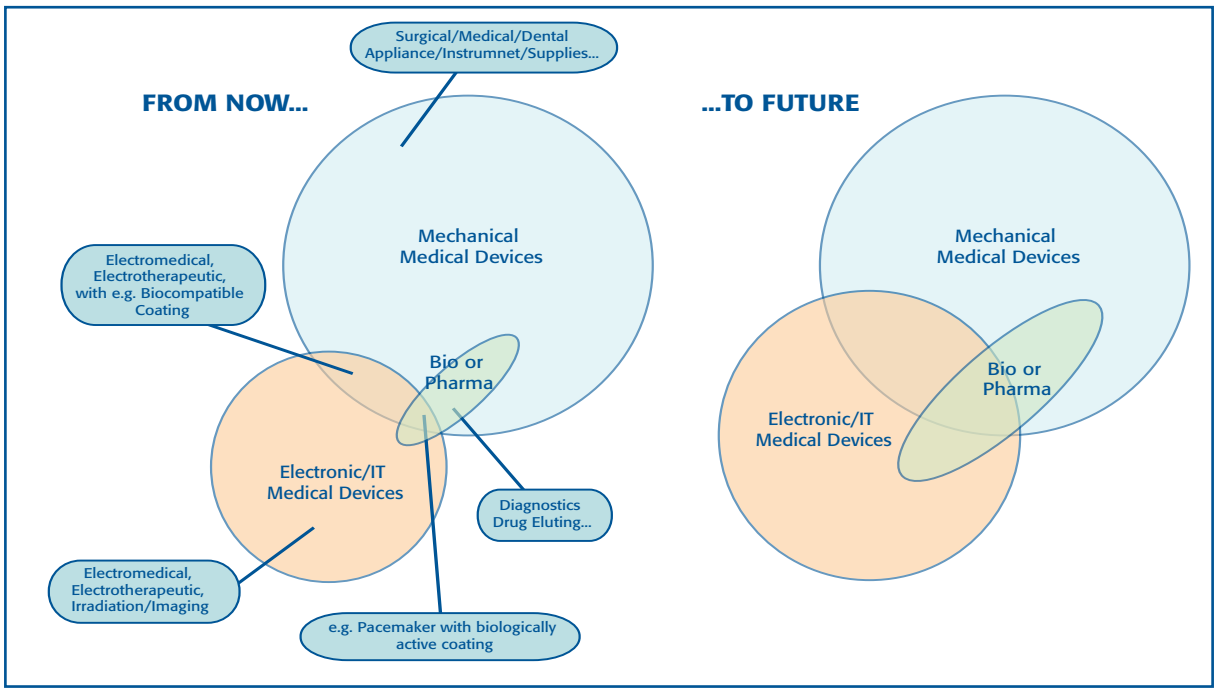
Figure 5.1: Technology Convergence in Medical Devices Industry

Materials science, nanomaterials, nanotech are cross-cutting technologies	Not biologically active	Biologically active component to enhance physical device	Balanced combination	Physical device to enable use of biologically active substance	Biologically active substance – no physical device
Mechanical device	Largest part of existing sector globally	Some existing – key emerging area	Likely to eventually be important Part of Med Devices	Drug Delivery, Test Arrays Emerging Diagnostic kits well established Part of Med Devices	Mainstream Pharma and Biotech Sectors Not Part of Med Devices
Combined mechanical and electronic device	Some existing – key convergence area	Some existing – key convergence area			
Electronic/IT device	Substantial part of existing sector globally	Some existing – key emerging area			

Figure 5.2 gives an approximate sense of the relative penetration of the main types of technology within medical devices, and of the existing scale of convergence. It also aims to give a sense of how this will develop into the future, with growing convergence.

Biosciences and pharmaceuticals are depicted only in overlap with mechanical and electronic/IT medical devices, as bio and pharma materials not attached to a medical device fall outside the medical devices sector's scope.

Figure 5.2: Increasing Technology Convergence in International Medical Devices Industry (Not to an Exact Scale)



5.5 Irish Medical Devices Trends

5.5.1 Introduction

This section addresses trends in the following areas for the Irish medical devices sector:

- Trends in research and development;
- Higher education research;
- Outsourcing and supply chains; and
- Education and training developments.

5.5.2 Industry Research and Development[7]

Medium and Large Firms

While the Irish medical device sector's origins are in production, many of the major companies in the sector have developed research and development operations. Based on company interviews in Ireland, and on interviews with US-based staff of companies with Irish operations (conducted in the course of the US study visits), it is apparent that the R&D work done by these operations is typically core to the businesses for which it is done. The Irish R&D operations hold their own, working on innovations, and solving problems, that are of central business importance.

7 *Source of data quoted in this section: Research and Development Performance in the Business Sector Ireland 2005/6, Forfás, 2007. Data quoted is for the "Instruments" sector which is predominantly composed of medical devices companies.*

A number of industry interviewees specifically credited IDA Ireland with being the inspiration behind the initial establishment of key R&D operations.

Numbers working in R&D in medium and large firms in the sector rose from 462 in 2001 to 735 in 2005.

Interviews with major Irish medical devices operations involved in R&D indicated that many of them work closely with leading clinicians – mostly from outside Ireland, but some within Ireland.

Small Firms

Small firms in the sector also undertake a considerable volume of R&D:

- Some are start-ups, whose primary activity is R&D;
- Some undertake development work for other companies on a contract basis; and
- The leading subsupply companies undertake significant development work on their own behalf to develop capabilities that will allow them to compete more effectively, with a number of them generating and holding patents.

Numbers working in R&D in small firms in the sector rose from 192 in 2001 to 323 in 2005.

Interviews with medical devices start-ups indicated that they work closely with leading clinicians – mostly from outside Ireland, but some within Ireland. There are instances where subsupply and contract development operations also do this, but their research more often focuses on incremental improvements, informed by the needs of their direct customers.

5.5.3 Higher Education Research

Science, technology and medical research in the Irish higher education sector has grown rapidly in recent years, with research relevant or potentially relevant to the medical devices sector being funded publicly through:

- Science Foundation Ireland;
- The Higher Education Authority, through the Programme for Research in third-level Institutions;
- The Health Research Board;
- Enterprise Ireland;
- The Irish Research Council for Science, Engineering and Technology; and
- EU research programmes, particularly the Seventh Research Framework Programme.

Higher education research also receives funding from industry, although the majority of this originates from government sources. Nationally, funding by Irish businesses accounted for 3% of higher education research funding in 2004[8].

With technological convergence, medical devices sit at the junction between many of the main areas of focus for higher education research. In 2004, 38.8% of higher education research spending went into the natural sciences, 16.7% went into engineering and 17.6% went into the medical sciences.

8 *Source: Table 1, Survey of Research and Development in the Higher Education Sector 2004, Forfás, 2005.*

Research directly relevant to medical devices accounts for just a small share of this, but the availability of research funding has upgraded it from a matter of interest to a small number of academics to a notable area of activity, generating significant research activity and a flow of PhD graduates. The National Centre for Biomedical Engineering Science at NUI Galway, the Trinity Centre for Bioengineering at Trinity College Dublin and the National Centre for Sensor Research at Dublin City University are the most visible manifestations, but significant research is also being done at a number of other institutions.

In the main, the research that is directly relevant to the medical devices sector is being undertaken by academics and graduate students in engineering, with a particular focus on biomechanical engineering, but also some activity in bio-materials and bio-electronic engineering. However, they are engaging in cross-disciplinary work with other disciplines, including biological sciences and medicine, on significant numbers of research projects. Even so, they identify a low overall level of engagement by clinicians in research as being a major challenge for the future of medical devices research in Ireland. They identify a number of reasons for this, the most significant being that most senior clinicians do not have enough time available to make a serious contribution to research.

Higher education researchers do research relevant to medical devices that ranges from projects bearing directly on the needs of medical devices companies to participation in EU-funded cross-national research projects.

40% of medium and large firms in the medical devices sector report collaborating on research with Irish higher education institutions, while 23% report collaborating with higher education institutions outside Ireland. Equivalent figures for small firms are 26% and 6% respectively[9].

5.5.4 Increased Use of Outsourcing and Extended Supply Chains

Some major parts of the medical devices sector have quite complex supply chains, drawing components from operations in geographically dispersed locations, and both from within corporations themselves and from subsuppliers. The Irish medical device sector's reliance on imported components and on Irish based subsuppliers is increasing.

There are a number of reasons for this.

- Cost considerations often favour importing components, or sourcing them from a subsupplier, before final assembly and testing in the company's own operations in Ireland.
- There are often economic benefits to sourcing inputs from a specialist supplier, in areas such as packaging, testing or sterilisation, rather than providing a full range of facilities in-house.
- A number of Irish providers of subsupply and medical devices engineering design services have developed very high levels of expertise, and it is often faster and more cost effective for an established company to draw on this expertise than to solve design, engineering or operational problems internally.
- Outsourcing can offer considerable operational flexibility to a medical devices company:
  - Making it easier to vary production volumes;
  - Allowing it to access additional capacity without the need for investment in infrastructure, equipment and people (the capital cost of clean room facilities is a significant issue for many companies involved in manual assembly); and

9 *Research and Development Performance in the Business Sector Ireland 2005/6, Forfás, 2007. q.v. Data quoted is for "Instruments" sector which is predominantly composed of medical devices companies.*

- Allowing it to access production capacity involving equipment and facilities that the company may not wish to acquire for itself.

- Typically companies in any industry endeavour to maintain and develop their core differentiating competences in-house, and are prepared to outsource activities that are less central to their competitive position. To varying degrees, the core differentiating competences of large established medical devices companies are in selling and marketing to particular markets. This leaves scope for some of these companies to outsource even very advanced engineering work. Indeed, many established companies outsource much of their most fundamental innovation by buying innovative start-ups with proven technologies.
- The strong base of subsuppliers and providers of engineering design services makes it practical for Irish start-ups to outsource elements of their operations that they have difficulty undertaking for themselves.

5.5.5 Major Education and Training Developments

The education and training infrastructure supporting the medical devices industry has developed rapidly in recent years.

Relatively early developments relevant to the sector, dating to the mid-1990s or earlier, included:

- Certificate, diploma and degree courses in polymer engineering; and
- Various toolmaking courses.

Since then, the scope of technologies addressed through the education and training infrastructure has widened, from an early focus on basic production technologies (particularly injection moulding and extrusion of plastics), to a much broader engineering focus on production processes, product development and product improvement. The technological scope has broadened from mechanical engineering and polymer engineering, to also encompass electronic engineering and a broader base of materials engineering.

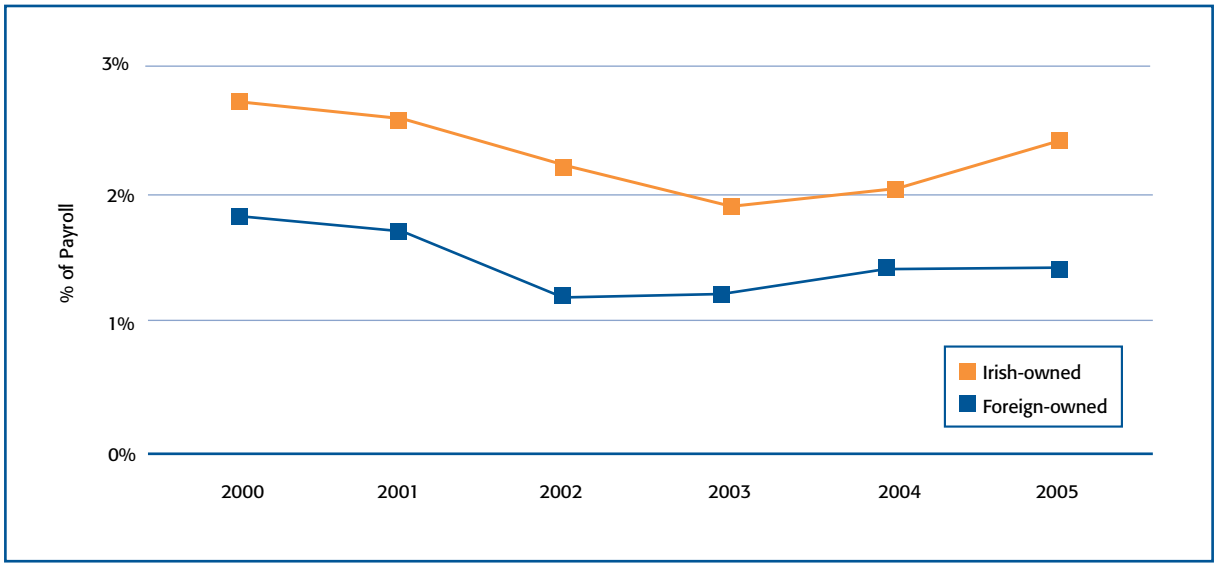
The levels at which higher education courses are delivered have also broadened. It is less than ten years since the first specialist biomedical engineering degree course was introduced. Now, approximately nine institutions have Honours Bachelor Degree courses in biomedical engineering or with biomedical engineering options. There are also now graduate level courses.

The range of institutions providing relevant specialist higher education courses below Level 8 has also broadened, and courses at these levels have been revised and updated to meet current industry needs.

At operative level, FÁS, the Irish Medical Devices Association and other interested parties have collaborated to develop a Level 5 special purpose qualification in Medical and Allied Devices Production. Training leading to this qualification is provided at company level, often with funding from training support programmes operated by Skillnets or FÁS.

The medical devices sector invests relatively heavily in training. Foreign-owned companies in the sector invested the equivalent of 1.4% of payroll in formal structured training in 2005. Irish-owned medical devices companies invested an impressive 2.4% of payroll, outspending Irish-owned companies in almost every other manufacturing or internationally traded services industry.

Figure 5.3: Expenditure on Formal Structured Training as a Percentage of Payroll – Medical Devices/ Instruments, 2000-2005



Source: Annual Business Survey of Economic Impact 2005, Forfás, 2006.

From 2008, the Irish Medical Devices Association will operate the **IMDA Skillnet**, based on a plan under which companies in the sector have identified shared training needs. The Skillnet will provide training to address these needs cooperatively. It is supported by Skillnets, the body funded through the National Training Fund, whose function is to support enterprise-led training networks. Major priorities for the IMDA Skillnet are in the area of manufacturing excellence, with a strong focus on lean manufacturing, continuous improvement and the communication, data gathering, problem solving and analytical skills required to underpin these. Skills in health and safety, Good Manufacturing Practice and clean room operation are also priorities.

5.6 Growth and Value-added by Industry

It is common in business strategy to assess the attractiveness of different parts of a portfolio of businesses in terms of profitability and market growth, using frameworks such as the Boston Consulting Group (BCG) Matrix. It is possible to do something similar for the medical devices sector using US data.

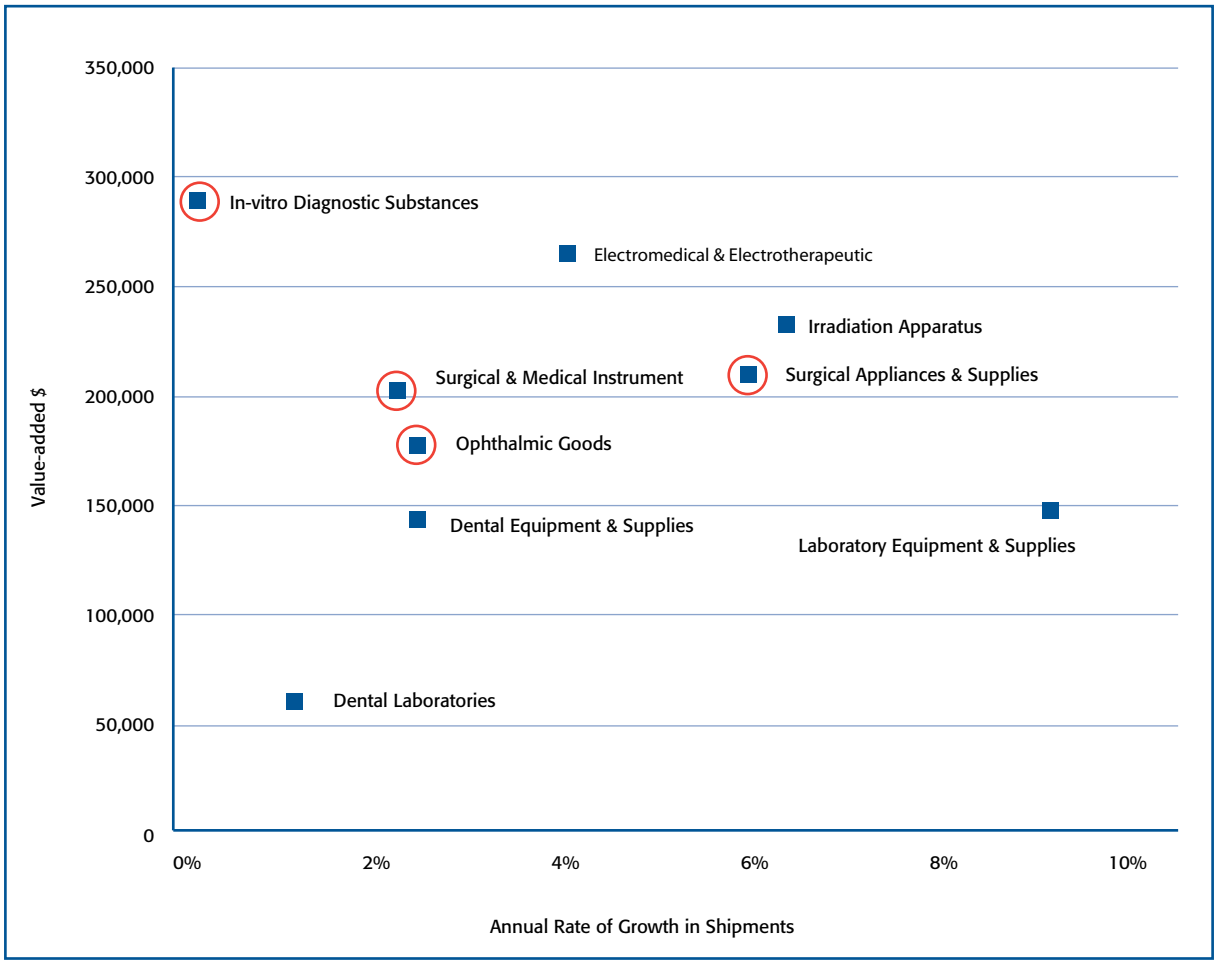
Figure 5.4 plots value-added per employee versus the rate of growth in shipments for each US medical devices industry. Higher value-added industries should be suited to Ireland's high skilled positioning. Other things being equal, higher growth industries should offer good opportunities either to grow employment, or to achieve high rates of improvement in productivity without loss in employment. The four industries that dominate the Irish sector are circled in the Figure.

It can be seen that the industries in which Ireland is positioned are relatively strong in value-added terms, and that the single industry that is biggest in Ireland – surgical appliances and supplies – is one in which value-added per employee and the rate of growth in shipments are both quite high.

The strong positioning of irradiation apparatus in this framework may be overly positive – much of the growth in this industry in the US appears to have come from security applications rather than medical applications, so the actual rate of growth in the medical imaging part of the industry may be lower than this.

Conversely, the weak positioning of in-vitro diagnostic substances on the growth dimension of the framework may be overly negative in the context of a future of personalised medicine that relies on heavy use of diagnostic products.

Figure 5.4: Value-added per Employee versus Annual Rate of Growth in Shipments in US Medical Devices Industries, 2005



Red circles O denote industries in which the Irish medical devices sector has a significant presence.

Source: Based on data from US Annual Survey of Manufactures.

The main points emerging from Figure 5.4 that are relevant to the Irish medical devices sector are as follows:

- The sector is positioned in relatively high value-added industries;
- The largest part of the sector is in surgical appliances and supplies, which is relatively high both in growth and value-added terms;
- At this level of analysis, the key attractive areas in which the sector is weak are electromedical & electrotherapeutic devices, and irradiation apparatus (this is primarily imaging). This reflects a general weakness in medical devices based on electronics, which is interesting considering Ireland's traditional strengths in other electronics manufacturing and design industries; and
- Ireland's significant position in ophthalmic goods is probably more attractive than it appears from this framework, as some of the key companies producing ophthalmic products in Ireland are particularly positioned in high value-added, highly automated areas such as contact lenses.

5.7 Conclusions

The medical devices sector is one in which there is a considerable amount of innovation. Much of this involves providing the tools necessary to support improvements in treatment, driven by trends such as the increasing use of minimally invasive techniques, increasing use of data collection and of responsive devices and (into the future) personalised medicine.

Other factors such as integrated therapy provision, geographic differentiation between medical devices operations of different types, and a possible trend towards commoditisation of medical devices may also drive change.

Technology convergence, with biologically active substances, electronic/ICT and mechanical engineering technologies coming together will be a major driver of medical devices innovation into the future, not only shaping devices but also shaping the innovative processes that go into developing them, and the production processes involved in making them.

Major trends in the medical devices sector in Ireland include:

- The number employed in R&D occupations has grown substantially in both foreign and Irish-owned companies;
- More higher education research that is relevant to the sector;
- Increased use of outsourcing and extended supply chains; and
- Much greater provision of education and training that is relevant to the sector.

A high-level comparison of medical devices sub-sectors in Ireland with those in the US shows that the major industries present in Ireland are in relatively high growth and high value-added activities. The main gap it highlights is that Ireland does not have a strong presence in medical devices based on electronics.

Chapter 6: Innovation and Entrepreneurship

6.1 Introduction

This chapter explores patterns of innovation and entrepreneurship in the medical devices sector. New product development, and incremental improvements to products, are centrally important to the future of both foreign-owned and Irish-owned medical devices companies in Ireland.

Entrepreneurial start-ups are important to the future of the Irish-owned part of the sector and are also relevant to the future of foreign-owned companies in Ireland as possible acquisitions.

Relevance of Chapter to Skills Analysis

Innovation resulting in entrepreneurship or intrapreneurship (the equivalent of entrepreneurship within a significant existing business) is crucial to the future of the medical device sector in Ireland. Success will allow the development of a significant entrepreneurial indigenous sector, and will underpin the future of the foreign-owned sector in Ireland.

While developing entrepreneurship is often treated as a separate issue from skills development in wider policy discourse, skills in this area are seen as being crucially important to the future to the medical devices sector. Skills-type interventions can do much to boost entrepreneurial and intrapreneurial capacity.

6.2 Where Innovation Occurs

According to interviews conducted during the US study visits, "about 50%" of all medical devices innovation takes place in established companies, and the other half takes place in innovative start-ups. However, "about 90%" of the more fundamental innovations take place in innovative start-ups.

This is because established companies tend to focus more on incremental innovation, while innovative start-ups are more open to developing products that represent a radical departure from existing clinical approaches.

Discussions in the course of the US study visits indicated that this pattern occurs because the barriers to established companies being involved in very innovative products tend to be greater than those for entrepreneurial start-ups, and because established companies know that start-ups will provide a stream of proven innovations that they can acquire. According to interviewees, while established companies are often interested in looking at what early stage start-ups are doing, they are much more likely to buy out a company with a medical device solution that is at least doing well in clinical trials, if not already successfully launched on the market. This is despite the fact that they will pay many times more for a company with a proven product than for an early stage company.

This is not very different to the pattern in other technology industries where major companies regularly acquire start-ups to plug gaps in their range, or tap into market opportunities. It is simply not feasible for a large company to create every innovation that it needs internally, and it is difficult for a company to anticipate where the more fundamental innovations emerging from clinical practice may come from.

Added to this are issues with risk control that are specific to the medical devices sector. The decision to undertake a clinical trial on a very innovative product is subject to significant risks. It is at this point that the cost of moving a product towards market reaches tens of millions of dollars or euro, and the investment at risk if it fails becomes significant. Established companies are cautious about approving proposals to bring a new product through clinical trials, largely for this reason.

Another consideration in risk control is that a proportion of clinical trials that have gone through rigorous approval processes show the new medical devices being trialled to pose risks or to be less effective than anticipated. Where patients can make a case that they have been hurt, this can give rise to damage to the reputation of the company responsible for the product, and potentially to lawsuits. The risk that this will happen tends to be greater for very innovative devices than for devices based on incremental improvements. The financial stakes if it happens are greater for established companies with wide product portfolios than for single product companies, making it easier for start-ups to decide to go ahead with clinical trials for a very innovative product that has passed clinical oversight hurdles.

Even so, major companies seem to be taking the lead on some key convergence innovations. A number of reasons for this are apparent:

- Clinical trial requirements are greater than for mechanical and electronic devices, and it may be easier for a large company to organise and fund large scale trials. Despite this, the interview evidence is that some start-ups now get venture funding for large trials.
- Convergence innovations are less suited than traditional biomechanical and bioelectronic innovations to the "clinician and engineer" model of innovation that is prevalent in medical devices start-ups, often being rooted in deeper scientific research, and requiring scientific as well as engineering skills.
- Some convergence innovations are suited to following technology roadmaps, giving a greater degree of predictability than is traditional for innovations in the industry. For example:
  - The addition of drug-eluting qualities to stents is one of the main big-company innovations of recent years. It followed an industry-wide realisation that drug-eluting stents addressing the problem of restenosis[10] were likely to quickly displace traditional stents from most of the market.
  - There are currently moves to introduce telemetry to some implants, making it possible for them to communicate data from the body, or to have their settings changed, without the need for surgery. This reflects a road map which anticipates that more data, and the capability to adjust a device without recourse to surgery, will ultimately result in better healthcare outcomes. It also projects lower healthcare costs, as problems are caught and addressed before they become critical, perhaps preventing hospitalisation.
- The possibility of developing a platform technology that can be leveraged into many innovations is likely to be much more attractive to a large company than to a small company. Traditionally, successful new medical devices companies focus in narrowly on addressing a single significant clinical problem, which maximises their chances of market success, and makes them attractive to funders and possible acquirers. A large company is more likely to be able to benefit from a platform technology with a range of possible applications.

10 Re-narrowing of a vessel that has been widened.

- There seems to be a greater risk that a project to develop a viable solution to a specific clinical problem will fail when it involves convergence technologies than with relatively mature biomechanical and bioelectronic technologies. This may be less of a deterrent to established companies, capable of leveraging what has been learned into other products, than to start-ups.

6.3 Patterns of Development by Innovative Product Start-ups

6.3.1 Company Development

Successful medical devices start-up companies that wish to develop their business have to address a number of practical realities:

- They have to find an economic solution to selling their first product to healthcare providers:
  - They may be able to achieve this through their own sales force if margins are high and the base of key decision making customers is relatively small;
  - They may partner with an existing major company, using its sales force and sharing the proceeds. This is sometimes a halfway house to an acquisition; and
  - In some medical and surgical specialisms it may be viable to use a distributor to sell the product, but generally only in specialisms where distributors have a strong existing presence.
- They have to keep developing their product. New versions of a medical device are typically launched every 18 months to two years. If they fall behind on this schedule, a competitor is likely to overtake them with a better product;
- They have to develop a product portfolio, which will generally be focused on a particular medical or surgical specialism. This often involves acquiring other start-ups with complementary products. There are a number of reasons why medical devices companies have to do this in order to build a business:
  - It makes a direct sales force more viable, by spreading the cost of sales to the target market across a wider product range. It can also drive other scale advantages;
  - A single medical devices product line is constantly vulnerable to the risk that an innovation in medical practice, or a significantly better new competing product, will suddenly take away the market. A portfolio of products reduces the risk that this poses to the company's survival; and
  - The star product that gave the start-up high margins and access to clinicians at launch may not remain as distinctive over time, despite investment in new versions, making it necessary to draw on other sources of advantage.

While the more common outcome is that a successful start-up is acquired, there are also many cases in the US where start-up companies have addressed these practical realities, and built successful and lasting businesses. In some cases, this has reflected a desire by the founders to build a business rather than cashing out. In other cases, companies have seen a broad gap in the market not well addressed by others, and have moved to fill it, seeing this as the best route to maximising the value of the business. In other cases, companies interested in being acquired have failed to find a buyer at an attractive price, and have decided on building the business as an alternative strategy.

6.3.2 Acquisition

There is a strong tendency towards concentration in most medical devices industries. Large companies have a pattern of deriving much of their product innovation from the acquisition of innovative start-ups.

The economics of selling are one of the main drivers. Selling expenses are high for start-ups selling just one product line directly to healthcare providers. These expenses can be reduced greatly if the product is instead added to the portfolio of an existing sales force addressing the same market. This usually follows the acquisition of a start-up, creating economic value through eliminating expenses.

Acquisition of start-ups often suits the main parties involved in a start-up too:

- It allows entrepreneurs to cash out, and move on to the next project. Serial entrepreneurship is very common in medical devices in the US. Indeed, it is not unusual for successful entrepreneurs to be involved, directly or as angel investors, in several medical devices start-ups at once;
- It gives investors an opportunity to cash out, which is particularly important to venture capital investors;
- Most frequently (although there are exceptions), the acquiring company wishes to keep the engineering team to develop new generations of the product. Acquiring companies are typically also conscious that if they do not keep the engineers there is a risk that they will develop a competing product which may turn out to be more successful; and
- Most frequently (although there are exceptions), the acquiring company wishes to keep the existing production operations, if only to avoid disruption to operations, the possible loss of important tacit knowledge, and unnecessary regulatory issues.

The interview evidence from the US is that successful medical devices start-ups are usually acquired about two to three years after being established. This is after the product has at least substantially succeeded in clinical trials, and often after it has been brought to market.

The interview evidence from Ireland is that it takes longer than this to bring a new medical device to market. However, this may reflect additional time arising from the technologically innovative nature of some of the products that have been brought to market by indigenous Irish companies to date, rather than any more fundamental difference between the countries.

6.3.3 Implications for Ireland

The main implications for Ireland are:

- If Ireland is successful in developing a stream of innovative medical devices product start-ups, the likelihood is that a significant portion of them will be acquired. This does not, however, apply to medical devices subsupply and contract development companies, which are much more likely to remain independent;
- If there is a strong flow of start-ups, by entrepreneurs interested in building companies, it is reasonable to think that a proportion of start-ups will survive independently. The business realities are that these will be forced to grow, and broaden their product range, in order to remain independent;

- While it might in principle be preferable if successful innovative start-ups could all remain independent, acquisitions have a number of important positives for the further development of the Irish medical devices sector:
  - They provide an alternative route to promoting inward investment. In most cases, when a start-up is acquired, the likelihood is that it will continue to operate as a unit of the acquiring company;
  - Acquisitions of Irish start-ups by other Irish companies may be necessary to build the company scale and breadth of product range necessary to operate effectively, while continuing to be based firmly in Ireland; and
  - Acquisitions free up entrepreneurial talent, and supply the talent with the money it needs to drive serial business entrepreneurship in US regions studied. This is already visible in Ireland on a small scale.

6.4 Environment for Start-ups

6.4.1 Introduction

The three US study visits undertaken for this study were to California, Massachusetts and Minnesota, which are the three regions generally recognised as being leaders in medical devices innovation. California and Massachusetts are leaders in generating new medical devices ventures. While Minnesota is a major centre of established companies, it is not a major player in generating new start-ups.

In 2006[11], 52% of US venture capital funding for medical devices start-ups went to California, most to the Bay Area/Silicon Valley. New England came second with 13%, most to Massachusetts. The whole Midwest attracted just 3% of US medical devices venture capital funding.

6.4.2 California

The study visit to California was made up of interviews mainly in the San Francisco Bay Area, several of them with leading lights in medical devices innovation, and with organisations frequently quoted in the literature as being central players in the Silicon Valley phenomenon. They had very much a shared view as to what makes the Bay Area successful in medical devices entrepreneurship.

The main factors they highlighted are as follows:

- All the key players involved in medical devices innovation and commercialisation know each other, either directly or by reputation;
- Lines of communication between key players are very open. It is easy for people who are members of the community to pick up the phone, and ask for guidance, with the implicit quid-pro-quo being that they will deal fairly, and will be helpful themselves if asked. People working in medical devices are mobile, and even if they are unlikely to need help in their current role, they may be in a completely different position two years into the future;

11 Source: Data from PricewaterhouseCoopers Money Tree Survey.

- A prospective entrepreneur who does not already have contacts can tap into this network by working with an advisor, such as a lawyer specialising in medical devices. Professional service firms will often work with an unfunded start-up on the basis that they can recover fees if the start-up is successful, and will most likely have access to continuing work;
- As a medical devices start-up develops, it regularly needs access to new elements of expertise, or to new services, sometimes temporarily, and sometimes for the longer term. A Bay Area medical devices company is able to identify the most suitable provider quickly, and take advantage of existing relationships, enabling it to act exceptionally quickly;
- The Bay Area is home to an exceptionally strong concentration of leading universities, providing:
  - A strong supply of graduates in engineering, medicine and biological sciences at a range of levels;
  - Access to leaders in clinical practice at medical schools; and
  - An exceptionally strong local base of research.
- There is a very strong culture of entrepreneurship, and starting technology companies is regarded as a normal part of a career. There are many cases where companies have been started by physician-entrepreneurs. Many leading academics in medicine and engineering interested in medical devices have a history of company start-ups in their background, and continue to participate in, or advise start-ups. They are linked strongly into the region's network of relationships.

Several key players interviewed quoted Annalee Saxenian's 1994 study "*Regional Advantage: Culture and Competition in Silicon Valley and Route 128*"[12] as capturing the essence of what makes the Bay Area successful in medical devices, as in information technology. This classic study focuses on the network of relationships, and on innovative institutions that support them, as the main differentiating source of the region's advantages in creating new technology companies.

6.4.3 Minnesota

The study visit to Minnesota showed a strong interest in building capability in creating new companies. Organisations such as the BioBusiness Alliance of Minnesota and LifeScience Alley are endeavouring to develop cross-organisation relationships, both at organisation and individual level, in order to shorten the chain of contacts that a prospective innovator will have to go through in order to get access to the right expertise and resources, whether internally within an existing company, or through an entrepreneurial start-up.

The state has a strong history of innovation in medical devices, and indeed the medical devices sector accounted for more than three-quarters of Minnesota's biobusiness technology employment in 2002. After dipping between 1997 and 2002, medical devices employment in the state rose significantly between 2002 and 2005[13]. The state is known more for its established medical devices companies, and for the infrastructure of subsupply and engineering services companies that support them, than for large numbers of innovative start-ups.

12 *Harvard University Press.*

13 *Source: Biobusiness: Minnesota's Present Position and Future Prospects, The BioBusiness Alliance of Minnesota, 2006.*

Minnesota has major strengths in bio-sciences, with a substantial existing life sciences industry and substantial academic research activities, particularly at the Mayo Clinic and the University of Minnesota, and on a smaller scale among the state universities. Interviewees believed that leveraging these strengths into new bio-sciences based businesses, whether in medical devices or in other life sciences industries, is a strategic challenge that must be tackled. They see future opportunities in medical devices coming particularly in biosciences convergence areas.

Interviewees described cases where new ventures built on Minnesota research had been established elsewhere, apparently because of pressure to establish in locations that have stronger biosciences industry credentials. They also mentioned the absence of a significant local pharmaceutical industry, and the fact that Minnesota is distant from key venture capital centres (while it has is own venture capital industry) as significant factors.

6.4.4 Massachusetts

Massachusetts is a major medical devices industry centre, home to the headquarters of a number of major multinational medical devices companies. It also has a history of generating new medical devices start-ups, although in smaller numbers than California.

In MassMedic, (the Massachusetts Medical Device Industry Council), it has a well established central organisation that both develops, and advocates on behalf of, the industry. In some respects, it plays a role similar to that of the State development agencies in Ireland, promoting policy research, encouraging educational institutions to provide relevant courses and promoting medical devices entrepreneurship through a programme called MedTech IGNITE. MedTech IGNITE's main activities include a structured mentoring programme and Boot Camps for entrepreneurs.

As with the Bay Area, Massachusetts is home to a number of major research universities, providing a strong supply of graduates in engineering, medicine and biological sciences and a strong base of research. It is also home to an exceptionally large and strong healthcare industry, with many well-known hospitals and clinics.

The cost of living in Massachusetts is relatively high, particularly in the more metropolitan areas in the east of the state that otherwise tend to be most attractive to professionals. There were indications that the high cost of living is leading to problems with retaining high performing graduates within the state, contributing to a shortage of development engineers. Medical devices production operations are increasingly located in the west of the state, where costs are lower.

6.4.5 Bio-convergence Technologies

The strong focus on biosciences as a source of medical devices innovation seen among those interviewed in Minnesota contrasted with that of key medical devices community players interviewed in California and Massachusetts, who were more focused on opportunities that can still be pursued using relatively mature biomechanical and bioelectronic technologies.

While recognising that bio-convergence technologies are gaining in importance for medical devices, interviewees in California and Massachusetts argued that new clinical insights are still producing a strong flow of opportunities that can be exploited with the more traditional technologies. They also pointed to traditional approaches to medical device innovation working well for the participants, with a start-to-opportunity-to-cash-out period of just two to three years, with limited clinical trials costs, and with a relatively good likelihood of success for a well chosen project.

Adding innovative biological substances to the mix will extend the time-to-market, will increase the clinical trials requirement, and will increase the level of risk for the firm. This will not stop a good convergence project from being funded, but it raises the market opportunity threshold that a project has to reach in order to be fundable.

This divergence of approach raises a conundrum for Ireland in terms of policy. Should the main policy focus be on traditional medical devices innovation, should it be on innovation using convergence technologies, or should it strike a balance between the two?

6.4.6 Irish Contact with Key Networks

An observation from the study visits is that Enterprise Ireland appears to have had considerable success in linking itself into the network of medical devices relationships in Massachusetts, and also has significant contacts in other regions. Aside from its executives' own contacts, the members of its Medical Devices Advisory Board seem well positioned to introduce Irish businesses to the contacts they might need in key parts of the US, including Massachusetts and the San Francisco Bay Area.

6.5 Key Initiatives to Promote Innovation and Entrepreneurship

6.5.1 Stanford Biodesign

Introduction

The most interesting and developed initiative to promote medical devices innovation seen in the course of the study visits was Stanford Biodesign. This is a recent development – Stanford's first courses in medical devices started in 1999.

Stanford Biodesign is located in the Clark Center on the main Stanford campus, which is home to the Stanford Bio-X initiative to promote cross-disciplinary initiatives between biosciences and medicine, and other disciplines. This architecturally interesting landmark building provides space for interdisciplinary initiatives around a walking route between the main medical and engineering school locations on the campus.

Stanford Biodesign is involved in providing a wide range of bio-design related courses, which are relevant to the medical devices industry, in areas from device design to regulatory affairs. It also provides a wide range of seminars and networking events. It provides a range of online resources. It gets involved in areas such as arranging internships with medical devices companies and career services for students and alumni. Much of this work contributes to reinforcing and renewing the Bay Area network of relationships described earlier, while also meeting the needs of students, researchers and alumni.

However, the really interesting innovation in Stanford Biodesign is in a fellowship programme for eight 'fellows' per year, and in its spin-off into an elective course for graduate and postdoctoral students.

Biodesign Innovation Team Fellowship Programme

Admission to the Fellowship Team programme is competitive, and there is no requirement for an applicant to have any link with Stanford. Applicants with a background in engineering, medicine, biosciences or relevant business /technology are encouraged to apply. People with masters, medical and doctoral degrees and with significant relevant experience, and residents/fellows in surgery "who enjoy applying technology to solve unmet clinical needs", are preferred.

The fellows are formed into two multidisciplinary teams of four graduate and/or postgraduate engineers, business professionals, bioscientists and physicians. Each team undertakes a project to invent a new technology to address a major clinical or surgical need over a 12 month period. The 'fellows' are supported by a stipend.

Each team goes through a structured process, starting with clinical immersion, to:

- Identify and verify clinical problems that could be addressed with a new technology;
- Choose from among the problems identified based on factors such as feasibility, importance, size of market, reimbursability and financial considerations;
- Invent a solution;
- Prototype the solution; and
- Undertake early stage testing.

Biodesign Innovation teams have filed multiple patents, have introduced new technologies into clinical practice, and have started a number of new companies.

The leaders of Stanford Biodesign have strong innovation and business backgrounds, as well as strong academic credentials. In addition to Stanford clinical and engineering faculty, the teams are mentored by many experts in design, prototyping, regulatory, reimbursement, finance and other aspects of medical devices technology implementation.

While the programme is focused on the development of new companies, there has been at least one instance where a major company has used it to develop a high potential engineer (admission was still competitive).

Subsequent to the study visit, it was announced that the programme would be replicated in India. Stanford India Biodesign is initially based in New Delhi, with funding from Stanford and the Government of India, administered as a collaboration between the Indian Institute of Technology and the All India Institute of Medical Sciences.

Biodesign Innovation Elective Course

The Biodesign Innovation elective course is open to graduate and postdoctoral students from the schools of business, engineering, humanities & science, law and medicine. It effectively replicates the team innovation approach used in the team fellowship programme with teams of graduate and postdoctoral students, but on a shorter and less intensive time scale. The course combines lectures from guest speakers and faculty with a hands-on project.

The projects are typically based on good concepts that the fellowship teams decided not to pursue themselves. Fellows from the team fellowship programme contribute to mentoring the projects.

Biodesign Innovation Programmes are not Research

It was stressed during the study visit that Stanford's biodesign innovation programmes are about learning to innovate, and to bring innovations to market. They are not primarily about generating fundamental new knowledge or about learning to generate such knowledge, so the work involved is not considered to be research.

6.5.2 MIT Mechanical Engineering Design

Another interesting initiative seen was in a graduate mechanical engineering design course at Massachusetts Institute of Technology. The course combines lectures and project work. Each year, the professor teaching the class solicits physicians to suggest clinical problems that could potentially be addressed with a medical device. Out of about 30, around twelve are selected, based on their potential, and on an assessment of the contribution the physician will be able to make.

The students investigate the problem in detail, with the physician's help and advice, and propose possible solutions. They collaboratively choose one, and develop it into a testable prototype. The graduates are in strong demand from the local medical devices industry, and there are indications that some of the devices developed on the course may be brought to market.

6.6 Conclusions

The medical devices sector has an established and apparently stable pattern of relying on innovative start-up companies for much of the sector's more fundamental innovation.

A proportion of successful innovative product start-ups build lasting businesses, often acquiring other start-ups to build a coherent portfolio of products. Others are acquired, most often continuing to exist as units of the acquiring company. Medical devices subsupply and contract development companies tend to remain independent.

52% of US venture capital funding for medical devices start-ups went to Silicon Valley-based companies in 2006. Silicon Valley interviews highlighted strong interpersonal networks as being key centrally important, giving entrepreneurs a means to tap into leading expertise and services as needed, minimising delay and waste in bringing a product to market.

Other factors highlighted in Silicon Valley include:

- The concentration of leading universities, which generates a strong supply of graduates, access to leaders in clinical practice at medical schools and an exceptionally strong local base of research; and
- The very strong culture of entrepreneurship, which includes a tradition of successful physician-entrepreneurs.

Stanford Biodesign is a major programme with strong contacts into the Silicon Valley medical devices community. It is involved in a wide range of activities. Its Biodesign Innovation Team Fellowship Programme is particularly interesting as a mechanism for educating participants in medical devices innovation, and driving the creation of new medical devices companies.

Chapter 7: Skill Needs and Solutions

7.1 Introduction

This chapter starts by looking at likely future demand for new recruits into the medical devices sector at all levels. It presents two employment scenarios and makes projections of demand based on these, and on assumptions about future patterns of upskilling in the sector.

It then looks in more detail at skills requirements and assesses the adequacy of the available supply in both quantitative and qualitative terms.

It comments on measures that may be required to address the skills needs identified.

Relevance of Chapter to Skills Analysis

This chapter focuses directly on the skill needs arising in the medical devices sector based upon projections of future skills demand and patterns of upskilling. It considers Irelands capability to meet these needs and possible solutions through the use of existing and new initiatives.

7.2 Employment Scenarios

Employment in the Irish medical devices sector has grown continually since at least the early 1990s, and increased at a compound average rate of 6.5% per annum between 2000 and 2006. Employment growth between 2005 and 2006 was much less than this average, at just over 1%, but there have been periods in the past when the sector's growth slowed, before speeding up again, so this does not provide clear evidence of a systematic slowdown.

The sector's future employment trajectory, will be impacted by a number of factors.

Factors reflecting positively on the prospects for employment include the following:

- The sector is upskilling rapidly, and moving progressively into higher value-added activities;
- Country of origin labelling is important in the market for many medical device products. This tends to ensure that production, or at least final assembly and test, are retained in developed countries with good reputations among healthcare providers. "Made in Ireland" is one of the best labels a medical device can have;
- The most labour intensive parts of the sector, which are engaged in final assembly and test of products, already make significant use of components from locations with lower labour costs;
- A number of the operations that were most cost sensitive, making lower value products, and where the country of origin was not a major issue, have already closed;

- Inward investment from the medical devices sector into Ireland is continuing; and
- The number of innovative medical devices start-ups being formed is increasing. These could become a significant driver of employment growth.

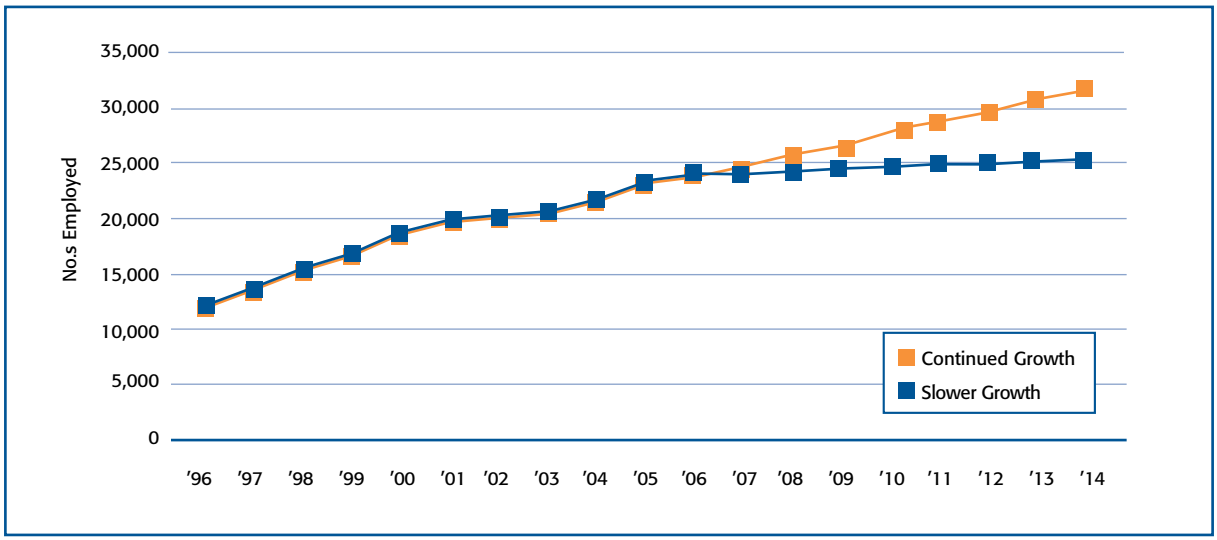
Factors pointing towards a reduction in the rate of growth, or even employment loss, over coming years include the following.

- The cost of operating in Ireland has become relatively high. Pay costs are a significant issue for the more labour intensive parts of the sector, and are factored into corporate decisions even in the more automated parts of the sector. Energy costs were also mentioned as an issue in interviews undertaken for this study.
- The US dollar has fallen in value by more than 40% against the euro since 2000, making European locations including Ireland less competitive for inward investment, although boosting dollar-denominated returns from European markets.
- While the general migration of manufacturing employment from developed countries to low labour cost locations has been slow to impact on the medical devices industry, migration to Asian locations seems to be gathering pace. This may pick up as Asian locations build capabilities and reputations in medical devices production.
- Parts of the sector are highly labour intensive, and it seems unlikely that this is sustainable. Eventually, many of the jobs in final assembly and test seem likely either to migrate overseas, or to be automated.

Given these factors, it is desirable that a skills strategy for the sector should take into account both the possibility that employment in the sector would increase in line with the historical trend and/or that it would level off.

Figure 7.1 presents two plausible scenarios for the future. "Continued Growth" is based on a continuation of the general trend of recent years. "Slower Growth" is based on a continuation of the slower growth seen in the immediate past (2005 to 2006).

Figure 7.1: Two Scenarios for Medical Devices Sector Employment to 2014



The scenarios assume the sector suffers no major shocks. A possible point of exposure is that the sector is particularly dependent on the continued use of stents in treatment of cardiovascular disease. An innovation in clinical practice that significantly reduced the requirement for stents, such as a more effective drug treatment for vascular plaque, could potentially cause such a shock.

7.3 Skills Demand Under Scenarios

The main trends in the occupational mix likely to be required under either scenario are as follows.

- The share of employment accounted for by managers, which is lower than in other comparable sectors, may increase a little.
- The share of employment accounted for by engineers and scientists is likely to increase.
- The share of employment accounted for by people who would be counted in national statistics as technicians is likely to increase.
- There is likely to be an increase in the share of employment accounted for by people in sales, as Irish-owned companies develop, and as foreign-owned companies move into higher added value activities. There is also likely to be an increase in the share of employment accounted for by purchasing staff, as outsourcing increases.
- There is likely to be a fall in the share of employment accounted for by people in operative level positions.

Figure 7.2 sets out assumptions as to the shift in occupational mix between 2006 and 2014. (The 2006 mix is based on the data in Figure 4.1.)

Figure 7.2: Assumed Shift in Occupational Mix, 2006 to 2014

Occupational Group	2006 % Share	2014 % Share
Managers	4.8	6.0
Engineers/Scientists/Analyst-programmers	6.7	12.0
Technicians	5.3	9.0
Administration	9.1	9.1
Trades	13.0	13.0
Medical Auxiliary	2.4	2.4
Sales/Purchasing	1.9	3.0
Operatives	56.7	45.5
All Occupations	**100**	**100**

Figure 7.3 sets out the demand for skills that this shift in occupational skills mix implies under each of the scenarios. It is assumed that it will be necessary to replace 3% of employees in the sector each year. These projections should be seen as a guide to the scale of demand, rather than precise predictions.

Figure 7.3: Demand for Skills Projected under Continued Growth and Slower Growth Scenarios (Combined Expansion and Replacement Demand)

Continued Growth Scenario									
	Managers	Engineers/Scientists/ Analyst-programmers	Technicians	Administration	Trades	Medical Auxiliary	Sales/Purchasing	Operatives	Total
2007	106	240	178	145	206	38	58	614	1,584
2008	112	259	192	147	210	39	62	594	1,614
2009	117	279	206	150	213	40	66	573	1,644
2010	123	299	220	153	217	40	70	552	1,675
2011	128	320	235	156	221	41	75	530	1,705
2012	134	341	249	158	225	42	79	506	1,735
2013	140	362	265	161	229	42	84	483	1,765
2014	146	384	280	164	233	43	88	458	1,795

Slower Growth Scenario									
	Managers	Engineers/Scientists/ Analyst-programmers	Technicians	Administration	Trades	Medical Auxiliary	Sales/Purchasing	Operatives	Total
2007	67	181	132	72	102	19	41	174	789
2008	69	188	137	73	103	19	43	163	795
2009	71	196	142	73	104	19	44	152	802
2010	72	203	147	74	105	19	46	141	808
2011	74	210	152	74	106	20	47	130	814
2012	76	217	158	75	107	20	49	119	821
2013	78	225	163	76	107	20	50	108	827
2014	80	232	168	76	108	20	52	96	833

7.4 Engineers and Scientists

7.4.1 Introduction

Projections of demand for engineers and scientists rise from 240 in 2007 to 384 in 2014 under the Continued Growth scenario, and from 181 to 232 under the Slower Growth scenario.

The requirement is for graduates from a range of disciplines, and at levels ranging from Honours Bachelor Degree to PhD.

For the immediate future, the key disciplines are:

- Biomedical engineering;
- Mechanical engineering;
- Production/industrial/manufacturing engineering; and
- Mechatronic/automation engineering.

There are also requirements in biological sciences (particularly from diagnostics companies), pharmacology/chemistry, materials engineering and electronic engineering.

Over the longer term, there is potential for the share of demand accounted for by biological sciences, pharmacology/chemistry and electronic engineering to increase, with technological convergence. As nanotechnology features more, there will be a need for people specialised in various areas of nanoscience, including nanotoxicology.

The key roles for engineering graduates are in:

- Product development;
- Production and manufacturing engineering;
- Design of automated production processes;
- Validation engineering;
- Quality engineering; and
- Production management and troubleshooting.

The industry also employs science graduates in some of these roles, including validation engineering and quality engineering.

The diagnostics part of the sector, and parts of the sector involved in bioconvergence technologies employ science graduates both in product development and production. These are primarily in biosciences and chemistry.

7.4.2 Adequacy of Current Skills Supply Pipeline

Engineering

The medical devices sector is the main source of demand for graduates in biomedical engineering, and has become one of the main sources of demand for graduates in mechanical engineering and production/industrial/manufacturing engineering.

The interview evidence is that the supply of graduates available to the sector currently is generally adequate in quantity. Indeed, US observers of the Irish sector consulted during the study visits felt that the supply of engineering talent available in Ireland represents one of the sector's greatest strengths.

The number of students taking biomedical engineering is ramping up rapidly, and graduate numbers in this discipline are estimated to be likely to reach approximately 90 in 2010 based on the 2006 intake. To put this in perspective, the whole of NAICS 3391 (Medical Equipment and Supplies Manufacturing) in the US employed 2,160 biomedical engineers in 2005.

There should be sufficient graduates in biomedical engineering available to not just fill every role that would be filled by biomedical engineers in the US, but also many of those that would be filled by mechanical engineers and production engineers. Most biomedical engineering graduates are, in any case, effectively specialised mechanical engineers, and the interview evidence is that many Irish graduates in biomedical engineering are working in medical devices production roles.

The likelihood is that most graduates in biomedical engineering will be available to the sector for employment if they are wanted, either directly upon graduation or after undertaking a further higher education qualification. With a substantial part of the sector's requirement for engineers effectively already reserved for the sector by their choice of course, medical device companies will only be competing with other industry sectors for perhaps half of their requirement for engineering graduates under the Continued Growth scenario.

However, the size of the pool of graduates in mechanical, mechatronic and production/industrial/manufacturing engineering that the sector is recruiting from has fallen significantly in recent years. Acceptances of places on Level 8 ab-initio courses in these disciplines fell by about 15% between 2001 and 2006[14], this decline was largely compensated in higher education mechanical engineering departments by the expansion of courses in biomedical engineering.

It is possible that increasing demand from the sector for engineering graduates could add enough to total demand for mechanical and production/industrial/manufacturing graduates to cause a shortage. An increase in demand of the order of 100 could be enough make a meaningful impact on a supply of some hundreds, although this would depend on trends in demand from other sectors of the economy.

However, there are also more clear-cut supply issues in engineering.

- The sharp fall in graduate numbers in electronic engineering that has taken place in recent years, combined with competition from the ICT sector for the best graduates, risks being an obstacle to companies considering locating electronics-based medical devices operations in Ireland, and may prove an obstacle to the emergence of innovative start-ups focused on applying electronics and ICT technologies in medical device applications. With electronics and ICT technologies likely to be an important feature of medical devices technology convergence, this is a significant issue for the sector's future development.

14 Based on an analysis of course level CAO data.

- A number of interviewees commented that the number of new engineering graduates available to the sector who are very strong in engineering design is less than they need. They suggested that there is a need for a greater focus on practical mechanical engineering design in mechanical and biomedical engineering courses at Level 8 and above.
- A number of interviewees identified a shortage of engineers with the skills to design end-to-end automated medical devices production processes. While the numbers required are not large, this is a critical role in improving productivity and quality.

Science

The interview evidence is that the supply of biological scientists and phamacologists/chemists is generally adequate for the needs of the medical devices sector at present. Into the future, the adequacy of the supply will depend mainly on the level of competing demand from biotechnology and pharmaceutical companies, and on the response of college entrants to the opportunities in these sectors when choosing higher education courses. While demand from the medical devices sector is likely to grow significantly as technological convergence progresses, this could bring it to perhaps 100 to 150 per annum, which would still account for just a fraction of total graduate numbers in these disciplines.

Demand for PhDs

The interview evidence is that the medical devices sector is now recruiting PhDs with specialist skills and knowledge that are relevant to their products and operations. Demand is coming from:

- Indigenous start-ups engaged in developing innovative new medical devices products;
- Foreign-owned companies involved in R&D, and improving the engineering of their existing product range; and
- Providers of subsupply and contract development services deepening their technological capabilities.

Based on the interview evidence, it is estimated that the sector could absorb 10 to 20 PhDs in a year at present, across a range of disciplines but particularly in biomedical and mechanical engineering[15]. The annual output of PhDs in biomedical engineering from Irish higher education institutions is still in single digits, and indications are that the medical devices sector would take more if they were available.

Future demand will depend on three main factors.

- Technological convergence is likely to drive more demand for PhDs. Where traditionally the sector has innovated using mainly fairly mature engineering technologies, technological convergence will increase the emphasis on more fundamental technological and scientific innovation. As biological and chemical sciences become a more significant part of the technology mix, the fact that R&D in these areas tends to be led by PhDs will further drive PhD recruitment.
- Current Irish patterns of start-up formation in the medical devices sector suggest that a self-reinforcing cycle of company formation, leading to business success, leading to the formation of more companies may be starting to emerge. If this happens, it will generate substantial demand for PhD graduates, particularly in biomedical engineering.
- Irish operations will be competing for R&D investment with other locations operated by foreign-owned corporations.

15 These are included in the projections of demand for engineers and scientists presented in Figure 7.3.

7.5 Technicians and Trades

7.5.1 Introduction

The term "technician" has a variety of uses within the medical devices sector. It encompasses roles with a technical content which may be filled by staff with higher education qualifications at Level 6 or Level 7, and also typically encompasses those with apprenticeship-based qualifications such as fitters and electricians, as well as others with formal technical training. This section covers these "technicians".

The term is sometimes also used to describe technically skilled staff who might be described at operators in other industries. These are addressed later under "Operators and Assemblers".

A small minority of staff described in the sector as technicians are more highly qualified, with up to masters level qualifications. These generally have key technical roles in product development (e.g. prototyping) or commissioning and managing technical aspects of production.

The sector has a history of fulfilling its requirements for skills at this level through a combination of routes, including:

- Recruiting new graduates at Levels 6 and 7, typically with qualifications in engineering, or sometimes science;
- Recruiting people with Level 6 craft qualifications, such as fitters or electricians;
- Recruiting people with other technical qualifications, for example following courses provided by FÁS, or training by other employers; and
- Upskilling employees from operator level backgrounds, either through company-provided training or through supporting them in studying part-time for a Higher Certificate or Ordinary Bachelor Degree.

On the whole, the emphasis has historically been on recruits demonstrating evidence that they have, or can quickly learn, the practical skills required to do the job, rather than on specific requirements for qualifications.

Interviews undertaken during the US study visits show a broadly similar pattern, with:

- Some technicians being recruited straight out of full-time study leading to a community college certificate or associate degree;
- Others being recruited with relevant practical skills (sometimes with a prior qualification, sometimes not) and trained; and
- Some being recruited at operator level, and advancing through training or undertaking part-time education.

Both in Ireland and the US, graduates straight from college account for only a minority of recruits.

Diagnostics

In the diagnostics sector, the requirement is primarily for people with a relevant, laboratory-based technician qualification at Level 6 or Level 7.

7.5.2 Adequacy of Supply

The number of technicians required by the medical devices sector will increase as production becomes more automated, and as the emphasis on R&D grows.

Medical devices companies will continue to recruit their technicians from a range of backgrounds. The scope to increase recruitment of new graduates at Levels 6 and 7 is limited. Numbers graduating from full-time engineering education at these levels have been falling in recent years[16], and the share of these that continue their education to Honours Bachelor Degree level has been growing, leaving relatively few graduates available for recruitment by industry. Only a small number of these are specialised in biomedical engineering (although Level 6 and 7 qualifications in disciplines such as mechanical engineering are also relevant to the sector).

For this reason, the main emphasis will have to be on upskilling of employees from operator level, and on recruitment of people with technical skills from other sectors. Depending on the scenario for the future, of the order of 100 to 200 will need to be upskilled in a year.

As the medical devices sector makes progress on automating production, there will be an increasing need for technicians with skills in areas such as robotics and machine vision to assist in developing automated lines, and to participate in managing, troubleshooting and improving them. There will be a need to train existing technicians to work on automated systems.

Diagnostics

The particular requirement that the diagnostics sector has for people with formal technician qualifications at Level 6 and 7 has become increasingly difficult to satisfy in recent years, with fewer students entering relevant courses, and more of those starting at Levels 6 and 7 choosing to progress to Level 8, rather than entering the labour market with a technician qualification.

There is at least one initiative underway to provide part-time education to upskill diagnostics sector employees with technician qualifications.

7.5.3 Upskilling and Certification

Technicians in the medical devices sector hold a wide range of qualifications, few of which are specific to the sector.

Technicians broadly require two sets of skills:

- The technical skills required to carry out their specific technical role, which can vary considerably from one company to another, and between different roles within a company; and
- Skills and knowledge requirements that are common to all medical devices companies, involving a knowledge of how the industry works, some human biology, the essentials of medical devices regulatory affairs, design and manufacturing of medical devices, basic statistics, Good Manufacturing Practice and Good Laboratory Practice.

16 Numbers accepting places on Level 6 courses in mechanical, production and electromechanical/mechatronics engineering decreased by 36% to 206 between 2001 and 2006. Numbers accepting places on Level 7 courses fell by 26% to 267 over the same period.

The sector already has an initiative in place to deliver a common programme of training at operator and assembler level, with a strong focus on Good Manufacturing Practice. As seen earlier, this leads to the award of a special purpose FETAC certificate at Level 5. This responds both to the need to upskill these employees, and to a regulatory affairs competence certification agenda.

The same agenda is also relevant at technician level.

A practical way to pursue this would be through a common course in biomedical technology, leading to certification under the National Framework of Qualifications. This course would focus on the skills and knowledge requirements that are common to all medical devices companies, rather than on the technical specifics associated with particular technical roles.

The Biomedical Technician Certificate course seen during the study visit to Minnesota at Anoka-Ramsey Community College provides a model that such a course could follow[17]. This course focuses on the workings of the industry, human biology, medical devices regulatory affairs, design and manufacturing of medical devices, statistics, ethics and some general education requirements. When taken full-time, the certificate course takes one year, although most students take it part-time while working. Anoka Ramsey Community College, which is seen as a national leader in the area in the US, also has a Biomedical Technologist Associate in Science Degree.

Based on the occupational mix data presented in Figure 4.1, there are approximately 4,000 technicians and trades employed in the sector, for whom such a course would potentially be relevant. This should be seen as a ceiling on the numbers of existing staff requiring training, rather than an estimate of likely uptake. It is envisaged that the Anoka-Ramsey model would be adapted to a special purpose qualification positioned at Level 6 in the National Framework of Qualifications. Delivery would follow the model established with the Level 5 award in Medical and Allied Devices Production.

Such a course would also be relevant to technicians entering the sector, or being upskilled from operator level.

There is an increasingly well developed infrastructure of courses and training facilities for the pharmaceutical and biopharmaceutical sector, which should address many of the technician level training needs of medical devices companies involved in the production of bio-convergence products.

7.6 Operators, Assemblers and Quality Control Staff

7.6.1 Introduction

Under both the Continued Growth and Slower Growth scenarios, the percentage of employees in the sector accounted for by operative level occupations is projected to fall.

This primarily reflects:

- Increasing skill requirements in some machine operator jobs bringing these jobs to technician level; and
- A reduction in the share of employment accounted for by assemblers doing manual final assembly, and quality control staff doing manual and visual inspections, with increasing automation and possibly the net migration of some work to lower cost locations.

17 *See http://www.an.cc.mn.us/career_programs/CareerBioMed.cfm.*

Even so, under both scenarios demand arising from the need to replace people exiting the sector, combined with increases in overall employment, is sufficient to maintain a net positive demand for new recruits.

- Recruits at this level are typically educated to Leaving Certificate level or equivalent. Manual dexterity, the ability to conscientiously comply with formal working procedures, sufficient awareness to identify visible problems with components and assemblies, and the flexibility to move between assembling different products are the key qualities required of **assemblers**.
- **Machine operators** are also typically educated to Leaving Certificate or equivalent. Manual dexterity is less important, but technical aptitude is more important, and will increase in importance as production becomes more automated. The same applies to process operatives, who will increase in numbers as bio-convergence products become more common.
- **Quality control** staff are typically promoted from assembler and machine operator positions.

In all roles at this level, an understanding of Good Manufacturing Practice and/or Good Laboratory Practice is important. Generic skills in areas such as communication and problem solving are also becoming increasingly important, as new lean manufacturing and quality management practices are implemented in the sector.

Depending on local labour market conditions, some companies make significant use of inward migrants at this level. This is similar to what was seen in the study visits to the US; interviewees indicated that many operative level jobs in the sector are staffed from recently arrived immigrant communities.

7.6.2 Adequacy of Supply

Numbers required at this level are modest relative to the supply of people with Leaving Certificate or equivalent qualifications. It is unlikely that there will be significant difficulty in meeting demand, other than possibly local constraints if a company seeks to expand in an area with a limited supply of labour.

7.6.3 Upskilling and Certification

As with technicians, operators and assemblers require two broad sets of skills:

- The specific skills required to carry out their day-to-day operational role; and
- Skills and knowledge common to all medical devices companies in areas such as Good Manufacturing Practice/Good Laboratory Practice and the generic skills required to participate effectively in lean manufacturing and quality management practices.

Production technologies and processes vary between companies, limiting the scope for joint action on company-specific skills.

The FETAC special purpose Level 5 award in Medical and Allied Devices Production makes a major contribution to addressing the skills and knowledge common to all medical devices companies. Training leading to this award has already been delivered to substantial numbers of operators, assemblers and quality control staff, often with support from FÁS or Skillnets. It is desirable that this training should continue to be rolled out to existing staff, and should be made available to new recruits to the sector.

There is also scope for joint action on shorter courses, targeted on topics such as lean manufacturing, continuous improvement, process control, quality, Good Manufacturing Practice and the communications, problem solving and data analysis skills required to underpin them.

There is an increasingly well developed infrastructure of courses and training facilities for the pharmaceutical and biopharmaceutical sector, which should largely address the operator level training needs of medical devices companies involved in the production of bio-convergence products.

The recently established specialist FÁS bioprocessing training centre in Carrigaline, Co. Cork, forms an important part of this infrastructure.

It is desirable that FÁS, Skillnets, Enterprise Ireland and IDA Ireland should continue to support the sector's work in this area, whether organised cooperatively or by individual companies.

7.7 Medical Devices Industry Skills

7.7.1 Introduction

It is important that anyone working in management or in a professional role in the medical devices industry has a good general understanding of a number of key topics that are specific to the industry, and have a major impact on business effectiveness.

These include:

- Regulatory affairs;
- Quality in the medical devices regulatory environment;
- Product development in the medical devices regulatory environment;
- Healthcare economics and reimbursement;
- Clinical trials;
- Intellectual property; and
- Sales and marketing of medical devices.

In addition start-ups and businesses such as venture capital firms need specialist knowledge in areas including financing, sourcing of specialist advice and services and management of entrepreneurial medical devices start-ups.

The industry also requires specialists in each of these areas. Most companies in the sector employ significant numbers of regulatory affairs specialists. Those involved in the management and administration of research and development activities need specialist knowledge in order to comply with regulations affecting the product development process without unduly extending the time to market. The number of specialists required in each of the other areas are more limited.

More generally, the sector has a requirement for strong leadership skills with managers, professionals and entrepreneurs who are capable of building business success, both in the overseas-owned and Irish-owned parts of the sector. This requires both a broad base of industry, product, technology and market knowledge and the skills to leverage this knowledge into effective organisational action.

7.7.2 Adequacy of Supply

General Understanding among Managers and Professionals

Study visit interviews showed that each of the regions visited in the US has mechanisms in place to inform and update those working in the medical devices sector on topics such as those listed above.

In Massachusetts, the MassMedic sponsors and organises seminars and conferences. Worcester Polytechnic Institute offers a non-credit Medical Device Management Certificate Program, which provides an introductory overview of the medical device industry covering 11 topic areas, and a more substantial Medical Device Critical Leadership Certificate Program. These programmes cover the sort of topics listed above.

In Minnesota, various organisations including LifeScience Alley, a trade association that works cooperatively with the BioBusiness Alliance of Minnesota, sponsor and organise seminars and conferences. Anoka-Ramsey Community College's Biomedical Technician certificate and Biomedical Technologist associate degree are sufficiently broad in their content so that they attract students from non-technician backgrounds, seeking to advance their careers, as well as technicians and operators, with previous qualifications up to PhD level.

Stanford Biodesign offers seminars and courses, many open to industry, covering these wider topics, complementing its more technically oriented activities.

Interviews in Ireland indicated that there is a need for many of those working in management and professional roles to have a broader appreciation of medical devices business, and that continuing education in the area could address this need.

Of the models seen in the US, the ones that seem most transferable to Ireland are:

- A part-time continuing professional development course broadly similar to those provided by the Worcester Polytechnic Institute in Massachusetts; and
- Regular seminars providing updates on development and key topics.

It is suggested that higher education institutions based near major concentrations of medical devices industry should look at Anoka-Ramsey Community College's certificated courses, and assess whether they believe there would be enough local demand to justify providing similar courses part-time, leading to major awards at Levels 6 or 7 in the National Framework of Qualifications.

Specialist Professionals

The study visits to the US also showed examples of education provision for specialists in a number of the above areas. For example:

- St. Cloud State University in Minnesota has introduced a Masters degree programme in regulatory affairs, which is one of a small numbers of such programmes nationwide;
- The Regulatory Affairs Professional Society provides a range of continuing professional development material;
- Anoka-Ramsey Community College provides a one year clinical research professional certificate programme, targeted on people with qualifications in nursing, pharmacology or biological sciences, which is one of a significant number of such programmes nationwide; and
- The Worcester Polytechnic Medical Device Critical Leadership Programme described above has specialist streams for people in:
  - Regulatory affairs and quality;
  - Operations;
  - Product development; and
  - Sales and marketing.

There is a clear need for more people with specialist skills across each of the topics important to the industry that are listed in the introduction to this section. For most of these topics the requirement is limited enough so that it would be difficult to justify providing a course that would be run repeatedly.

However, there is a clear shortage of regulatory affairs professionals, and the numbers required are likely to be sufficient to justify running a course every year. The model of a masters degree, seen in St. Cloud State University, would be likely to fit the Irish context well, as early career professionals are increasingly open to returning to study for a masters degree. When it was described in interviews with Irish companies, interviewees were positive about it as a solution to the shortage of regulatory affairs professionals.

While it is not clear whether demand for clinical trials management professionals in the medical devices sector would be sufficient yet to justify the provision of a regular course, if this demand was combined with that from the pharmaceutical and clinical trials industry the total demand might be sufficient to justify the provision of a certificated course targeted on professionals with a relevant existing qualification, in an area such as nursing, pharmacology or biological sciences.

For specialist professional areas, such as healthcare economics and reimbursement, intellectual property, sales management and marketing for medical devices, venture financing and management of medical devices start-ups, demand for education and training will be more limited. Specialist continuing education courses in these areas could be provided once and then repeated as demand arises.

7.8 Clinical Involvement

The relatively low level of involvement by Irish clinicians in medical devices innovation is likely to act as a drag on innovation in the industry. The key centres of medical devices innovation are distinguished by a high-level of interaction between clinicians and engineers. Ireland is not big enough to meet all of the needs for clinical interaction locally, so overseas clinical contacts will always be important. However, an increase in involvement by clinicians in medical devices innovation could give the industry a major innovative boost.

Clinicians themselves could potentially benefit financially, or in terms of reputation. New devices are often known by the name of the clinician whose insight they are based upon. In the US, and particularly in California, some physicians make rewarding careers as medical devices entrepreneurs.

The Irish health service could benefit too, in terms of quality of treatment, and potentially in terms of sharing the financial rewards.

7.9 Skills for Convergence

Technological convergence in medical devices will become deeper over time. It will impact on skills requirements in a number of ways.

- It will broaden the range of disciplines that are core to the medical devices sector, from (in Ireland) mechanical engineering, biomedical engineering, materials engineering and medicine, to also include biological sciences, electronic engineering, pharmacology and chemistry.
- While the main requirement will be for people with a deep knowledge of their discipline who can work in a multidisciplinary environment, there will also be a requirement for people with skills that span different disciplines.
- It is likely that technologies will emerge that are core to areas of convergence, and which will have to be understood by significant numbers of people from different disciplines. Likely examples of such areas are telemetry, sensors, nanocoatings, drug release technologies, microarrays and personalised medicine.
- At operational level, the main skills growth areas arising from convergence are likely to be in bioprocessing and pharmaceutical processing, where the primary skills requirements will be similar to those of the biopharmaceutical and small molecule pharmaceutical industries.

Existing initiatives to ensure the supply of skills required for the biotechnology and pharmaceutical industries are likely to substantially address the medical device sector's need for people with skills in biological sciences, pharmacology and chemistry, and in bioprocessing and pharmaceutical processing.

Other initiatives will be required:

- In initial education to prepare students to work in the converged technology environment; and
- In continuing education to give people already working in the medical devices sector access to the cross-disciplinary skills and knowledge that they will need.

7.10 Skills for Shared Services

The medical devices sector is increasingly locating shared services and sales-support functions in Ireland, alongside operations and R&D functions. This is generating requirements for skills in areas such as accountancy, customer service, logistics, supply chain management, billing and sales support.

In the main the skills required are not specific to the medical devices sector, and are used by many other sectors, The main difficulties likely to occur in supplying these skills are locational. Many medical devices companies are located in relatively small centres of population, and it may in some cases be difficult to source enough of these skills locally.

7.11 Opportunities to Differentiate Ireland based on Skills Supply

The main immediate opportunity to differentiate Ireland positively from other medical devices locations is on the supply of high quality engineers. This is an area where Ireland is recognised in the US as being strong, and where the underlying reality of graduate supply is broadly consistent with the perception of strength.

There is a particular need at present to develop strong engineering capabilities in automation of medical devices production, and success in this area is likely to give Ireland a boost in attracting inward investment.

As technological convergence progresses, there will also be an opportunity to position Ireland as a location that is strong both in biomechanical engineering and in pharmaceutical and biopharmaceutical technologies, well equipped to undertake R&D and production operations in bio-convergence products.

It will be more difficult to position Ireland strongly on ICT/electronics convergence, given current shortages of electronic engineers, and given the fact that Ireland's major ICT sector has little involvement in medical devices. Even so, if successful start-ups emerged in this area, it could potentially change perceptions, given the Irish ICT sector's underlying size and strength.

If the demand for regulatory affairs professionals is addressed effectively, this may also contribute to differentiating Ireland from other locations, where shortages are common, although this consideration is not likely to swing investment decisions by itself.

More generally, the proposals that this report makes to address weaknesses in skills supply are likely to remove negatives even where they do not contribute positively to perceptions of potential inward investors. The fact that the Irish Government is working supportively with industry on skills provision is likely to be seen as a significant positive.

Initiatives to develop entrepreneurial skills targeted primarily on Irish-owned companies are likely to have spin off benefits for foreign-owned companies, improving the climate for innovation, potentially teaching intrapreneurial as well as entrepreneurial skills, further strengthening the base of subsupply and contract development companies, and growing the pool of innovative Irish-owned companies with which to develop value-adding business relationships.

7.12 Conclusions

The chapter presented two employment scenarios for the sector, one based on a continuation of the growth seen since 2000, and the other based on slow growth. It made projections of future demand for recruits based on a view of the future under which the share of employment in operative level occupations falls, while that in engineering, scientific, technician, sales and purchasing occupations rises. Job numbers in manual assembly are likely to fall, with increased automation and possibly some movement to locations with lower labour costs.

The chapter finds that, aside from the possibility of strong competing demand from other sectors, the supply of engineers and scientists appears likely to be sufficient in numbers, although there is an issue with the supply of electronic engineers.

Demand for PhDs is increasing, and the likelihood is that it will continue to increase. Developments in research in relevant disciplines are timely.

The term "technician" has a broader usage in the medical devices sector than in many other sectors, typically encompassing staff with a wide range of technical qualifications and skills, only a minority of whom have higher education qualifications at Level 6 or 7. The main emphasis in providing an adequate supply will be on upskilling of employees from operator level, and on recruitment of people with technical skills from other sectors.

There will be an increasing need for technicians with skills relevant to automated production lines.

The need to upskill technicians, and to ease the integration of technically skilled workers from outside the sector, could be addressed in part through a common training programme focused on skills and knowledge requirements that are common to all medical devices companies.

Relatively modest numbers of new operators, assemblers and quality control staff will be needed. The existing initiative to train employees at this level in skills common to all medical devices companies, leading to the award of a special purpose FETAC qualification, should continue to be rolled out.

It is important that anyone working in management or in a professional role in the medical devices industry has a good general understanding of a number of topics that are specific to the industry, and have a major impact on business effectiveness. These include: regulatory affairs; quality in the medical devices regulatory environment; product development in the medical devices regulatory environment; healthcare economics and reimbursement; clinical trials; intellectual property; and sales and marketing of medical devices. In addition start-ups, and businesses such as venture capital firms, need specialist knowledge in areas including financing, sourcing of specialist advice and services and management of entrepreneurial medical devices start-ups. The industry also requires specialists in each of these areas. The areas where significant numbers are required are in regulatory affairs and the management and administration of research and development activities. Various interventions could be considered to address these needs.

There is a need for greater involvement by Irish clinicians in medical devices innovation.

Technological convergence in medical devices will become deeper over time. Existing initiatives to ensure the supply of skills required for the biotechnology and pharmaceutical industries are likely to substantially address the medical device sector's need for people with skills in biological sciences, pharmacology and chemistry, and in bioprocessing and pharmaceutical processing.

Other initiatives will be required: in initial education to prepare students to work in the converged technology environment; and in continuing education to give people already working in the medical devices sector access to the cross-disciplinary skills and knowledge that they will need.

The main immediate opportunity to differentiate Ireland on the basis of skills is in the supply of high quality engineers. As technological convergence progresses, there will also be an opportunity to position Ireland as a location that is strong both in biomechanical engineering and in pharmaceutical and biopharmaceutical technologies, well equipped to undertake R&D and production operations in bio-convergence products. Initiatives to develop entrepreneurial skills targeted primarily at Irish-owned companies are likely to have spin off benefits for foreign-owned companies.

Figure 7.4 (see next page) provides a descriptive summary of expected future requirements for key skill areas.

Figure 7.4: Summary of Future Skills Requirements for Key Roles in Sector

Key Roles	Future Requirements
Assemblers	Relatively low-skilled. Numbers likely to fall steeply with automation, or eventually migration of some work overseas.
"Technicians" (sometimes "operators" at lower end) – wide range of types and levels of skill	Numbers, and level of technical and teamworking skill required, to rise as automation increases.
Biological Scientists and/or Chemists in bioconvergence areas	Numbers to increase from very low level, as bio-convergence progresses.
Operations Managers and Supervisors	To require more technical skill. Also people management skills required will change as work force moves to a higher level of skill and education.
QC Staff	Becoming more technically demanding as automation progresses and quality management improves. Numbers may fall significantly in some operations as inspection becomes more automated.
Process Design Engineers	Very small numbers in industry (or in consultancy operations) with sufficient skill. Critical area where significantly more are needed to drive effective automation.
Validation Engineers	To increasingly require engineering graduates rather than scientists. To become more intellectually challenging as automation makes processes more complex.
Production Engineers and QA staff	To become more intellectually challenging as automation makes processes more complex.
Engineers (mechanical, biomedical, electronic, and a few materials engineers)	Need more experienced development engineers. Need more new graduates who are strong in practical engineering design.
Clinicians (mainly external)	Need much greater engagement in innovation and commercialisation by Irish clinicians.
Development Technicians (especially prototyping)	Increasing need as development increases, but total numbers will still be quite small. Likely to come from a variety of educational backgrounds – craft as well as higher education.
Clinical Trial Managers	More innovation will require more people strong in design and management of clinical trials. Often come out of nursing in the US.
Regulatory Affairs	Need more now and in future.
Healthcare Economists	Need to develop locally. In interim, may need contacts with US specialists for part of work.
Specialist Legal, VC, …	Need to develop locally. In interim, need contacts with US specialists for part of work.
Sales Management and Sales	Need to develop sales management skills. May need experienced staff in-country rather than Irish sales people for start-ups.

Chapter 8: Conclusions and Recommendations

8.1 Introduction

Ireland is one of the leading global medical devices industry centres. Employment in the sector here has risen rapidly over the decade. Inward investment from overseas has also grown, particularly in manufacturing, but also in world-class research and development. The major medical devices industries here are in relatively high growth and high value-added activities such as the manufacture of medical and surgical instruments, and surgical appliances and supplies. There are also significant R&D operations. Foreign-owned companies accounts for over 90% of employment. Even so, employment in Irish-owned companies is rising somewhat faster than in foreign-owned companies. Sales by medical devices companies in Ireland are worth about €6 billion per annum – with exports accounting for over 95% of sales. "Made in Ireland" is regarded as one of the best labels a medical device can have.

The Irish medical devices sector is at a critical point in its development.

- Inward investment from overseas has grown rapidly over the last ten years, particularly in manufacturing, but also in world-class research and development. This record of growth is now being challenged by rising costs, unfavourable exchange rate trends, and the improving manufacturing capabilities of competing low cost economies.
- The indigenous industry has established a strong position in subsupply and in contract development services, targeted at both the inward investment base and export markets. The number of indigenous companies successfully bringing completed medical device products to market, although small at present, is increasing, Expertise and money from the first generation of successes are feeding the establishment of innovative new entrepreneurial medical device ventures, attracting venture funding and PhD graduates.
- The sector globally is in the early stages of what is likely to be rapid convergence between technologies, with devices combining biomechanical, electronic and biologically active components likely to be a major focus of innovation into the future.

Thus, the essence of any skills strategy for the sector must be to:

- Build operational excellence, so as to address the challenges to competitiveness, and root medical device manufacturing more deeply in Ireland, whether foreign-owned or Irish-owned;
- Drive product and technology innovation for the benefit of both foreign-owned and Irish-owned industry;
- Develop and support entrepreneurs and intrapreneurs;
- Fill any major gaps in the skills development infrastructure; and
- Address changes in skills needs arising from technological convergence.

8.2 Building Operational Excellence

Building excellence in medical devices operations requires progress on three closely integrated fronts:

- Automation, to address the high costs associated with manual assembly and test, and to improve quality performance;
- Lean manufacturing, to eliminate waste and speed logistics; and
- Improving quality and eliminating waste by adopting world-class quality management practices, such as Six Sigma.

These all have significant skills implications. While many companies in the sector are already working on automation, lean manufacturing and quality management, concerted action on the necessary skills has the potential to accelerate their progress. Key areas where action is required on skills are:

- The industry needs more engineers highly capable in the design of integrated automated production systems for medical devices, employed both in the industry itself and in Irish companies providing automation engineering services. The skills required for automation of medical device production differ from those required for process industry automation particularly in having:
  - A heavy emphasis on robotics;
  - A heavy emphasis on machine vision and machine inspection; and
  - In many cases, short production runs.
- Where production processes are automated, this raises significantly the level of technical skill required in production related occupations:
  - Machine operators require higher levels of technical understanding in order to: identify and resolve incipient problems; undertake basic troubleshooting and contribute to more advanced troubleshooting; undertake basic maintenance; and work on machine set-up between batches;
  - Technical production staff, including technicians and production engineers, have to overlay their existing skills with a good knowledge of the automated systems, and with deeper problem solving skills to cope with greater complexity and subtlety in the problems that tend to arise; and
  - A fully integrated automated production line is technically complex, making it challenging for validation engineers to validate that it behaves as specified. This is required for regulatory purposes and is likely to raise the level of technological and problem finding skill required by validation engineers, as an operation becomes more automated.
- Implementation of lean manufacturing and world-class quality management practices raises the skills required at all levels in production operations. It requires a workplace partnership culture with a focus on continuous productivity and quality improvements. It increases the importance of generic skills such as communication, numeracy and problem solving. It also raises the importance of understanding in areas more specific to the medical devices sector in areas such as GMP (Good Manufacturing Practice), GLP (Good Laboratory Practice) and Regulatory Affairs. At operator level, these skills needs are being addressed by many companies through in-house training leading to the award of a FETAC Medical Device Operator Certificate. This was developed through collaboration involving the IMDA and FÁS, with funding from Skillnets.

- Furthermore, lean manufacturing and quality management increase the need for technical expertise in quality, in areas such as statistical process control, and more broadly in the quality management practices that the company has adopted. Some companies in the sector have had significant numbers of staff trained in Six Sigma practices.

Recommendation 1: Centre for Medical Device Manufacturing Excellence

A **Centre for Medical Device Manufacturing Excellence** should be established in the higher education sector to assist industry in developing the skills required for automation, lean manufacturing and quality management. The Centre should focus on:

- Automation technologies, with a particular emphasis on robotics and machine vision that are specifically relevant to the sector, as well as on the control and data management technologies that the sector has in common with process industries;
- Advanced engineering design of automated systems;
- Quality management (Six Sigma and similar approaches) in the context of the regulatory environment;
- Lean manufacturing;
- Supply chain management;
- Energy efficiency;
- Validation engineering for complex automated systems; and
- Training technicians to work with automated systems.

The Centre is likely to operate in a number of modes, including:

- Provision of short duration courses, on site or on-campus;
- Provision of masters level courses, part-time and possibly full-time;
- Contributing to undergraduate courses in relevant disciplines;
- Applied research with industry partners; and
- Making high-level expertise from overseas accessible to smaller operations.

The Centre should be modest in scale. It should be established for a limited period, renewable while its services continue to be required. It would make use of existing facilities in the higher education sector.

It is envisaged that the Centre would be established on the basis of proposals from higher education institutions (possibly from consortia) to IDA Ireland and Enterprise Ireland, which would provide core funding. While actual costs would depend on the detailed arrangements for the Centre, it is approximately estimated that core funding of the order of €5m capital and €1m recurring would be required.

Recommendation 2: Upskilling Operators and Technicians

Companies in the medical devices sector should continue to upskill their operators and technicians, and the various State organisations supporting training in the sector (including FÁS, Skillnets and Enterprise Ireland) should, as appropriate, continue to support them in doing this.

Interested parties from Irish Medical Devices Association, FÁS, Skillnets and other organisations should cooperate in the following.

- Companies should continue to roll out training leading to the award of the Level 5 FETAC **Medical and Allied Devices Production Certificate**. FÁS, Skillnets and other providers of funding for training should support companies wishing to do this when funding training plans in medical devices companies. They should also support companies in providing shorter training interventions targeted on upskilling operators and technicians.
- A **course in biomedical technology** leading to a special purpose Level 6 qualification should be developed. It is envisaged that it would be modelled on the Biomedical Technician Certificate seen in the study visit to Minnesota at Anoka Ramsey Community College. This focuses on topics that are relevant to a broad cross-section of medical devices companies. The delivery model would be based on that for the existing FETAC Medical and Allied Devices Production certificate, most likely with involvement from one or more Institutes of Technology. Participation should be paid for by companies, with some support from FÁS, Skillnets and other public providers of funding for training.
- The proposed **Centre for Medical Device Manufacturing Excellence should provide courses to train technicians to work with automated medical device production systems**. These courses would be provided in-company, and part-time on-campus. They would complement more specialised training in specific automation technologies that companies might continue to source from private providers. Participation in these courses should be paid for by companies, with some support from FÁS, Skillnets and other public providers of funding for training.
- Institutes of Technology, diagnostics companies, and other medical devices companies requiring more biosciences technicians should continue to cooperate in providing **bioscience technician courses** at Levels 6 and 7 to upskill operators, or in reskilling technically qualified people from other disciplines.

Taking account of the fact that medical devices companies have already done significant work in this area, it is envisaged that approximately 5,000 assemblers, operators and technicians would require upskilling training in the next three years[18].

8.3 Driving Innovation

8.3.1 Introduction

Innovation is already an important feature of the Irish medical devices sector. A continuous focus on ongoing innovation is key for the industry to thrive and renew itself into the future.

Many overseas owned companies have significant research and development operations, typically involved in developing new generations of the products that they manufacture in Ireland.

18 The total number counted as receiving training would be larger than this as many would participate in more than one training intervention. IMDA Skillnet have plans to train 800 trainees over the period 2008-09.

Many Irish-owned subsupply companies are also active in innovation, improving the components they supply, and in some cases patenting and/or branding their innovations. Contract development work also forms a significant part of their business.

There is also increasing venture-funded and angel-funded start-up activity in new medical device products.

Key skill-related areas where action is required fall into two areas:

- Providing the medical devices industry with the high-level engineering and scientific skills it requires for innovation; and
- Achieving a much greater degree of involvement by Irish clinicians in medical device innovation, to complement the sector's involvement with overseas clinicians.

8.3.2 High-level Engineering and Scientific Skills

Key areas where action is required to underpin the future supply of high-level engineering and scientific skills for medical devices innovation include:

- Ensuring a supply of PhD graduates in relevant disciplines who are well prepared to enter the industry, of the order of 20 per annum at first, particularly in biomedical and mechanical engineering, but also encompassing materials engineering, electronic engineering, pharmacology/pharmaceutical chemistry and increasingly (over time) biological sciences;
- Better preparation for undergraduate biomedical and mechanical engineers to work as practical engineering designers, reflecting a shift in the balance of roles taken up by graduates from production management and production engineering to engineering design of products and production processes; and
- To the extent that they can attract students, greater involvement by electronic engineering departments in biomedical electronics, to produce a largely new flow of engineers, qualified from Level 8 to Level 10, capable of innovating in ICT enabled medical devices.

Initially, the opportunities for electronic engineers are likely mainly to be in indigenous innovation. It is anticipated that the focus on biomedical electronics will increase interest in electronic engineering among college applicants, benefiting both the medical devices and ICT sectors.

The universities involved in biomedical engineering research made a joint application for funding for a "**Fourth Level Institute" graduate school in Biomedical Engineering** under the first round of IRCSET and IRCHSS's Graduate Research Education Programme. According to IRCSET "the graduate education programmes proposed by all applicants were each of a high calibre"[19], but only 5 out of 27 were approved. The Biomedical Engineering proposal was unsuccessful. Further funding rounds are planned.

19 *http://www.ircset.ie/grant_schemes/grep_info.html*

Recommendation 3: High-level Engineering and Scientific Skills

It is recommended that higher education institutions involved in graduate studies in biomedical engineering should continue to work towards establishing a graduate education Institute, so as to prepare graduate students to contribute effectively to medical devices sector innovation, and to strengthen the network of relationships among future key players in Irish medical devices innovation. The Expert Group supports the need for such an institute. The EGFSN also acknowledges the need for excellence in proposals for such an institute.

Access to the services of the Institute should be open to graduate students in disciplines other than biomedical engineering, from biological sciences to business, with an interest in medical technologies, so as to maximise the benefits to students and industry.

The Stanford Biodesign Programme, described in the body of this report, performs many of the functions of a graduate school, and would form a useful model for the Irish graduate school.

Institutions providing Level 8 to 10 programmes in biomedical engineering, and in mechanical engineering where significant numbers of graduates enter employment in the medical devices sector, should review the balance of their programmes, with a view to **identifying ways in which they can better prepare their students to work in engineering design**.

Electronic engineering departments with interests in bioelectronic engineering should examine whether there is **scope to add biomedical content to their programmes**, or to place **additional emphasis on medical technologies in their research**.

8.3.3 Involvement by Irish Clinicians in Medical Device Innovation

Attaining greater involvement by clinicians in medical device innovation is not just a matter of developing and translating clinical research, although this is a significant part of what is required. In this regard, the Expert Group welcomes the recommendations of the Advisory Council for Science, Technology and Innovation on developing Irish clinical research in its 2006 report *Towards Better Health: Achieving a Step Change in Health Research in Ireland*[20], and urges their rapid implementation.

As significant medical devices innovations frequently emerge informally from the application of engineering principles to clinician insights rather than from formal clinical research, it is important that the Science Council's recommendations should be implemented in a way that supports medical device innovation activities whether or not they are formally constituted as research.

In addition, initiatives should be undertaken in a number of areas to develop the supply of people with combinations of clinical and engineering skills, as people with such skill combinations are particularly well suited to innovating in medical devices.

20 The report of the Cross Sectoral Clinical Trial Taskforce also addressed part of the same territory, making broadly similar recommendations.

Recommendation 4: Engaging Irish Clinicians in Medical Devices Innovation

Entry into the new **graduate programmes in medicine (currently being established) by engineering graduates** has the potential to produce a supply of graduates qualified both in medicine and engineering. If a significant flow from engineering into medicine does not emerge, the reasons should be reviewed, and corrective action should be considered.

Medical and engineering schools should jointly create **more opportunities for clinicians in training to undertake studies and/or research in medical technology and biomedical engineering**. Medical schools should feature career paths involving participation in medical technology innovation, ranging from limited advisory roles to entrepreneurship, when advising medical students as to their career options.

The Medical Technologies Council should undertake or sponsor **initiatives to raise the profile of medical devices innovation among clinicians,** particularly those still in training. Initiatives could include:

- Sponsoring lectures and workshops by successful clinician-entrepreneurs from overseas; and
- Awards for medical technology student projects and research projects involving clinicians.

Industry and Enterprise Ireland should provide funding to support these interventions.

8.4 Entrepreneurs and Intrapreneurs

The future of the sector will depend on turning medical devices innovations into new businesses and improved product ranges for existing businesses. This will require a significant increase in entrepreneurial activity, developing new businesses, whether stand-alone or within existing companies.

Recommendation 5: Developing Entrepreneurs and Intrapreneurs

Enterprise Ireland should continue to develop its range of training and coaching supports for medical devices entrepreneurs, and for prospective entrepreneurs, drawing on experience in other life science sectors, on experience with the software sector, and on US initiatives such as MassIGNITE.

Enterprise Ireland should also consult with Irish higher education institutions interested in medical technologies with a view to developing a **programme to boost the supply of effective entrepreneurs and intrapreneurs**.

The Stanford Biodesign Fellowship Programme is one possible model to consider. This year long programme takes two groups of four talented graduates/postgraduates through a process of identifying opportunities for innovation, evaluating them, and developing a new medical device with strong market potential to prototype stage. It produces people well equipped to operate as entrepreneurs and intrapreneurs, and has led directly to the launch of a number of companies.

The Programme also makes a major contribution to graduate education, with the fellows mentoring teams of graduate students through a similar process, working on the best opportunities that the fellows did not pursue. If such a programme was reproduced in Ireland, it could form a core part of the activities of the "Fourth Level Institute" in biomedical engineering.

An Irish version of the fellowship programme should draw on leading US expertise in creating medical devices businesses.

It is envisaged that funding for such a programme would be considered by Enterprise Ireland. The cost will be contingent on the detailed design of the programme, which will be influenced particularly by the extent and nature of US involvement in programme delivery.

8.5 Industry Understanding and Specialist Skills

The US study visits showed a wide range of learning opportunities in areas of skill and knowledge specific to the medical devices sector, both at the level of general understanding for managers and professionals, and at the specialist expert level. These courses address skills development needs that are also present in the Irish industry.

Two broad types of **professional development** intervention are required:

- There is a need for managers and professionals working in the medical devices sector to develop a broad working knowledge of a range of topics that are important and specific to the medical devices sector, along with the leadership skills required to leverage this knowledge into business success; and
- There is a need for relatively small numbers of managers and professionals working in the sector to have a deep specialist knowledge in the key areas of:
  - Healthcare economics and reimbursement;
  - Intellectual property in medical devices;
  - Sales and marketing for medical devices; and
  - Financing of medical devices start-ups.

There would be benefits to professional development in these areas also being accessible to limited numbers of professionals in complementary industries serving the medical devices sector such as IP professionals, venture capitalists and legal professionals, to assist these industries in developing specialist medical devices expertise.

Two areas of specialist skill would be better addressed through **postgraduate study** – with part-time courses targeted on those already in the workforce initially, but possibly with full-time courses open to new graduates over the longer term. These areas are:

- Regulatory affairs; and
- Clinical trials management.

Recommendation 6: Professional Development

A part-time professional development course targeted on medical devices sector managers and professionals and on those on a management track, should be developed and introduced by a higher education institution, covering topics including:

- Regulatory affairs;
- Quality in the medical devices regulatory environment;
- Product development in the medical devices regulatory environment;
- Healthcare economics and reimbursement;
- Clinical trials;
- Intellectual property;
- Sales and marketing of medical devices; and
- Organisational leadership.

It is envisaged that this would be modelled broadly on Worcester Polytechnic Institute's education programmes for the medical devices industry[21]. While it may be possible for an institution to take the lead in developing and providing a course, Enterprise Ireland, the Medical Devices Council, FÁS, should intervene to support development of the programme if this does not happen. It is envisaged that the recurring cost of provision would be recovered from participants through fees.

It is proposed that Enterprise Ireland, in cooperation with the Irish Medical Devices Association and other interested parties, should consider commissioning the **development of part-time professional education courses** in:

- Healthcare Economics and Reimbursement;
- Intellectual Property in Medical Devices;
- Sales Management and Marketing for Medical Devices; and
- Venture Financing of Medical Devices Start-ups.

These courses should be targeted on industry professionals who are working in the area, or likely to move into the area. Professionals from complementary industries such as venture capital, IP advisors and legal firms might also be admitted if sufficient space were available.

It is envisaged that one iteration of each course would be run initially, with additional iterations being run if sufficient demand is apparent. Part of the cost of provision would be recovered from participants, in line with Enterprise Ireland's usual practice.

21 Note that the study visits undertaken for this study consulted with individuals and organisations with exposure to WPI's work in this area, but did not consult directly with WPI.

Recommendation 7: Postgraduate Taught Courses

A **Masters Course in Regulatory Affairs** should be developed and introduced by a higher education institution, either targeted specifically on the medical devices sector, or targeted jointly on medical devices and pharmaceuticals sectors, but with a medical devices specialisation. It should be developed in collaboration with the industry in order to ensure relevance and encourage uptake. The course could be delivered in a number of formats, including part-time, full-time and through distance/blended approaches.

It is envisaged that this course would initially take 20 part-time students per annum.

The Expert Group on Future Skills Needs is of the view that there will be sufficient demand for **education in the management of clinical trials**, in the foreseeable future, to justify the development of a graduate diploma or masters degree in the design, management and conduct of clinical trials. The medical devices sector will be just one of a number of sources of demand for skills in this area.

It is recommended that higher education institutions should consider the creation of such a course.

It is envisaged that the cost of provision would be recovered from participants, as with other part-time postgraduate courses.

8.6 Technological Convergence

Technological convergence in medical devices will become deeper over time. It will impact on skills requirements in a number of ways.

- It will broaden the range of disciplines that are core to the medical devices sector, from (in Ireland) mechanical engineering, biomedical engineering, materials engineering and medicine, to also include biological sciences, electronic engineering, pharmacology and chemistry.
- While the main requirement will be for people with a deep knowledge of their discipline who can work in a multidisciplinary environment, there will also be a requirement for people with skills that span different disciplines.
- It is likely that technologies will emerge that are core to areas of convergence, and which will have to be understood by significant numbers of people from different disciplines. Likely examples of such areas are telemetry, sensors, nanocoatings, drug release technologies, microarrays and personalised medicine.
- At operational level, the main skills growth areas arising from convergence are likely to be in bioprocessing and pharmaceutical processing, where the primary skills requirements will be similar to those of the biopharmaceutical and small molecule pharmaceutical industries.

Existing initiatives to ensure the supply of skills required for the biotechnology and pharmaceutical industries are likely to substantially address the medical device sector's need for people with skills in biological sciences, pharmacology and chemistry, and in bioprocessing and pharmaceutical processing.

Recommendation 8: Technological Convergence

As technological convergence in medical devices progresses:

- Courses in important convergence topics should be introduced into undergraduate biomedical engineering courses (see 7.9);
- Masters programmes in important convergence topics should be introduced, to facilitate graduates in specialising in key areas of skills demand, targeted on graduates both from relevant scientific and engineering disciplines; and
- Where clear industry demand exists, colleges should consider establishing specialist or cross-disciplinary undergraduate degrees.

There is a need to pace these developments so that courses are not provided too far in advance of convergence related skills being needed.

8.7 Industry Networks

Interaction and networking between professionals and managers with interests in medical devices will be crucial to developing processes for innovation reflecting what can be seen in the Bay Area of California and in Massachusetts. The Irish Medical Technologies Council has significant potential to promote this interaction, both directly through its own activities, and by opening doors to communication between industry leaders, entrepreneurs, leading scientists and engineers, academics, clinicians and industry development agencies.

Recommendation 9: Medical Devices Industry Networks

The Irish Medical Technologies Council should actively promote communication and networking between industry leaders, entrepreneurs, leading scientists and engineers, academics, clinicians and industry development agencies involved in medical technologies.

8.8 Overview

Figure 8.1 is an overview map of existing and proposed provision organised by skill area and type of education or training.

- Green boxes represent areas where there is already significant activity.
- Blue boxes represent additional areas where this report proposes action.
- Numbers refer to the recommendations for action presented in this chapter.

For example, the '8' under 'Graduate Studies' refers to Recommendation 8 on technological convergence.

Recommendations propose action both in areas of existing provision and in a range of new areas.

Figure 8.1: Overview Map of Existing and Proposed Provision (See Text)

		Initial Education and Training				Continuing Education and Training				
		Level 5	Levels 6 & 7	Level 8	Graduate Studies	Level 5	Levels 6 & 7	Level 8	Graduate Studies	Short or Professional Ed. Course
Engineers	Biomedical			1, 8	1, 3, 8				1, 5	1, 6
	Mechanical with medical devices specialisation			1	1, 3, 8				1, 5	1, 6
	Automation with medical devices specialisation			1					1	1, 6
	Materials with medical devices specialisation				3, 8				5	6
	Electronic with medical devices specialisation				3, 8				5	6
	Physics with medical devices specialisation									6
	Mechanical/Electronic/ Mechatronic/Production etc. without medical devices specialisation									1, 6
Scientists	Biological Sciences				3, 8					6
	Chemistry/Pharmacology				3, 8					6
Technicians/ Trades etc.	Biomedical						2			
	Relevant skills, not specialised in medical devices						2			
Operators/ Assemblers/QC Staff						2				
Industry Specific Specialist Professionals	Regulatory Affairs				7				7	6
	Healthcare Economics/ Reimbursement									6
	Clinical Trials								7	6
	Sales/Marketing									6
	Medical devices IP									6
	Medical devices Venture Financing									6
Clinicians				4	4				5	4
Entrepreneurs									5	5

Appendix A: Steering Group Members

Representative	Organisation
Dr. Sean McDonagh	Former Director, Dundalk IoT
Mr. Finbar Dolan	Engineers Ireland/Medtronic
Mr. Richard Reilly	Engineers Ireland/UCD
Prof. Paddy Prendergast	TCD
Mr. John McAteer	Abbott Ireland
Ms. Sinead Keogh	IMDA
Mr. Niall O'Donnellan	Enterprise Ireland
Mr. John McGrath	FÁS
Mr. Pat Howlin	IDA Ireland
Mr. Martin Shanahan	Forfás
Mr. Gerard Walker	Forfás

Appendix B: EGFSN Members

Representative	Organisation
Ms. Anne Heraty (Chairperson)	CEO CPL Resources PLC
Ms. Ruth Carmody	Assistant Secretary, Department of Education and Science
Ms. Anne Forde	Principal Officer, Department of Education and Science
Ms. Liz Carroll	Training and Development Manager, ISME
Mr. Enda Connolly	Divisional Manager, IDA Ireland
Mr. Fergal Costello	Head of IoT Designation, Higher Education Authority
Mr. Ned Costello	Chief Executive, Irish Universities Association
Mr. Brendan Ellison	Principal Officer, Department of Finance
Mr. Roger Fox	Director of Planning and Research, FÁS
Mr. David Hedigan	Manager, Sectoral Enterprise Development Policy, Enterprise Ireland
Mr. Gary Keegan	Director, Acumen
Mr. John Martin	Director for Employment Labour and Social Affairs, OECD
Mr. Dermot Mulligan	Assistant Secretary, Department of Enterprise, Trade and Employment
Mr. Pat Hayden	Principal Officer, Department of Enterprise, Trade and Employment
Mr. Frank Mulvihill	President, Institute of Guidance Counsellors
Dr. Brendan Murphy	Director, Cork Institute of Technology
Mr. Alan Nuzum	CEO, Skillnets
Ms. Aileen O'Donoghue	Director of Financial Services Ireland, IBEC
Mr. Peter Rigney	Industrial Officer, ICTU
Ms. Jacinta Stewart	Chief Executive, City of Dublin VEC
Mr. Martin Shanahan	Head of Human Capital and Labour Market Policy Forfás, and Head of Secretariat

Appendix C: Publications by the Expert Group on Future Skills Needs

Report	Date of publication
The Future Skills and Research Needs of the International Financial Services Industry	December 2007
National Skills Bulletin 2007	October 2007
Monitoring Ireland's Skills Supply: Trends in Educational/Training Outputs	June 2007
Tomorrow's Skills: Towards a National Skills Strategy	March 2007
National Skills Bulletin 2006	December 2006
Future Skills Requirements of the International Digital Media Industry: Implications for Ireland	July 2006
Careers and Labour Market Information in Ireland	July 2006
Skills at Regional Level in Ireland	May 2006
SME Management Development in Ireland	May 2006
Monitoring Ireland's Skills Supply: Trends in Educational/Training Outputs	January 2006
Data Analysis of In-Employment Education and Training in Ireland	January 2006
National Skills Bulletin 2005	October 2005
Skills Needs in the Irish Economy: The Role of Migration	October 2005
Languages and Enterprise	May 2005
Skills Requirements of the Digital Content Industry in Ireland Phase I	February 2005
Innovate Market Sell	November 2004
The Supply and Demand for Researchers and Research Personnel	September 2004
Literature Review on Aspects of Training of those at Work in Ireland	June 2004
Financial Skills Monitoring Report	November 2003
Responding to Ireland's Growing Skills Needs – The Fourth Report of the Expert Group on Future Skills Needs	October 2003
The Demand and Supply of Skills in the Biotechnology Sector	September 2003
Skills Monitoring Report – Construction Industry 2003/10	July 2003
Benchmarking Education and Training for Economic Development in Ireland	July 2003
The Demand and Supply of Engineers and Engineering Technicians	June 2003
The Demand and Supply of Skills in the Food Processing Sector	April 2003
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 Irish Labour Market: Prospects for 2002 and Beyond	January 2002

Labour Participation Rates of the over 55s in Ireland	December 2001
The Third Report of the Expert Group on Future Skills Needs – Responding to Ireland's Growing Skills Needs	August 2001
Benchmarking Mechanisms and Strategies to Attract Researchers to Ireland	July 2001
Report on E-Business Skills	August 2000
Report on In-Company Training	August 2000
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
Business Education and Training Partnership Report on the Inaugural Forum, Royal Hospital Kilmainham	March 1999
The First Report of the Expert Group on Future Skills Needs – Responding to Ireland's Growing Skills Needs	December 1998

Appendix D: Glossary of Acronyms

CSO	Central Statistics Office
EGFSN	Expert Group on Future Skill Needs
FÁS	National Training & Employment Authority
EI	Enterprise Ireland
EU	European Union
FDA	US Food and Drug Administration
FETAC	Further Education and Training Awards Council
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICT	Information Communication Technology
IDA	Industrial Development Agency Ireland
IMDA	Irish Medical Devices Association
IRCSET	Irish Research Council for Science, Engineering and Technology
NACE	General Industrial Classification of Economic activities in the European Communities
NAICS	North American Industry Classification System
QC	Quality Control
QNHS	Quarterly National Household Survey
R&D	Research and Development
SLMRU	Skills and Labour Market Research Unit (FÁS)
US	United States
VC	Venture Capital