Irish Medtech Association
SKILLNET

Future skills needs analysis for the medical technology sector in Ireland to 2020

AN ROINN OIDEACHAIS AGUS SCILEANNA | DEPARTMENT OF EDUCATION AND SKILLS

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Foreword

Making Ireland the best country in which to do medtech business

Conor Russell, Chairman, Irish Medtech Association and VP Operations, Boston Scientific

Ireland's economy has been transformed in the past two decades. This transformation was driven by a combination of factors: a competitive business environment underpinned by our competitive corporation tax rate, access to 500 million consumers in the EU, and a strong pipeline of talented graduates amongst others.

In the 2016 International Institute for Management Development (IMD) World Rankings, Ireland was named as the seventh most competitive economy in the world, jumping nine places from sixteenth the previous year. As a small open economy, we were greatly affected by the recession and remain vulnerable to external influences. Ibec forecasted a nearly 3% growth for Ireland for 2017, a downgrade of nearly 1%, due to the uncertainty caused by political shifts in the UK and US. However, this growth is double the EU average and there are steps that can be taken to help us maximise this growth.

Government help is needed to allow companies to transition and diversify, explore the risks associated with potential trade barriers, and invest in education and infrastructure. Moreover, if we remain adaptable and dynamic, changes in the UK and US could create new business and investment opportunities for Ireland.
Ireland's growth has been driven by increased productivity and improved competitiveness. With its proven track record in innovation, operational excellence and lean business models, the medtech sector in Ireland stands out as a success story.

Ireland's reputation as a global hub is well established with 18 of the world's top 25 medtech companies based here. In addition, the number of companies has increased from 50 in the early 1990s to well over 450 in 2017, marking a sustained period of growth for small and medium enterprises (SMEs), with as many as 60% of these being home grown. Additionally, in this survey of individuals working in the medtech sector in Ireland, one in 10 respondents identified their site as their organisation's European Headquarters, highlighting Ireland's role not just as a good place to start and grow a business, but as a strategic location of choice to access key markets.

Employment levels remain one of the most reliable indicators of growth. In Ireland, employment has reached two million people for the first time since 2008 and the economic downturn. Moreover, employment is forecasted to grow 2.4% in 2017, bringing it up to the level seen in 2006. Similarly, in the medtech sector, strong jobs growth is expected in the years ahead. More than 2,000 jobs have been added in recent years and, as outlined in this report, it is planned to create an additional 4,000 jobs by 2020.

While some of these jobs represent the replacement of existing staff, most are newly created positions with expanding companies. To ensure that the sector is adequately equipped to ensure the talent pipeline for the future, the Irish Medtech Association and the Irish Medtech Association Skillnet commissioned Grant Thornton to research the skills that will be needed in the medtech sector from now until 2020. The result is this report. The Irish Medtech Association is a business group within Ibec that represents the medical technology industry in Ireland.

Talent for the 21st century workplace

Sinead Keogh, Director, Irish Medtech Association

As the medtech sector entered a new age with the beginning of the 21st century, it marked a new period of innovation and growth. To support it on its journey, the Irish Medtech Association was founded in 2000. Since that time, managing the talent pipeline to help the sector reach its potential has been a priority. Now technology is transforming both our workplaces and our workforce. To help companies continue to compete and adapt as a leading global medtech hub we've identified three key approaches:

- **Blended skillsets**
  New technologies will mean more connectivity and collaboration, employees will need more blended skillset to innovate and develop medtech solutions beyond traditional departmental divides.
- **Structured employee development**
  New structured training programmes will need to be developed and customised to ensure that employees have the adequate skills, beyond third level qualifications, to work in a constantly evolving industry.
- **Attracting talent with transferable skills**
  New avenues for recruitment must be pursued with a focus on talent with transferable skills from other hi-tech sectors and introduce procedures to ensure successful integration of these professionals.

The findings highlight two key requirements in the sector: to upskill existing staff and to work to ensure third-level courses remain relevant for the changing workplace. There is also a need for new courses, training programmes, as well as new models of delivery which work in the workplace.

Global disruptors are also revolutionising how the medtech industry does business. With guidance from the Irish Medtech Association Board and input from the wider membership, the research identified five global industry disruptors that will affect the skills requirement for the future, namely:

- New healthcare delivery models (connected health and smart drug delivery)
- Serving lower socio-economic and emerging markets
- Technology and information communications technology (ICT)
- Cost containment
- Evolving regulatory frameworks across key jurisdictions

Irish Medtech Association
Ibec

Most advanced economies are now witnessing a major demographic shift, with aging populations and chronic diseases which are affecting more people, including younger cohorts who are making poor lifestyle and health choices. In fact, by 2020, 40% of Ireland's population is expected to have a chronic disease.

But, we know that medtech can be instrumental in alleviating the burdens placed on our healthcare systems as well as help to identify new patient pathways to make sure people get the treatment they need. At the heart of this is the to move from developing products to solutions, our focus, in the medtech industry now, is on a more holistic approach which encompasses a suite of services, not just life saving devices or products.

The next link in the chain is ensuring that we have empowered patients. This comes from two core elements, better understanding and new technologies. And with 12,400 patents filed by the medtech sector, in 2015, in Europe according to the latest figures it's clear that we're innovating for future healthcare. But the next big phase of our development will include convergence with other sectors such as pharma for sophisticated smart drug delivery and ICT/software for connected health.

Ireland is uniquely placed to become a leader in connected health, with not only a global medtech hub, but also nine of the top 10 biopharma companies and 10 of the top 10 ICT companies. The Irish Medtech Association has started to bring our shared expertise together, through Ibec, by setting-up an Internet of Medical Things Skillnet, with Technology Ireland and BioPharmaChem Ireland.

Another initiative that the association has been leading is the development of two new apprenticeships in manufacturing at NFQ level 6 and NFQ level 7 which will be launched in 2017 to help support the development of key manufacturing skills for the sector. What is evident from the research is the need to invest in infrastructure to support the upskilling of niche high-end advanced and additive manufacturing skills.

We strongly recommend the establishment of an advanced centre for manufacturing to support the development of skills for the discrete manufacturing sector. Already international medtech jurisdictions such as the UK, Germany, Singapore and the US are making strides with significant investment in research and technology organisations for manufacturing. The UK Advanced Manufacturing Catapult (Coventry) has been identified as an example of best practice for both manufacturing research which is nearer to commercialisation at technology readiness levels (TRL's) 4 – 7 and for high-end training. For Ireland to compete globally, it must invest in the necessary and appropriate infrastructure to ensure we don't fall behind.

The Irish Medtech Association is committed to working with the various stakeholders to support the development of the infrastructure to equip people with the prerequisite skills for future careers in the sector.

Equipping Ireland's talent for growth

Irish Medtech Association Skillnet Manager, Pauline O'Flanagan

Since 2008, the Irish Medtech Skillnet has been a major driver of upskilling in the medtech industry in Ireland with more than 7,500 people trained in over 37,000 days. This highlights the importance and need for industry-led programmes to prepare professionals to work in this exciting and innovative sector.

According to the OECD, Ireland has a higher than average rate of third level educational attainment, with 52% of 25–34-year-olds holding a degree compared to 42% in the rest of Europe. This has helped us to attract foreign direct investment (FDI) and grow businesses, but to compete, we must build on and develop alternative routes to high-quality medtech careers.

In the most recent Science Foundation Ireland (SFI) Science Barometer, conducted in October 2015, 88% of respondents said that the supply of science, technology, engineering, and maths (STEM) graduates are vital to the economy.

There has also been a continued rise in the uptake of students studying STEM subjects at Leaving Certificate level, resulting in more people pursuing STEM-related courses at third level.

Now, as an industry, we must capitalise on this interest and make students, teachers, and parents aware of the high-quality career opportunities in our growing industry. This report helps to identify opportunities and paths to medtech careers.

Medtech companies are eager to engage with the public: they annually join the Ibec stand at the BT Young Scientist Exhibition, they are involved in Smart Futures and in the Ibec Global Graduate programme, and they have organised several well-publicised regional outreach events across the country. Additionally, the Irish Medtech Association will continue to work with our members and MedTech Europe to increase the awareness and understanding amongst the public of how medtech saves and transforms lives.

Irish Medtech Association SKILLNET

In 2016, the Irish Medtech Association commissioned RED C to conduct a survey to gauge public awareness of the medtech sector. The survey showed that those in the 18–24-year-old age category had a higher awareness and understanding than the older category, with nearly two thirds (63%) saying that they had heard of medtech.

Additionally, the survey found that when medtech is described as the use of technology to diagnose, monitor, and treat patients – from developing reading glasses to improve eyesight and pacemakers for heart conditions, to improving hospital monitors and ultrasounds, over one in four (28%) claimed that they knew somebody working in the industry. This highlights the reach of the industry across the population.

Ireland has a particularly young population, with approximately 40% below the age of 30, so it is positive to note that the awareness of medtech is high amongst this important age group. These demographic trends will also have meaningful repercussions on business practices in the next few years, with millennials making up 50% of the global workforce by 2020.

With such a young workforce, we need to prepare for the long-term growth of the medtech industry in Ireland, by taking note of the strengths of our education and skills development as well as identifying both gaps and opportunities. This report identifies these strengths, gaps, and opportunities, and signifies the ongoing work by the medtech industry to build a workforce of the future.

Executive summary and recommendations

Growing Ireland's global medtech hub

Ireland is internationally recognised as a global medtech hub with 18 of the world's top 25 medtech companies based here. In addition to the significant operations by foreign direct investment (FDI) businesses, as many as 60% of the 450+ medtech businesses in Ireland are home grown, and 80% are small and medium enterprises (SMEs). Strong growth in the sector has seen significant investment with nearly €750 million announced since 2014. In addition, exports account for 10% of Irish goods exports and are worth €12.6 billion. This has led to continued jobs growth with more than 29,000 people now working in the sector, making Ireland the second largest employer of medtech professionals in Europe, per capita.

To support the sustainable growth of this ambitious industry that has seen annual global growth of 5.5% and is forecasted to grow to $477.5 billion (€455 billion) by 2020, the Irish Medtech Association and the Irish Medtech Association Skillnet consulted its members to identify their future skills needs. A detailed survey was carried out by Grant Thornton in 2016 with the participation of 52 Irish Medtech Association members. The respondents represent approximately 20,411 employees, which accounts for 70% of the 29,000 people employed in the Irish medtech industry.

Medtech talent pipeline

Senior business leaders were asked to identify the current number of employees required to meet their current skills demand, as well as the forecasted number of employees required in each function of their organisation up to 2020. An estimated 4,000 additional jobs are planned by 2020, the details of which can be seen in the following table.

Table 1: Future skills gaps by function up to 2020

Business function	Additional number of employees required up to 2020 (% increase from 2016)
Operations	2,033 (18%)
Engineering	376 (23%)
R&D	363 (51%)
Supply chain	164 (29%)
Regulatory	54 (43%)
Quality	287 (17%)
Finance/procurement	35 (10%)
Sales/marketing	90 (49%)
Human Resources (HR)	20 (12%)
Business excellence	100 (78%)
Commercialisation	10 (23%)
Data analytics	30 (56%)
Scientists	102 (74%)
Other	320 (9%)
TOTAL	**3,984**

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Survey

Global industry disruptors

The survey respondents identified several global industry disruptors that significantly impact the medtech industry as a whole, as well as the skills needed within. An overview of the disruptors covered in the report is outlined in the following sections.

1. New healthcare delivery models

Technological advancements have enabled medtech companies to reassess the traditional approach to the delivery of healthcare. The two key factors are connected health technologies and smart drug delivery solutions, and both are outlined in the report.

1.1 Connected health technologies

Connected health aims to advance healthcare by moving solutions from the clinic into the day-to-day lives of patients, to ultimately deliver better health outcomes for the patient and a more efficient process for hospitals. This is achieved using mobile technology, computers, networked devices, and remote monitoring tools. Connected health will increase medtech companies' requirements for software and other skillsets related to connected health.

1.2 Smart drug delivery solutions

Drug delivery systems are engineered technologies for the targeted delivery and controlled release of therapeutic agents. Drugs have long been used to improve health and extend lives. The practice of drug delivery has changed dramatically in the past few decades and even greater changes are anticipated soon, with advanced and innovative delivery systems needed. With Ireland's strong presence of medtech and pharmaceutical companies, we are uniquely positioned to compete in this growing market, which will need new and additional skillsets.

2. Serving lower socio-economic and emerging markets

When exploring emerging markets, medtech companies must consider the available opportunities in lower socio-economic settings where low cost and value are the priorities. Exploring emerging markets has led to companies generating local growth in emerging markets by creating devices that can both improve patient outcomes and cut costs.

An example of this was highlighted in the University of Pennsylvania's 2010 paper, 'Reverse innovation', which detailed a manufacturer in Bangalore, India, who developed a handheld Electrocardiogram (EKG) device. Although the device does not have the full capabilities of the full-scale offering, it appeals to the emerging Indian market because it retails for half the cost of the full-scale device.

3. Technology and ICT

Technological innovation is leading to growth in several medtech disciplines including robotics, analytics, and machine-to-machine technologies. It is also leading to the development of innovative software applications. Advances have also contributed to the growth of trends such as additive manufacturing, also known as 3D printing. Through this technology, customised orthopaedic implants, preoperative models, prosthetics limbs, and customised casts can be produced to meet the specific requirements of the patient. Medtech companies will need employees with specific additive manufacturing skills, including computer-aided design (CAD), additive manufacturing machine operation, raw material development, robotics, and supply chain management

4. Cost containment

As the industry has evolved, the role of the consumer has changed which has also influenced the market demand. The relationship between medical device companies and the physician has become more complex and often less direct, as hospitals consolidate to increase buyer power. The formation of hospital groups has led to an increase in purchasing power for medical institutions, and the assigned procurement departments approach the buying process with a more commercialised focus than before. Changes will require the medtech sector to develop more sophisticated commercial skillsets, including health technology assessment and value-based procurement.

5. Evolving regulatory frameworks across key jurisdictions

Periods of regulatory change have continuously shaped the medtech industry but, globally, the sector is currently experiencing regulatory change at an unprecedented pace. New regulatory requirements with sometimes stringent implementation timelines are emerging from multiple global jurisdictions. There is a need for constant upskilling in the area of regulatory skills for global markets so that the industry can continue to compete and bring innovative technologies to market.

Recommendations

Theme 1: Ensuring Ireland's workforce are equipped for the jobs of the future

Ireland's high level of qualified graduates has been a major factor in attracting investment and driving growth. The number of new full-time undergraduates entering higher education has now risen to 41,400, an increase of 7% according to the Higher Education Authority (HEA). Moreover, an increasing number of graduates are entering the labour market, with 210,000 entering in 2014/2015, increasing from 196,000 in 2011/2012.

In addition, Ireland performs well for science, technology, engineering, and maths (STEM) qualifications. The most recent Eurostat data, from 2014, showed that we have the second highest percentage of students with a tertiary degree studying science, maths, and computing in the EU. While Ireland's young and well-educated workforce is an asset, it is essential that they have the right skills for the careers of the future.

Recommendations

1. Review third-level courses to ensure that the curriculum provides graduates with the right skills to work in industry. Consult industry to develop new course modules where necessary.
2. Tackle non-progression rates of students from first year to the next academic year. Concentrate on engineering, which is essential to the medtech and other technology sectors, but, according to the Higher Education Authority, has a very high non-progression rate. Prior academic attainment is an important predictor of non-progression so more needs to be done to ensure that STEM subjects, most notably maths, are adequately taught at second level.
3. Ensure that STEM teachers at second level have the appropriate qualifications. Currently, physics and chemistry are underserved whilst biology is over represented in schools.
4. Embed STEM education as a core part of the curriculum at primary level and equip teachers to become STEM champions through training and development.
5. Establish a medtech international graduate placement programme in key areas, such as sales and marketing, which are highly specialised in medtech compared with the wider business environment. Commercial skills are critical to start-ups and multinationals, but this expertise is not developed in traditional courses which lead to medtech careers.

Theme 2: Invest in further education, upskilling, and alternative routes to medtech careers

The increased funding for third-level education in Budget 2017 (€35 million) is a positive development as third-level education has been under great pressure in recent years due to funding cuts along with rising student numbers. Nearly all Irish universities fell in the Quacquarelli Symonds (QS) World University Rankings 2016/2017, including Trinity College Dublin (TCD), which is now the only Irish university in the top 100. However, traditional third-level courses are not the only routes to careers funded and supported by the Government.

The importance of having a world-class facility to support the upskilling of manufacturing professionals in the areas of additive, data analytics, industrial internet of things, cobots, simulation, cloud computing, systems integration, augmented reality, and cybersecurity cannot be underestimated. Already international medtech jurisdictions such as the UK, Germany, Singapore and the US are making strides with significant investment in research and technology organisations for manufacturing. For Ireland to compete globally, it must invest in the necessary and appropriate infrastructure to succeed.

The National Training Fund, which is financed by the business sector, was set up to support non-traditional routes. During the financial crisis, the focus was placed on getting people into jobs. As the recovery continues, this needs to change because only 20% is currently allocated to developing skills for those in employment. Ireland has a poor adoption of lifelong learning and upskilling, with a figure of 7.3%. This is below the EU average of 10.5%, so this needs to be addressed.

Recommendations

1. Establish a centre for advanced discrete manufacturing to support the upskilling of niche, high-end manufacturing skills for the discrete manufacturing sectors. The biopharma sector is well served in this regard through the National Institute for Bioprocessing Research and Training (NIBRT).
2. Invest in third-level education and review the funding models. Nearly 13 years ago, the OECD advised the Government that it was impossible to have quality higher education by predominantly relying on state funding. It was suggested that an income-contingent student loan system should be introduced.
3. Redress the balance in National Training Fund allocation. With continued strong growth that is underscored by improvements in employment, with employment numbers approaching 2006 peak levels and unemployment at 8% (non-seasonally adjusted), the focus needs to reflect labour market needs with more focus on upskilling.

4. Restore Skillnet funding to €23 million to support upskilling programmes with a proven record of responding efficiently to emerging skills demands. Also, continue to support the running of Springboard conversion programmes for engineers to feed the medtech sector. The recent inclusion of medtech under the new Springboard+ call is welcomed; however, skills that are in high demand and necessary for Ireland to continue to compete globally should be prioritised and funded under this call.
5. Ensure that the new apprenticeship model is properly funded for the long term and that the governance model protects the commitment for an enterprise-led programme similar to the successful German model.
6. Ensure that existing post leaving certificate courses are expanded and aligned to meet the needs of the medtech sector in level 6 skills, including quality, health, safety and environment, lean techniques, metrology, mechanics, preventative maintenance, electrics, programmatic logic control, robotics, and automation.
7. Target the underemployed and part-time employed engineering and science graduates working in non-related sectors to convert to full-time employment in the medtech and polymer sectors. This can be achieved by widening the entry requirements for the Springboard and Job Seeker Support Programme (JSSP) Skillnets programme to both people on the live register and recent graduates.
8. Continue to fund cross-department collaboration projects between the Industrial Development Authority (IDA) Ireland, the Department of Social Protection, and Skillnets. Also include Enterprise Ireland by running short targeted regional conversion programmes to meet the needs of the medtech and plastics companies. The Irish Medtech Association have successfully supported four regional forums in the northwest, midlands, southeast, and east.
9. Review the demand for developing a continuing professional development (CPD) policy for the medtech industry to provide alternative ways of maintaining a flexible and skilled workforce.
10. Support the Internet of Medical Things Skillnet, with the Irish Medtech Association, BioPharmaChem Ireland, and Technology Ireland. This new Skillnet will develop and deliver industry-led training and courses for people working in the sector and reskilling to work in this strategic growth area.

Theme 3: Develop competency models for the sector

Industry disruptors such as advanced manufacturing and connected health will require medtech companies to assess the skills of their existing employees, to ensure new hires have the required skills and competencies, and to assess the effectiveness of the training and education programme for their staff.

The role-related competencies that incorporate the necessary knowledge and abilities for the medtech sector need to be captured in the competency models that are used for recruitment and performance management by HR departments.

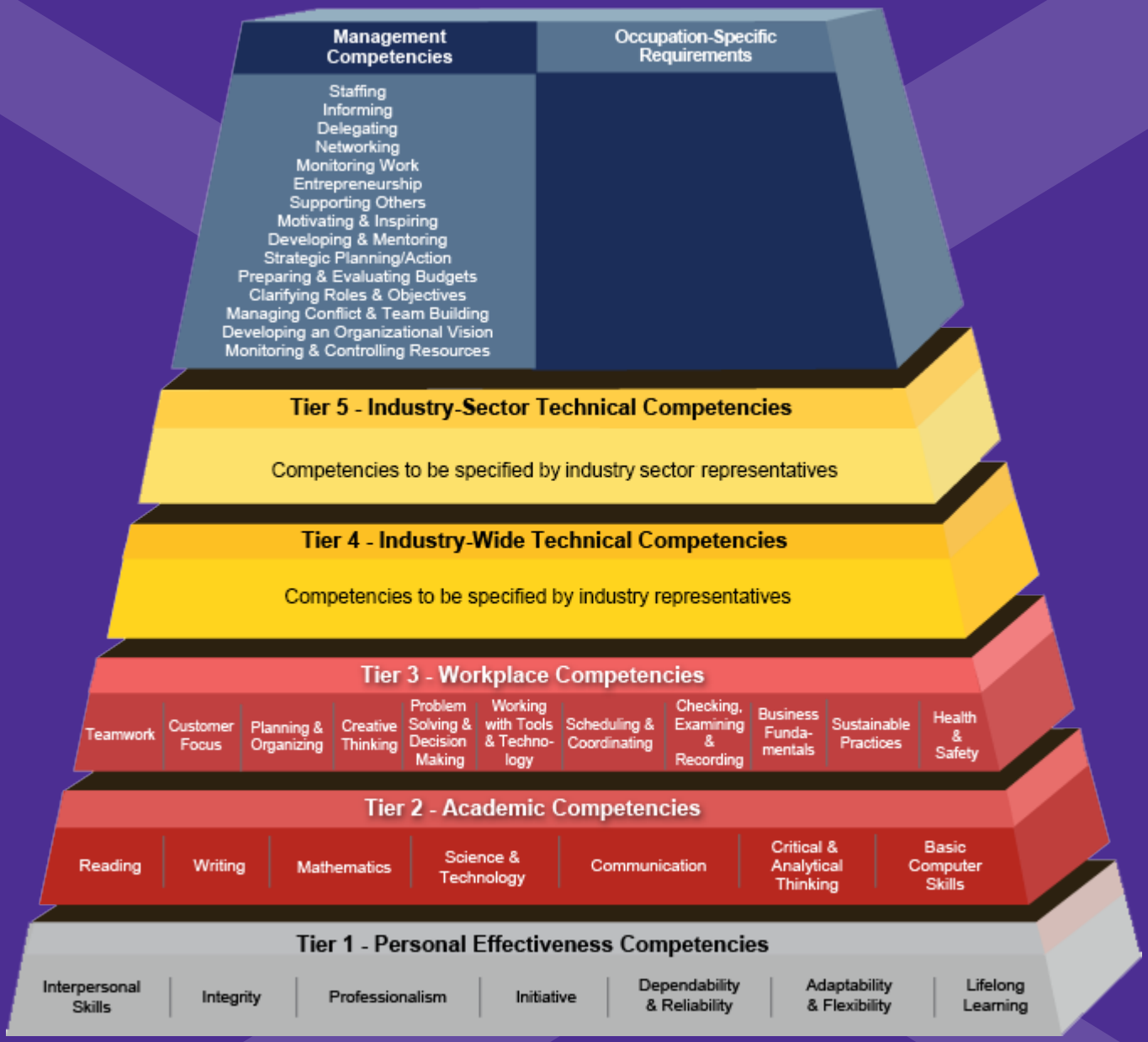
A competency model is a behavioural job description that must be defined by each occupational function and each job specifically.

To understand the requirements of a job role, they are often mapped out. The following figure illustrates general competency models from foundational competencies to management and occupation specific requirements.

Recommendation

1. Design and deliver industry competency models to identify knowledge skills and competencies for occupations in the medtech sector with a focus on key areas and disruptors such as advanced manufacturing, regulatory affairs, and connected health. International best practices, such as those set out in the US Department of Labour guides by the Employment and Training Administration, should be consulted to design and deliver these models.

Figure 1: General Competency Models



Source: The Employment and Training Administration, Departments of Labor and Education.

Theme 4: Promote medtech careers and improve understanding of the sector

In 2016, the Irish Medtech Association engaged RED C to conduct a survey to measure the public's understanding and perception of the medtech sector in Ireland, as well as compare it to understanding and perception of other technology sectors. The research was conducted online using RED C's nationally representative panel of over 31,000 panellists, with a sample size of 1,011. It was controlled and weighted for gender, age, social class, and region to ensure a nationally representative sample was achieved.

Without any description of the industry, 53% of respondents claimed to be aware of the medtech industry. However, an understanding of the industry was found to be lower than the awareness of it. Medtech awareness was highest among 18–24-year-olds, higher social classes, and those with a relationship to medtech, such as a friend or acquaintance working in the industry. When described as, 'the technology used to diagnose, monitor and treat patients - from reading glasses to improve eyesight, and pacemakers for heart conditions, to hospital monitors and ultrasounds', over 1 in 4 (28%) claimed that they knew somebody working in the industry.

The medtech industry in Ireland, supported by the Irish Medtech Association and Medtech Europe, has done extensive work to highlight how the sector saves and improves lives. However, the research indicates that while awareness is increasing, the sector would benefit from continued work to improve understanding amongst students, teachers, and parents of what this dynamic and diverse sector does and the benefits it brings both to the economy and society.

Recommendations

1. Support the Department of Education and Skills recommendations to recognise extracurricular initiatives that promote STEM education, at both primary and second level, such as the BT Young Scientist Exhibition, Smart Futures, SciFest, CoderDojo and so on. A higher level of industry involvement also needs to be encouraged.
2. Reform the career guidance service by providing schools with the resources to employ contracted specialist providers and ensure that they are adequately equipped to advise students, and their parents, on the entry requirements and career prospects offered by STEM.
3. Promote vocational education programmes to make medtech careers available to people from non-traditional academic routes. Encourage mature students to pursue STEM education and make them aware of reserved places in courses that may be beneficial.
4. Develop a roadmap to medtech careers charting which subjects are needed at Junior Certificate Level through to PhD level for core medtech roles to ensure students, parents, and teachers understand the opportunities and necessary qualifications.

Theme 5: Make Ireland an employment destination of choice for mobile talent

The medtech sector is an important strategic industry for driving jobs and exporting growth underpinned by regular investments. The medtech sector in Ireland has evolved over the past 15 years. The focus has shifted from the manufacturing of medical devices and products to a much broader offering in medical technology and holistic solutions. To drive further growth of this global industry and support innovation, we want the medtech sector to be represented by a dynamic global workforce.

Ireland has been very successful is attracting tourism through Fáilte Ireland and initiatives such as The Gathering. More than a third medtech investment to Europe goes to Ireland, thanks in part to the work of the IDA. Ireland should be marketed as a global location where medtech professionals come to fast-track their careers. We should market working in Ireland, not just in a particular company, as a significant achievement for talented medtech and engineering professionals.

Recommendations

1. Support a cross-industry and government department or agency initiative to market Ireland internationally as a leading location to develop medtech and engineering careers.
2. Support ongoing reform of the visa and work permit process, and maintain the newly established 'trusted partner' regime for Enterprise Ireland and IDA client companies.
3. Develop an international talent acquisition strategy for the medtech and engineering sectors. Expand the remit of Tech/Life Ireland, a national initiative to brand Ireland as a top destination to pursue a career in technology to include medtech. Tech/Life Ireland is a focused international marketing initiative with a dedicated website, www.techlifeireland.com, to attract talented and experienced tech experts to Ireland and to promote top tech career opportunities here.
4. Amend the personal taxation system to better reward work and make it more attractive to mobile talent. Due to Ireland's high marginal income tax rate, we will continue to struggle to compete with rival jurisdictions to attract foreign talent, particularly at a senior level to relocate here. Examples were provided by survey respondents where strategic senior roles were lost to other global jurisdictions because of the rate of marginal tax for high earners in Ireland. In many cases, these global roles generate further employment, growth and enhances the sites reputation from a corporate context.
5. Invest in infrastructure to help make Ireland the best place to both live and work. We need to consider planning and increased state investment in transport, broadband, water services, health, and education infrastructures throughout the whole of Ireland. With medtech sites in every Irish constituency, it is vital that we have the appropriate resources and level of connectivity.

Theme 6: Embed entrepreneurial education at second level

Entrepreneurship and start-ups are a vital part of the medtech ecosystem. As much as 80% of the 450 medtech companies are either an SME or a start-up, with 60% being indigenous. Many new innovations come from start-ups that are agile and can respond quickly to changing market dynamics.

The Irish Medtech Association supports initiatives such as BioInnovate that are aimed at giving budding entrepreneurs the necessary skills and guidance to start a medtech company in a structured world class environment. However, more must be done to support entrepreneurship much earlier in the education process, from primary level to higher education level.

In 2015, Ibec set out a vision for "Entrepreneurship Education: Policy recommendations to deliver the skills needed for the workplace of the future". This outlines several recommendations to support the development of more entrepreneurial thinking.

Recommendations

1. Change the thinking around entrepreneurship by embedding key aspects such as resilience, critical thinking, communications skills, intelligent risk taking, and collaboration across the curriculum from primary level to higher education.
2. Build creativity, innovation, problem solving, adaptability, and risk taking for entrepreneurship at all levels of education.
3. Continue to invest and expand the BioInnovate programme, to provide risk takers with the skills needed to start a medtech company.

Theme 7: Make Ireland a world leader for addressing the gender imbalance in STEM

According to the Science Foundation Ireland (SFI) Science Barometer in Ireland, conducted in October 2015, as many as 85% of adults think it is important to attract more girls into STEM. But according to Eurostat, women made up 39.2% of the total high-tech manufacturing labour force in the EU. In addition, over 50% of all high-tech manufacturing employees were women in just five EU countries.

At executive leadership level, the Advanced Medical Technology Association (AdvaMed), the US trade association for medtech, conducted a survey that showed that Fortune 500 companies with more than three women on the board had 66% higher return on invested capital and 42% higher return on sales. However, only 4% were CEOs, even though as many as 73% healthcare companies had female managers.

Irish women are more likely to have a third-level qualification than men, with more than half of women aged 25–35 having a third-level qualification compared to just four out of ten men. In addition, according to the Higher Education Authority, women have better progression rates than men. As a result, it's clear that we must diversify to attract the best people and build a broad base, to grow the pipeline.

Recommendations

1. Form and lead a national coalition, with government and industry collaborating to address the gender imbalance, including at senior level, in the medtech and the broader manufacturing sectors.
2. Make childcare more accessible and improve target expenditure payments through means testing. The Government should develop a new affordable childcare strategy by 2020, achieving an equal split between child benefit payments and childcare services. Bring Ireland's low adult-to-child ratio for childcare in line with other European countries.
3. In Ireland the tax treatment of married couples is one of joint taxation which results in tax disincentives for the second earner, often the female, to work. Participation Tax Rates (PTR) measure the proportion of income that would be taxed away when a person starts working due to tax or lost benefits. Due to the narrow tax base and low tax rates charged on initial incomes, average PTR's for second earners in Ireland appear to be the second lowest in the EU. This should mean that there is a very strong incentive to enter the workforce as only 18% of earnings would be taken away. However, this does not take into account childcare costs which also reduce the financial incentives from working. Once these costs are taken into account, PTR's go from being one of the lowest in the EU to one of the highest. Employees with no childcare costs will only lose 18% of their income, compared to 92% for someone with children.

Section 1: Global industry disruptors

Global industry overview

Introduction

This section provides an overview of the medtech industry, including the following:

- A breakdown of medical device classifications
- An overview of the medtech industry leaders
- An analysis of global industry disruptors

According to the Whitaker Institute, the medtech industry is one of fastest growing segments globally within the healthcare industry. As referenced by life science market intelligence group, Evaluate Ltd, in a 2015 industry overview report, the market size of the global medtech market was worth $375 billion in 2014 and it is forecasted to reach $477 billion by 2020.

The medtech sector is highly regulated. It is divided by the European Commission into the two following categories:

- Medical devices
- In-vitro diagnostic devices (IVDs)

This categorisation allows the risk classification of devices to be clear. While this breakdown is broad, it highlights the wide scope of medical devices and of the medtech industry. A definition of both categorisations is detailed in the following sections.

Medical devices

The European Commission defines medical technology as, *'Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.'*

'Devices are to be used for the purpose of:

- *Diagnosis, prevention, monitoring, treatment or alleviation of disease*
- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap*
- *Investigation, replacement or modification of the anatomy or of a physiological process*
- *Control of conception*

This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.'

IVDs

The European Commission defines an IVD as, *'any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*

- *concerning a physiological or pathological state, or*
- *concerning a congenital abnormality, or*
- *to determine the safety and compatibility with potential recipients, or*
- *to monitor therapeutic measures.'*

Medical device classification

According to Medtech Europe, there are currently over 500,000 medical technology product groups (medical devices and IVD combined) registered in the EU. The industry is typically sub-divided further into 16 categories of medical devices for clarity of patent registration, as determined by the Global Medical Devices Nomenclature (GMDN) Agency.

See the following table for further classifications and examples.

Table 2: Classification of types of medical devices as per GMDN

No.	Classification	Example
1	Active implantable technology	Cardiac pacemakers, neurostimulators
2	Anaesthetic respiratory technology	Oxygen mask, gas delivery unit, anaesthesia breathing unit
3	Dental technology	Dentistry tools, alloys, resin, floss, brushes
4	Electromechanical medical technology	X-ray machine, laser, scanner
5	Hospital hardware	Hospital bed
6	In vitro diagnostic technology	Pregnancy test, generic test, glucose strip
7	Non-active implantable technology	Hip or knee joint replacement, cardiac stent
8	Ophthalmic and optical technology	Spectacles, contact lenses, intraocular lenses, ophthalmoscope
9	Reusable instruments	Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes
10	Single use technology	Syringes, needles, latex gloves, balloon catheters
11	Technical aids for disabled	Wheelchairs, walking frames, hearing aids
12	Diagnostic and therapeutic radiation technology	Radiotherapy units
13	Complementary therapy devices	Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups
14	Biological derived devices	Biological heart valves
15	Healthcare facility products and adaptions	Gas delivery systems
16	Laboratory equipment	Most IVDs which are not reagents

Source: Global Medical Devices Nomenclature (GMDN) Agency (2010)

Medical technology companies

The table below outlines the largest medtech companies globally by revenue ($ billion), as of 2016.

Table 3: Global medtech companies by revenue

No.	Company	Global headquarters	Medtech revenue 2015 ($ billion)	No. of employees	Sample product categories
1	Johnson & Johnson*	USA	25.1	127,100	Orthopaedics Wound care Contact lenses Diabetes care
2	Medtronic*	Ireland	20.2	92,500	Cardiovascular products Neurological products
3	GE Healthcare*	UK	17.6	52,000	Anesthesia delivery instruments Clinical consumables
4	Siemens Healthcare*	Germany	14.5	45,000	Hearing instruments Laboratory diagnostics instruments
5	Philips Healthcare	Netherlands	11.9	37,008	Advanced molecular imaging solutions Clinical informatics solutions
6	Cardinal Health*	USA	11.4	34,500	Laboratory products Patient monitoring products
7	Danaher Corp.*	USA	10.9	81,000	Diagnostic solutions Dental solutions
8	Becton Dickinson and Company*	USA	10.3	49,517	Smart infusion pumps Automated medication Administration cabinets
9	Baxter international*	USA	10.0	50,000	IV and irrigation solutions Needle-free connectors
10	Stryker Corp.*	USA	9.9	27,000	Orthopaedic implants Neurotechnology and Operating Room equipment. including Endoscopy, Surgical Robotics and Powertools.

Source: Medical Product Outsourcing (MPO) – Top Global Medical Device Companies (2016)
** Indicates that the company has a manufacturing facility or facilities in Ireland*

Global medtech hubs

Introduction

The US and Europe have traditionally been global industry leaders in medtech innovation and revenue earned by companies operating within their markets. According to the US Department of Commerce (DOC), the US medtech market was valued at $148 billion in 2015, while Medtech Europe reported that the European market was valued at approximately $106 billion in the same year. However, a number of countries including Japan, China, Brazil, and India show high levels of industry growth. Analysis of both established and emerging global medtech hubs is detailed in Appendix B 'Global medtech hubs'. Figure 2 identifies the market share of the global medtech industry by geographical location in 2014.

This section analyses the medtech industries in a number of medtech hubs, including the US, China, the United Kingdom, and Germany. Table 4 outlines some of the key performance indicators of each established medtech hub as of 2014. Note that the Irish medtech market is represented in the table for comparison purposes and is analysed independently in Section 4, 'Future medtech skills needed for 2020', of this report.

Figure 2: Global medtech market share in 2014

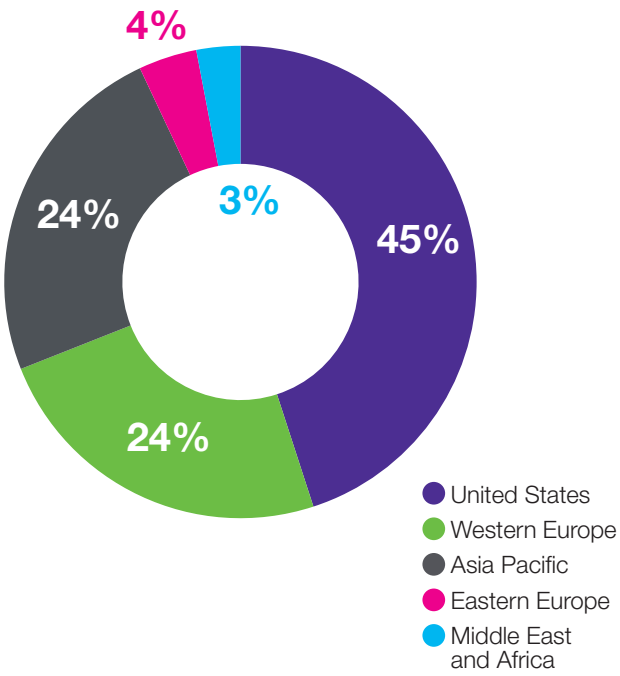


Table 4: Overview of international medtech hubs

Country	Number of medtech companies	Size of workforce	Export value (€ billion)	Health expenditure as a % of GDP
USA	7,000	400,000	42.6	17.5
Japan	30	>90,000	30.8	10.2
United Kingdom	Over 1,000	65,000	6.1	11.5
Germany	11,000	175,000	28.0	8.7
Ireland (2015)	450	29,000	12.6	10.2

Source: www.mitc.com - Medical Devices Resource Guide China and Japan (2014)
Source: www.mddionline.com
Source: medtech Europe - The European Medical Technology Industry in Figures (2014)
Source: www.worldbank.org

Global industry disruptors

As originally defined by Harvard Business School (HBS) Professor of Business Administration, Clayton M. Christensen, an industry disruptor is a:
'disruptive innovation that creates a new market and value network and eventually disrupts an existing market and value network, displacing established market leading firms, products or alliances.'

Medtech industry disruptors such as the emergence of new healthcare delivery models, advancements in ICT, cost containment, the need to serve lower-economic and emerging markets and increased regulation are significantly impacting the medtech industry in Ireland and internationally. According to A.T. Kearney's 2014 report, 'Medical devices: Equipped for the future?', disruptors have the potential to cost the global medtech industry up to $34 billion if companies do not adapt to the changing landscape of the industry.

This section outlines a number of global industry disruptors that have emerged in the medical device industry. These disruptors are outlined in figure 3.

New healthcare delivery models

Technological advancements have enabled medtech companies to reassess the traditional approach to the delivery of healthcare. A number of factors that impact the delivery of healthcare are outlined in this section, including the following:

- Connected health
- Smart drug delivery

Connected health

Connected health is a relatively new model for healthcare that uses technology to provide healthcare remotely. It aims to make accurate actionable information available in a timely manner to those that need it most. It allows patients and clinicians to make better decisions, can save lives and money, and can ensure a better quality of life during and after treatment.

Applied Research for Connected Health (ARCH) is an example of an industry driven technology centre for connected health research in Ireland. It provides access to world class clinicians, academics, and patient cohorts to explore and evaluate potential connected health solutions for the global market.

The adoption of connected health supports an environment where patients are treated in the best location, by the best person, using the most relevant and efficient methods. It reduces waste, duplication, and system costs while maintaining or improving patient quality of life.

Chronic diseases are long-term, life-limiting conditions that can be treated and controlled but not cured. According to the Health Service Executive (HSE), approximately 40% of the adult population in Ireland will have a chronic disease by 2020. The global facts are significant, with the World Health Organization (WHO) predicting that chronic diseases will increase by 10–15% in developed countries over the next decade. These clinical needs will require an increased level of monitoring and self-care management over the coming years. Connected health solutions can provide increased and flexible opportunities for patients to engage

Figure 3: Key global industry disruptors

Source: AT Kearney – Medical devices: Equipped for the future? (2015)

with clinicians and to better self-manage their care through the use of mobile technology, networked devices, and remote monitoring tools. A number of connected health solutions were identified throughout the research and stakeholder engagement processes. These solutions are as follows:

- Remote patient monitoring
- Patient engagement systems
- Medication adherence and monitoring
- Connected clinical trials
- Patient management systems
- Connected diagnostics
- Remote access to clinical expertise

The connected health solutions listed above are used in the treatment and management of a number of primary chronic diseases. In particular, connected health facilitates longer term disease management programmes for Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD), diabetes, hypertension, stroke, and various forms of cancer. For example, Health Recovery Solutions launched 'Patient Connect' in 2014, an application designed to enable patients with CHF to better manage their condition. The application allows patients to record medication, weight, activity, and symptoms. This data can subsequently be tracked by clinicians and caregivers.

The application also allows patients to communicate with their physician through text and video chat. According to Mobihealth News, the implementation of 'Patient Connect' reduced the 30-day re-admission rate for CHF patients at the University of Pennsylvania's 'Penn Care at Home' programme by 53%.

Connected health solutions allow the patient to be actively involved in the management of their own care. This increased engagement has significant regulatory implications, particularly in the fields of data sharing and cyber security. As connected health solutions continue to be developed at a rapid pace, regulatory frameworks must adapt to manage the dynamic landscape. As such, companies will be required to develop internal skillsets to meet future requirements.

Traditionally, connected health solutions are the result of the convergence of medical devices, diagnostics, and sensors with information and communication technologies. The Philips diabetes application is an example of how such collaboration between separate industries can facilitate the development of innovative connected health solutions.

Technological innovation has led to growth in a number of medtech sectors including robotics, analytics, machine-to-machine technologies, and the development of innovative software applications. Technological innovations in the medtech industry have encouraged new organisations to enter the market. For example, Google announced in 2016 that they have teamed up with French drug maker Sanofi to create a diabetes monitoring and treatment device

Technology, and robotics in particular, has played a major part in the advancement of neuroscience. Everything from rehabilitation devices to wearable robotic exoskeleton devices are substantially changing the way services are delivered, as well as the overall patient experience and the treatment outcomes. An example of this can be seen at the applied physics lab in John Hopkins University in the US. Here, they have developed a next generation prosthetic arm that uses remapped nerves from the patient's missing arm to send brain signals directly to the prosthetic limb.

Currently, 8 out of the top 10 global IT companies have operations in Ireland. As a result, Ireland is well-positioned to facilitate collaboration between medtech and ICT organisations and seeks to become a leading location for the development of connected health solutions. However, for Ireland to become a globally connected health hub, a cross disciplinary approach with a focus on research is needed.

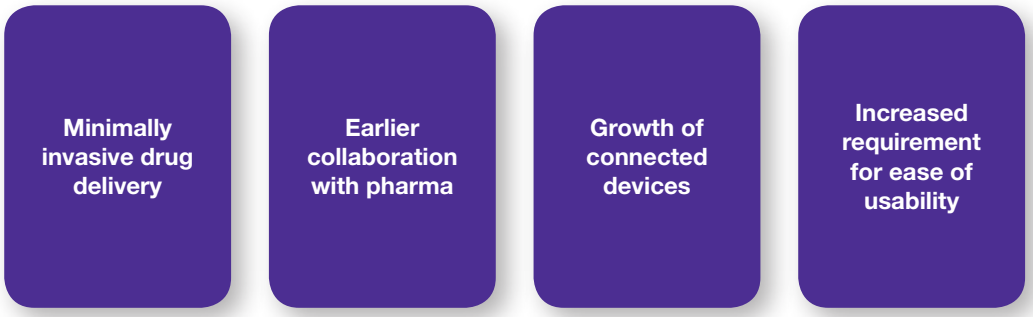
Smart drug delivery solutions

Drug delivery refers to the approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body, as needed, to safely achieve its desired therapeutic effect. There is a decisive shift in the medtech industry towards the delivery of primary healthcare in communities, with smart drug delivery becoming increasingly available in home and localised settings. Innovations in the sector have significantly broadened the range of methods used in the delivery of drugs. Key drug delivery products identified throughout the research and stakeholder engagement processes include the following:

- Control release tablets
- Hydrogels
- Pellet implantation
- Insulin pens
- Inhalers
- Transdermal patches
- Nanocarriers
- Thin film drug delivery
- Needle-free injection systems
- Drug pumps

As these innovative drug delivery systems are becoming increasingly prevalent, a number of trends have emerged, which seek to provide a more efficient and rounded treatment. Key trends identified throughout the research and stakeholder engagements are outlined in figure 4.

Figure 4: Trends in drug delivery market



Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

The trends outlined in figure 4 highlight the importance of collaboration in the drug delivery sector. Drug delivery is inextricably intertwined with the pharmaceutical industry.

According to Medical Device and Diagnostic Industry (MDDI) Online, an increasing number of pharmaceutical companies are actively seeking to enter the drug delivery sector by either commissioning exclusive rights to particular devices or by hiring employees with transferable skillsets to design and prototype devices up to the manufacturing stage. At this point, they then subcontract the production. Ireland is home to nine of the top 10 global biopharma companies. This represents a significant opportunity for medtech companies in Ireland to increase collaboration with pharmaceutical companies in the design and production of innovative drug delivery systems.

Advances in the form of targeted drug delivery also represent a significant opportunity for both drug and device manufacturers. This is an advanced method of delivering drugs to patients in targeted sequences, which increases the concentration of the delivered drug only to the targeted body part. Such advances enable better management of chronic diseases such as diabetes and various cardiovascular conditions. According to the US National Institutes of Health (NIH), recent advancements in drug delivery provide a number of benefits to patients suffering from these chronic diseases, including the following:

- Reduced toxicity
- Controlled drug release
- Targeted drug delivery
- Use of biocompatible substances
- Improved patient compliance

These benefits provide strong evidence of the clinical impact that drug delivery systems have on the effective management of diseases. The commercial impact is also significant. According to the research organisation, Markets and Markets, the drug delivery technology market is forecasted to grow from $1.05 billion in 2015 to $1.5 billion in 2020. To capitalise on this growth, medtech companies will require science and pharmaceutical expertise, as well as expertise in software development, electronic engineering, industrial design, and systems interoperability design skillsets.

New commitments to lower socio-economic and emerging markets

To achieve anticipated future growth, medtech companies must consider the opportunities available in lower socio-economic settings and emerging markets, as there is potential to leverage advantages from emerging countries where low cost is a priority.

This has led to companies generating local growth in emerging markets by creating devices that can both improve patient outcomes and cut costs.

Power within the international medtech market is shifting as emerging markets have started to advance in innovation, resources, and overseas activity. According to the WHO, in 2015, the top 30 emerging markets were responsible for 10% ($21.5 billion) of global medical device production, with China, Brazil, Mexico, India, and Turkey comprising 60% of the total emerging market production. Increasing awareness of the developments and opportunities being generated within emerging markets should be viewed as a strong priority for many medical institutions due to the associated benefits. Some of these benefits are highlighted in figure 5.

Figure 5: Benefits stemming from growth of emerging medtech markets

Source: PWC – 10 Minutes on Medical Innovation (2013)
Source: The Brazil Business – Brazilian Medical Industry Overview (2013)

According to the 2016 report, 'Emerging markets: Transforming global surgical care by 2030', from medtech product design and development organisation, Cambridge Consultants, medtech companies need to significantly change their approach to healthcare delivery to achieve substantial growth in emerging markets. The report points out that more than 85% of the world's population lives in emerging markets with most of those individuals not having access to healthcare. In those countries, the upper and middle classes represent a minority of the population; the remaining 60–70% of citizens earn a lower income and, even if they have access to a clinician in these markets' inadequate or fragmented hospital systems, they cannot afford care.

There are several key challenges associated with providing healthcare solutions in emerging markets, including the following:

- A lack of financial resources to fund healthcare
- A limited number of caregivers/clinicians
- Inadequate support systems for healthcare (policy makers/regulatory bodies/insurance)
- Unsuitable business models and price points of many medtech companies for emerging markets

As such, medtech companies must pursue the provision of adequate and suitable healthcare solutions appropriate to the market place. To achieve this goal, companies may be required to engage in reverse innovation. This involves the simplification of solutions and products, while still ensuring the primary function of a device is delivered to an adequate level. In particular, there are significant opportunities for the provision of affordable surgical solutions in emerging markets. Cambridge Consultants predict that innovations such as the introduction of team-based surgery, where the surgeon is the manager of a process and not the sole participant, will allow healthcare providers in emerging markets to serve more patients. By understanding innovations such as this, medtech companies can seek to provide solutions to best meet their requirements.

Companies are looking to merge local insight with global expertise to gain a firm understanding of the requirements of emerging markets. Examples of this can be seen with Medtronic and Boston Scientific, who have both established R&D centres in India. Emerging markets will have a significant impact on the global medtech industry in the future and companies will be required to adopt a new approach to serve these market.

Technology and ICT

Factory 4.0

Analytics and machine-to-machine technology are also changing the industry. Analytics and predictive analytics are being used to increase efficiencies in production, reduce costs, and potentially assist in predicting the demand for products from customers. Predictive analytics is also improving the performance of manufacturing processes and medical devices.

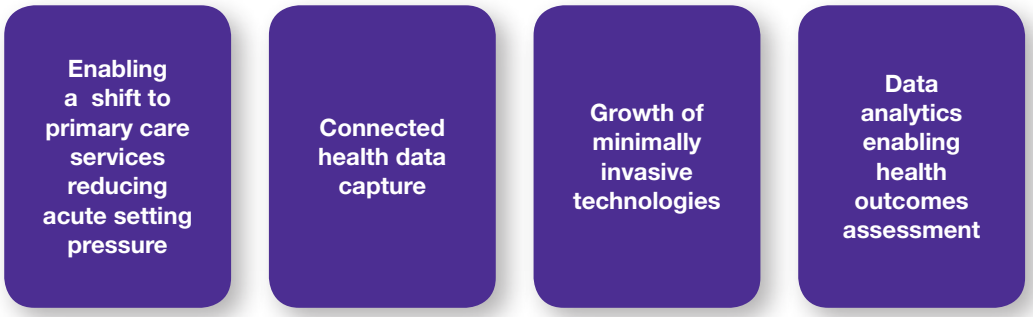
For example, IBM has generated a Watson powered smartphone application that detects patterns in diabetic patients and predicts hypoglycemic events up to three hours in advance. Machine-to-machine technology has also improved the efficiency and cut the cost of production assets maintenance, resulting in savings of 12% on scheduled repairs and a reduction in overall maintenance costs of 30%. There are numerous benefits of technological advancements to the medtech industry, including those outlined in figure 6.

The benefits outlined in the figure above allow innovative developments in the delivery of healthcare solutions.

Additive manufacturing

Additive manufacturing has been defined by the standards organisation, American Society for Testing and Materials (ASTM) International, as:
'a process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing technologies.'

Figure 6: Benefits stemming from technological advancements within the medtech industry



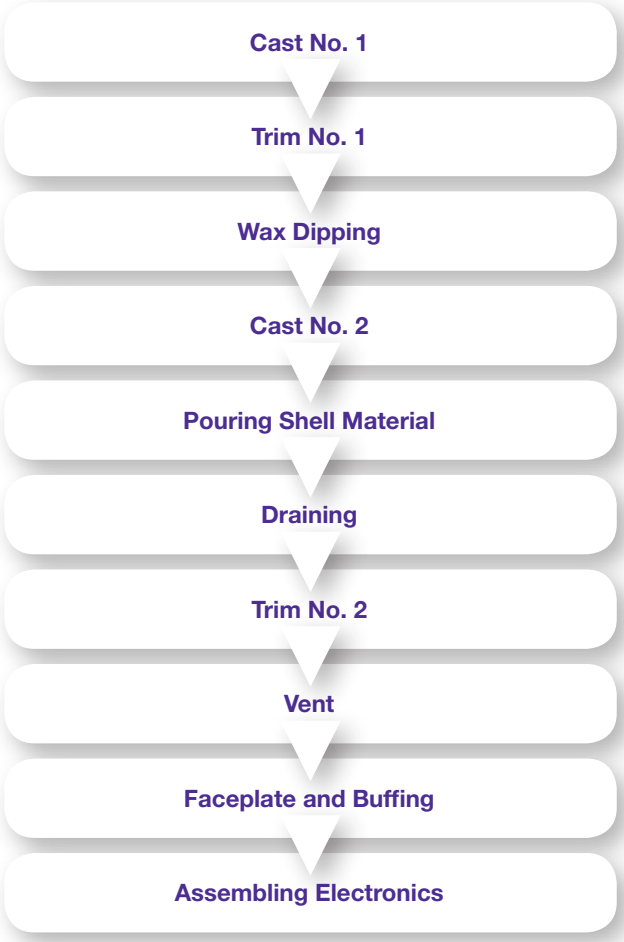
Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

According to the online publication, Medtec China, the medtech industry is one of the leading industries using additive manufacturing, representing more than 16% of the total market usage in 2015. Medtech companies engaging in additive manufacturing can experience significant benefits when it comes to producing highly individualised products in low quantities. However, it is still considered to be relatively expensive for large-scale manufacturing. As a result, additive manufacturing has many important benefits for medtech companies, including the following:

- Reduced inventory levels
- Increased collaboration leading to innovation in design
- Patient specific implants and surgical tools
- Supply chain evolution
- Rapid design, manufacture, and refinement of prototypes

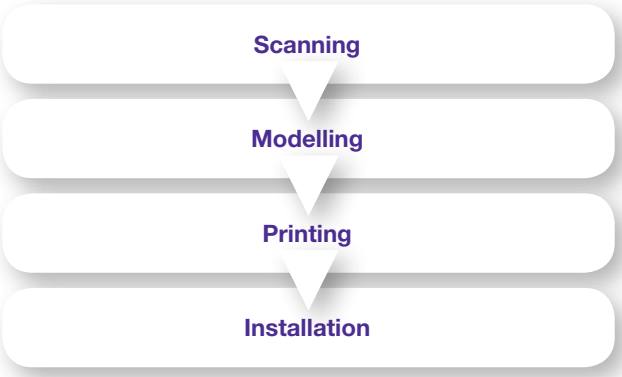
According to Ibec, the manufacturing sector contributes 24% of total economic output in Ireland. As such, increased operational excellence through processes such as additive manufacturing has the potential to significantly impact both the medtech industry and the discrete manufacturing sector as a whole. In particular, the alteration of supply chains, tools, and product design can help companies to lower expenditure. Additive manufacturing eliminates the requirement to manufacture individual components, which still need to be assembled. By using 3D printing to produce finished products, medtech manufacturers significantly reduce the number of steps required in the production process of a product. For example, figure 7 outlines the traditional manufacturing process for hearing aids, while figure 8 details the process for producing custom hearing aids using additive manufacturing technology.

Figure 7: Traditional manufacturing process for hearing aids



Source: Richard Cortez - "Changing with the times: Applying digital technology to hearing aid shell manufacturing (2014)

Figure 8: Manufacturing process for custom hearing aids using additive manufacturing technology



Source: Richard Cortez - "Changing with the times: Applying digital technology to hearing aid shell manufacturing (2014)

The reduced number of steps in the manufacturing process using additive manufacturing technology allows for the increased customisation of medtech products.

While additive manufacturing provides significant opportunities for Original Equipment Manufacturers (OEMs) in the medtech industry, there is also concern that lower tier suppliers may suffer. As outlined by Medtec China, a whole range of subcomponents that were previously required to assemble a product may no longer be needed. As such, additive manufacturing may negatively impact the producers of those parts.

As a whole, additive manufacturing has the potential to change the supply chain for medtech companies, as well as the design processes for products. Customised orthopaedic implants, preoperative models, prosthetics limbs, and customised casts can be produced to meet the specific requirements of the patient. Medtech companies will require employees with specific additive manufacturing skills, including computer-aided design (CAD), additive manufacturing machine operation, raw material development, and supply chain management.

Cost containment

The Irish medtech industry has responded well to cost containment to date by exploring every opportunity to increase efficiencies and reduce costs. However, they will need to continue to reduce costs as ambitious new players from China and India are now keen to take their low-cost designs to enthusiastic hospital buyers in Europe and North America. Now, device makers must find new ways to maintain their competitiveness. Like other industries before them—such as the automotive sector, consumer electronics and telecommunications—they are rethinking their product development processes. They are paying attention to the detailed design of their product ranges and are looking for opportunities to eliminate excess cost wherever possible, or gain market share by offering wrap around services. This will allow them to gain the flexibility to sell profitably in traditional markets where there are cost constraints.

As the industry has evolved, the role of the consumer has changed and has influenced the market demand. The relationship between medtech companies and the physician has become more complex and often less direct, as hospitals begin to group together to increase buyer power. The formation of hospital groups has led to an increase in purchasing power for medical institutions, and the assigned procurement departments approach the buying process with a more commercialised focus than before. Changes will require the medtech sector to develop more sophisticated commercial skillsets, including health technology assessment and value-based procurement.

Key skills include the following:

- System architecture
- Business excellence
- Systems engineering
- Interoperability
- Product effectiveness
- Lean engineering
- Supply chain dynamics
- Commercial
- Health technology assessment

An evolving regulatory environment

Periods of regulatory change have continuously shaped the medtech industry but, globally, the sector is currently experiencing regulatory change at an unprecedented and relentless pace. New regulatory requirements with sometimes stringent implementation timelines are emerging from multiple global jurisdictions. This does not necessarily consider what the cumulative impact may be on medtech manufacturers with products in multiple global markets.

Against a backdrop of emerging regulatory legislations, the revision of ISO13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes, has enhanced the standard's compatibility with latest regulatory requirements and expectations. However, it has created new quality management system (QMS) requirements for medical device manufacturers in markets outside the US. There are currently innovative shifts towards regulatory harmonisation across global markets, with international regulatory harmonisation initiatives such as the 'Medical Device Single Audit' programme, but harmonisation will take time. Therefore, key regulatory differentiators across strategic markets will continue to present challenges to manufacturers' regulatory strategies.

Many regulators are increasingly asserting their mandate to protect public health with new proposals and changes. The Food and Drug Administration (FDA) and other global regulatory bodies have recently shown a significantly increased expectation for robust, high-quality human factors studies to support regulatory submissions for medical and combination products. Regulators are increasingly focusing on a risk-based regulatory approach to health IT and cybersecurity as new eHealth technologies and solutions are developed for the marketplace.

Regulators are also conscious that patients will increasingly play a more active role in their own healthcare and are examining how device manufacturers can share data with patients. Changing technologies, such as additive manufacturing, have prompted regulators to issue draft guidance to provide manufacturers with guidelines about the technical considerations for the manufacture of 3D printed devices.

Medtech companies need to be fully aware of the emerging guidance and trends to prepare for the future. At the European level, the new regulations for medical devices and in-vitro diagnostic medical devices are significantly more detailed than the current directives and will, therefore, have a significant impact on the regulatory environment for both regulators and industry. Secondary legislation still to be developed will fundamentally determine how effectively and smoothly industry can transition to the new EU regulatory framework.

Regulation is increasingly recognised as having a business wide impact for organisations and companies. These organisations and companies will need to invest time and money to improve their upskilling strategies for their regulatory affairs professionals. Expertise and skills in interpreting and complying with both existing and emerging regulations will be critical in the context of increasing regulatory workloads. The demand is increasing for regulatory talent who can understand the implications of the rapidly changing regulatory landscape and that can help companies effectively bring new and innovative medical products to global markets. The steps that can be taken by companies to address increasing regulatory demands are outlined in figure 9.

The global regulatory landscape for medical technology companies will certainly continue to evolve at a rapid pace with ever-increasing expectations. Industry must now develop the regulatory skillsets required to meet future requirements.

Figure 9: Steps taken by medtech companies in response to increased regulatory scrutiny

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

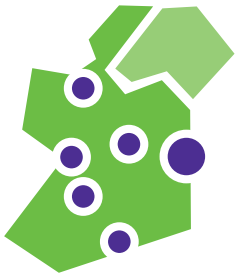
Section 2: Ireland's global medtech hub

Introduction

This section provides an overview of the Irish medtech industry, including some of the key growth factors and trends that have impacted, and continue to impact, the sector. Ireland is one of Europe's largest medtech hubs and employs over 29,000 people. This makes it the largest medtech employer in Europe on a per capita basis. Ireland is also one of the largest exporters of medical devices in Europe, with medtech exports of €12.6 billion annually. This figure has grown significantly from €6 billion in 2007, as outlined in the 2008 report 'Expert group on future skills needs'.

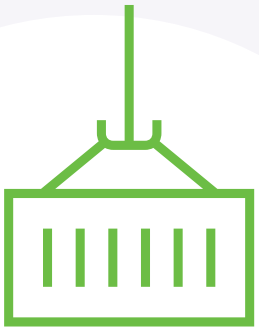
Facts and figures

According to figures from IDA Ireland and the Irish Medtech Association, the number of medtech companies located in Ireland has risen significantly from 50 in 1993 to over 450 in 2017. This growth has resulted in the medtech industry in Ireland being regarded as one of the primary emerging hubs globally. Additional key facts relating to the Irish medtech industry are outlined in the following figure.



60%
of the Irish medtech industry is indigenous

18
of the world's top 25 medtech companies have a base in Ireland



The annual value of Irish medtech exports is
€12.6 billion

Ireland is ranked
14th
internationally for quality of scientific research

Medtech accounts for approximately
10%
of overall Irish exports

Source: Irish Medtech Association – The Global Medtech Hub Statement of Strategy 2016-2020 (2016)
Source: BioInnovate Ireland – Key Facts about the Irish Medtech Industry
Source: Science Foundation Ireland (SFI) – Key highlights (2015)

Industry overview

This section provides an overview of several key factors contributing to the continued growth of the Irish medtech industry. This list is not exhaustive.

Industry collaborations

The Irish industry is well positioned to facilitate collaboration between companies operating in the medtech industry and companies in other industries. The presence of some of the world's largest multinationals, including pharmaceutical and technology companies, in Ireland contributes to this.

As previously outlined, IDA Ireland has reported that all of the top 10 global Information and Communications Technology (ICT) companies and nine of the top 10 global pharmaceutical companies are located in Ireland. The Irish Medtech Association 2020 strategy identifies the use of technological innovations to facilitate increased collaboration between industries as one of its primary aims. According to the SFI, these platforms for collaboration have resulted in several investments that centre on drug delivery, drug device combination, and connected health devices.

A highly skilled workforce

According to IDA Ireland, the country is ranked number one globally for the employability of its graduates, as companies benefit from the flow of skilled workers from Ireland's seven universities and 14 Institutes of Technology. As outlined in the 2015 An tSeirbhís Oideachais Leanúnaigh agus Scileanna (SOLAS) report, 'Monitoring Ireland's Skill Supply', 38% of the population of Ireland were third-level graduates. This was the third-highest share of third-level graduates across the EU in 2014. This percentage is significantly higher than the EU average of 27%.

Foreign direct investment (FDI)

According to the independent tax policy research organisation The Tax Foundation, the average corporate income tax rate in the EU is 22.4%. Ireland's corporate tax rate is 12.5% and it ranks as the twentieth lowest rate globally. According to the World Bank Group, the effective tax rate in Ireland of 25.9% is also substantially more economical than the EU average effective tax rate of 40.6%. These competitive tax rates act as a further incentive for multinational medtech companies to establish operations in Ireland.

Research and development (R&D) and innovation

The Irish Government has outlined a strategy to increase its total investment in science and technology research in Ireland by 2020, by investing over €5 billion per year. Reaching this target would almost double current levels of investment and bring R&D investment in Ireland to 2.5% of gross national product (GNP).

This investment will fund research initiatives such as the Advanced Materials and Bioengineering Research (AMBER) Centre, the Centre for Research in Medical Devices (CÚRAM), The National Institute for Bioprocessing Research and Training (NIBRT), and the Tyndall National Institute, among others.

Ireland is widely regarded as a global leader in medtech innovation. Initiatives such as BioInnovate Ireland and Health Innovation Hub Ireland (HIHI) continue to drive innovation in the sector through the identification, development, and commercialisation of product opportunities, and providing a testbed to support the instruction of new technologies into the health system. These initiatives also contribute significantly to the development of a medtech innovation ecosystem, which provides the platform for the continued growth of the medtech sector in Ireland.

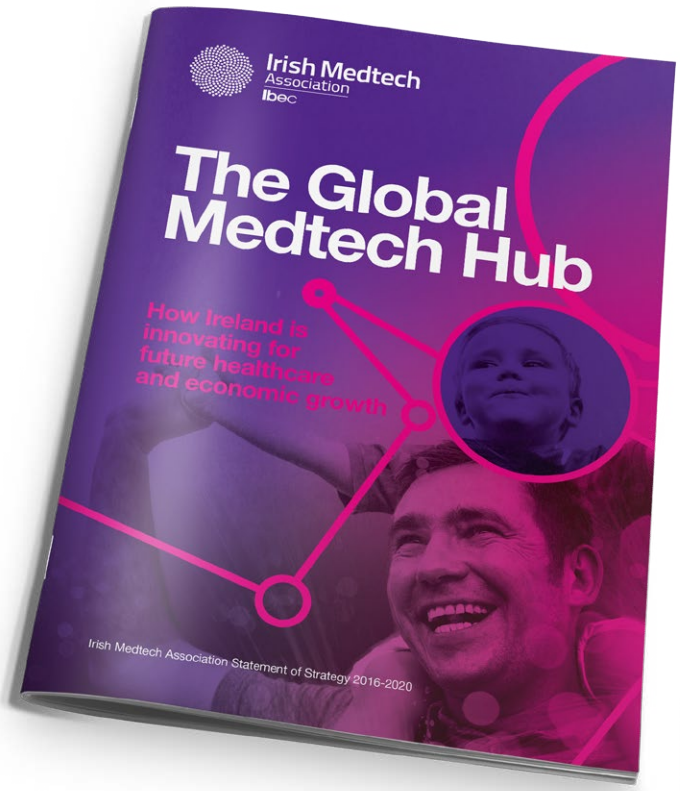
Growth of medtech start-ups

Ireland boasts a strong indigenous sector, in part due to the work of Enterprise Ireland. Research indicates that of the 450 companies based here over 60% are indigenous, with a significant proportion of these being small and medium enterprises (SMEs). Medtech start-ups in Ireland benefit from the Irish medtech hub, where the workforce and their level of experience and skillset are highly regarded. This growth is attractive to investors as global medtech venture capitalists come to Ireland to take advantage of this emerging environment, as well as FDI's seeking R&D pipeline, or acquisition opportunities.

The Irish Medtech Association strategy to 2020

The Irish Medtech Association has set out a strategy for 2020 called The Global Medtech Hub. The aim of this strategy is to ensure that the Irish industry continues to be a prosperous, innovative, and, ultimately, attractive location for both medtech companies and employees. This strategy document identifies several key priorities to ensure that Ireland continues to innovate to facilitate future healthcare and economic growth. These priorities include the following:

- **Drive our future:** Identify and influence key areas of focus such as trade barriers, skills needs, and changes to the business environment
- **Achieve the potential of the cluster:** Assist companies to utilise clusters to expand and achieve their potential by developing new technologies from concept to market
- **Use technological innovations to help patients:** Facilitate cooperation between sectors such as pharmaceuticals, biotechnology, and Information and Communications Technology (ICT), and realise the potential for advanced, additive, and cell manufacturing
- **Nurture entrepreneurship:** Develop policies and conditions, as well as new funding opportunities, to encourage entrepreneurship



The findings from both the survey and stakeholder consultations carried out as part of this study highlight several factors that will contribute to a successful Irish medtech hub. As the medtech industry as a whole continues to develop and change, the Irish medtech hub needs to adapt to meet the needs of the dynamic landscape in which it finds itself.

Section 3: Ireland's medtech skill mix

Current occupational overview

The Irish medtech industry employs more than 29,000 people across a range of business areas. For the skills needs analysis, occupations within the medtech sector have been broken down into 13 categories or groups, as outlined in the following table.

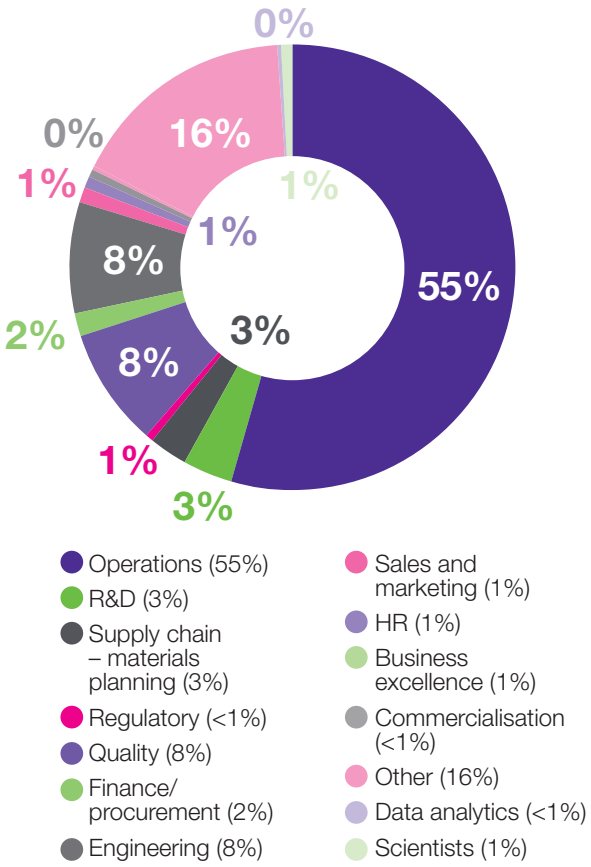
Table 5: Breakdown of medtech occupation groupings

Occupation Group	Examples
Operations	Machine Operatives Assembly Operatives
Engineering	Product Design Engineer Materials Engineer Maintenance Engineer
Research and development (R&D)	R&D Engineer
Supply chain	Logistics Manager Supply Chain Coordinator
Regulatory	Regulatory Affairs Officer
Quality	Quality Engineer Validation Engineer
Finance/procurement	Finance Manager Finance Accountant
Sales/marketing	Sales Representative Strategic Marketing Specialist
Human resources (HR)	Recruitment Specialist HR Manager
Business excellence	Operational Excellence Engineer
Commercialisation	Product Design Specialist Manufacturing Engineer
Data analytics	Data Analyst Reporting Specialist
Scientists	Microbiologist Medical Technologist

Source: Whitaker Institute – Medical Device Sectorial Overview Report (2015)
Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

As part of the skills needs analysis, a detailed survey of 52 Irish Medtech Association members was carried out. The selected respondents represent approximately 20,411 employees, which accounts for 70% of the 29,000 people employed in the Irish medtech industry. A breakdown of the employee occupations within the respondents' organisations is outlined in the following figure.

Figure 11. Employees by occupation in the Irish medtech industry



General skills overview

Skills definition

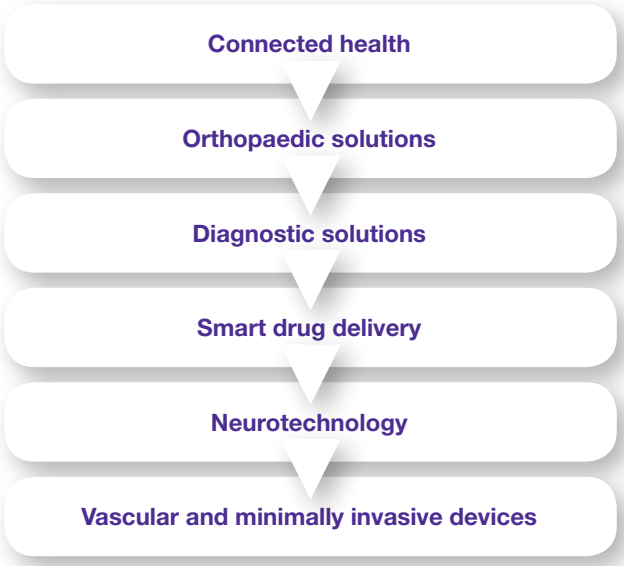
In the context of this study, skills refer to the ability of employees to perform their work. A skills gap in a particular business area means that companies are facing difficulties sourcing the required skilled workers to work in these areas. This may be due to a lack of skilled workers or a lack of experienced resources.

Due to the specialised nature of many roles in the medtech industry, specialised skills particular to the role are required. Examples include the design interface skills required by certain employees within the diagnostic solutions sector, and the metrology engineering skills required for the design of orthopaedic devices.

Primary workshop topics

As part of this study, six primary medtech industry sectors were identified and analysed in a workshop setting, to gain an understanding of their respective skills requirements, both now and in the future. The industry sectors were selected, in part, based on current levels of expertise and the functions of the sectors within the Irish medtech industry, along with the projected market growth of the sectors. The primary medtech industry sectors are detailed in the following figure.

Figure 12: Medtech sector groupings for skills requirements



Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

While the skills requirements of the medtech industry as a whole have been assessed, these chosen sectors provide an overview of the employment needs of the industry both from a general and a highly specialised perspective. It is worth mentioning that the sector also requires very general skills such as finance, human resources, occupational health and safety amongst others. These general business skills have not been highlighted in the report.

Table 6: General medtech skill requirements

General medtech skill	Description of skills required
Engineering	Examples of key engineering disciplines within the medtech sector include the following: • Biomedical Engineering • Production Engineering • Industrial Engineering • Manufacturing Engineering • Validation Engineering • Automation Engineering • Product Design Engineering • Polymer Engineering • R&D Engineering • Quality Engineering • Software Engineering • Electronic Engineering • Biomechanical Engineering • Bioelectronic Engineering

General medtech skill	Description of skills required
Regulatory	The role of Regulatory Affairs is to ensure the appropriate licensing, marketing, and legal compliance of medical technologies to control the safety and efficacy of products. With product approval and market-entry landscapes becoming increasingly complex around the world, companies require skills relating to regulatory development and operations. Regulatory affairs are increasingly being recognised as having a business impact on entire organisations. Expertise and skills in interpreting and complying with both existing and emerging regulations will be critical for companies within the medtech sector.
Research and development (R&D)	Medical technology R&D is characterised as a constant flow of innovations, generated by rapid and frequently iterative product design and development. Medtech R&D is unique due to the level of close cooperation between those developing the technology and the end user. Here, the end users are typically physicians/health care providers. Overall, there is a high level of R&D within the industry with over 12,400 patent applications filed in 2015 with the European Patent Office (EPO). There is increasing investment in R&D in Ireland. Companies including Medtronic, Cook Medical, Stryker, and DePuy Synthes all announced investments in new Irish R&D and innovation centres in the last three years. Thus, there is now an increased demand for R&D skills and experience.
Quality assurance	The medtech industry operates in a highly regulated environment to ensure the effectiveness of products manufactured and the highest levels of patient safety. Manufacturers must establish and follow quality systems to ensure that their products consistently meet applicable requirements and specifications. These systems are intended to ensure the design, production, and placing onto market of medical technologies that are fit for their intended purpose. Quality systems are the foundation for maintaining regulatory compliance, and thus, quality control and assurance skills are key skills consistently required within the medtech sector.
Commercialisation	Commercialisation skills to define go-to-market strategies for new devices and concepts are in short supply in Ireland, which has resulted in this work being performed abroad. The skills requirements for medtech commercialisation are somewhat unique to the sector. There is a requirement for a working knowledge of a wide range of factors affecting medtech devices and solutions, including the regulatory, clinical, information technology (IT), and commercial implications.
Project management	Effective project management policies and practices are vital for the successful development and introduction of medtech technologies and products. Like the commercialisation skills outlined above, a project management professional operating in the medtech sector is generally required to have a broader skillset than a traditional project manager. Additional working knowledge of the clinical, regulatory, IT, and commercial aspects of the delivery of a medtech-related project may be required. The specific skills required make it more difficult for medtech companies to fill these roles.
Manufacturing	There is considerable diversity among medtech manufacturing processes, which means that there are variations in the skills required for different production operations.
IT	A broad range of IT skills are required within the industry to support software needs within companies.
Supply chain management	Skills are required to ensure successful concept planning, project initiation, execution, and completion of all supply chain projects, particularly on a large global scale.
Healthcare economics	Economic skills are required to establish the benefits of devices quantitatively and communicate these benefits to healthcare providers, health insurers, and other reimbursement organisations. Report writing has been identified as a subset of this.
Clinical investigation design	In order to confirm their effectiveness and safety, medical technologies undergo many clinical trials before they are brought to market. Skills in design and management of clinical trials are required to produce reliable evidence that meets regulatory requirements 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.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Skills requirements for specific medtech segments

Overview

Certain skills requirements within the medtech industry are applicable to most business areas. However, there are also skills needs which have been identified by certain segments (e.g orthopaedics) within the medtech sector. This section outlines direct feedback from the six segment specific workshops. It is important to note that while specific skills from been identified in certain segments, for example moulding in diagnostic solutions, this this not preclude the need for moulding in other segments. The next section is an overview of the feedback from workshops specifically.

Connected health

Connected health uses healthcare IT systems to help people access and share information. This category also facilitates the subsequent analysis of health data across healthcare systems. In addition to this, connected health approaches or practices aim to maximise healthcare resources and provides increased, flexible opportunities for consumers to engage with clinicians and better manage their care using mobile technology, computers, networked devices, and remote monitoring tools.

There are a number of sector-specific skill requirements associated with the connected health sector, including those outlined in the following table.

Table 7: Sample connected health skill requirements

Skill category	Description of skills required
System architecture	System Architects devise, build, and maintain the network and computer systems required for full implementation of smart and connected devices. System Architects generally have an IT-based undergraduate degree in courses relating to programming, artificial intelligence (AI), algorithms, data structures, or probability statistics. A recent Monster.com survey (2015) identified that most employers require a candidate to have anywhere between two and seven years of experience in IT administration before becoming a System Architect.
Interoperability engineering	Interoperability between adopted connected health platforms (mHealth, eHealth, telehealth, remote care, and so on) ensures the successful adoption of innovations. An undergraduate degree in a field related to computer science or electrical engineering is generally required by large medical device companies, as well as a master's degree in specialised medtech engineering. An Interoperability Test (IOT) Engineer is the most common position in this field. An IOT Engineer is responsible for all phases of connected device testing and will generally have spent over five years in a software product testing role before working in interoperability.
Cyber security	Dynamic cyber security skills are needed to ensure the protection of highly sensitive consumer health information in a fast-paced sector. A Cyber Security Specialist generally has an IT/computer forensics background and a specialised security training qualification, such as the 'Certified Information System Security Professional' (CISSP) certification. Employees work across several roles in cyber security from product development to penetration testing and ethical hacking.

Skill category	Description of skills required
Software validation	Connected health products must be highly accurate and reliable. Software validation tests the systems used to develop the products, while also measuring and analysing connected health networks. Software validation roles require a computer science or science-related undergraduate degree, accompanied by a working knowledge of regulatory standards such as good practice (GxP) regulations or good automated manufacturing processes (GAMP), with a focus on compliance. Software validation employees are generally responsible for meeting quality, regulatory, and customer requirements associated with the implementation and maintenance of computerised systems.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Orthopaedic solutions

Orthopaedics is a medical speciality that focuses on injury to and disease of the musculoskeletal system in humans. This complex system includes bones, joints, ligaments, tendons, muscles, and nerves and allows people to move, work, and be active. The orthopaedic market has seen significant growth in recent years due to several factors, including a significant rise in obesity levels, an aging population, and people leading increasingly physically-demanding lifestyles. Companies operating within the orthopaedic sector are strongly represented in the Irish market has a strong presence of, with Zimmer, DePuy Synthes, Wright Medical and Stryker all having operations in Ireland. According to Ibec, 75% of the orthopaedic knee replacements manufactured globally are produced in Ireland.

There are a number of sector-specific skill requirements associated with the orthopaedic solutions sector, as set out in the following table.

Table 8: Sample orthopaedic solutions skill requirements

Skill category	Description of skills required
Orthopaedic product design	Orthopaedic product design requires highly detailed knowledge of mechanical systems in the body to design suitable devices to further the treatment of musculoskeletal disorders. Orthopaedic companies require design employees to have a university background in a biomedical/mechanical engineering-related field, along with a working knowledge of manufacturing technology software, such as 3D and 2D computer aided design (CAD). It is also desirable for an employee to have practical craft skills, with expertise in the use of manual tools being hugely beneficial.
Material science	Material Scientists/Engineers are needed to ensure the suitability of implant materials, as problems with these can lead to component loosening, pain, and infection. Employees working within the field have a minimum of a primary degree in materials engineering or metallurgy. Many companies also require a specialised post-graduate medical device degree. Employees in these roles are also often required to read and interpret detailed engineering drawings and, therefore, may need to understand geometrical dimensioning and tolerance.

Skill category	Description of skills required
Forging manufacturing	Forging skills are needed in the design and development of metal orthopaedic devices. Companies generally require a general engineering undergraduate qualification, although apprenticeships allowing hands-on manufacturing experience are also seen as being beneficial. Employees in the field also require an understanding of the relevant regulatory framework.
Additive Manufacturing	Additive manufacturing skills are needed in the development of medtech devices using specific 3D-printing technologies. Aptitude in design tools, computer aided modelling, data analysis, and process design are required. An ability to develop technical work scopes for incorporation with proposals for devices and solutions may be required.
Automation engineering	Automation engineering skills are required to ensure successful design, programming, simulation, and testing of machinery used to manufacture orthopaedic solutions. A bachelor's degree in engineering, computer science, or a related technological field is generally required to work within the field. Many companies now use Allen Bradley automation software. Therefore, a working knowledge of this or another relevant automation software is desirable.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Diagnostic solutions

Diagnostic solutions are clinical technologies and products designed to provide information on health status, disease propensity, and progression or therapeutic impact. Technological innovation is leading to significant growth in the sector, with fields such as imaging and molecular diagnostics becoming increasingly advanced. Within the Irish market, companies such as Abbott Diagnostics, Siemens Healthcare Diagnostics, Abbvie, and Trinity Biotech along with start-ups such as Metabolomic Diagnostics are operating in the sector. There are a number of sector-specific skill requirements associated with diagnostic solutions, as set out in the following table.

Table 9: Sample diagnostic solutions skill requirements

Skill category	Description of skills required
Microbiology	Diagnostic solutions require knowledge of microbiology in the development and analysis of solutions using clinical chemistry. Companies often require microbiologists to have an undergraduate degree in microbiology, as well as practical experience working in a regulated good manufacturing process (GMP) environment. It is desirable for microbiology employees to have experience of product release testing as well as bioburden/sterility validation experience to assist with the regulatory framework in place.
Medical imaging engineering	Several diagnostic solutions require detailed knowledge of imaging engineering for the development of devices such as X-Ray and magnetic resonance imaging (MRI) solutions. For the most part, medtech companies require employees to have an undergraduate degree in electrical engineering, with an imaging-specific master's degree also usually required.

Skill category	Description of skills required
Moulding skills	Diagnostic companies require moulding and craft skills in the R&D prototyping phases of development. Companies require employees to have a third-level degree in engineering, while a polymer qualification is also highly desirable. Ideally, employees have a working knowledge of moulding and polymer processes and technologies, including injection moulding design and development.
Human factor skills	Human factor skills are needed to ensure that products, particularly home care testing products, are usable and suitable. Companies usually look for usability engineering graduates from abroad because specific courses on usability engineering are not available in Ireland. A general mechanical/electrical engineering degree is also typically required. Any experience with cognitive psychology or computer science with human computer interface (HCI) is also seen as hugely beneficial.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Smart drug delivery solutions

Drug delivery refers to approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect. Technological advancements in the sector have significantly broadened the range of methods used in the administration of drugs. A decisive shift to primary healthcare in communities has also led to drug delivery becoming increasingly available in the home and localised settings. Nypro Healthcare, West and Aerogen are examples of companies operating in the drug delivery sector in Ireland.

There are a number of sector-specific skill requirements associated with drug delivery as set out in the following table.

Table 10: Sample drug delivery skill requirements

Skill category	Description of skills required
Biomedical engineering	Cross-disciplinary knowledge of engineering, biology, and medicine is vital in the development of drug delivery products and solutions. A degree in biomedical engineering or biomedical sciences is required. Experience in technical reporting within a medical device industry is also desirable. Companies require employees with practical craft skills and a working knowledge of solid works and 3D modelling.
Mechatronic engineering	Drug delivery devices often have both electronic and mechanical components, which require detailed mechatronic knowledge. Several mechatronic roles relate to ensuring sustained and efficient production within a regulated environment. A Level 7 Higher Education and Training Awards Council (HETAC) mechatronic qualification is often sufficient to meet these requirements if the employee has a broader engineering degree.

Skill category	Description of skills required
Software developers	Many drug delivery solutions contain smart elements that provide the patient with medical data in real time. Among their other responsibilities, Software Developers are needed to build programmes to support these functions. A degree, accompanied by a postgraduate qualification, in computer science, software development, or a related engineering field is required. Employees within this field must have detailed knowledge of programming languages, with C, C++, and C# systems frequently used.
Pharmacology	As drug delivery devices are involved in the distribution of medication, it is vitally important that companies have detailed knowledge of the uses, effects, and modes of action of drugs. Companies require employees to have a third-level master's degree in pharmacology, bio-pharmaceutical engineering, or a related discipline. A working knowledge of the regulatory frameworks in place within the medical device industry is also seen as important for potential candidates.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Neurotechnology solutions

Neurotechnology is a broad term used to refer to medical electronics that interact with the human nervous system, particularly the brain, to achieve a desired effect. Neurotechnology provides significant benefits in several clinical areas, including pain and spasticity management, ambulation, breathing assistance, and dysphasia, among others. Companies in Ireland include Stryker and Neurotech amongst others. There are a number of sector-specific skill requirements associated with neurotechnology, as set out in the following table.

Table 11: Sample neurotechnology skill requirements

Skill category	Description of skills required
Neural engineering	Companies in this sector require employees with neural engineering skills to understand, repair, replace, enhance, or otherwise exploit the properties of the nervous system. Companies usually require engineers to have a master's degree or PhD in an engineering or life science discipline relevant to neurophysiology, neuromodulation, or neuroprosthetics. Ideally, companies request that applicants have some working experience in implantable or non-invasive neural sensing, recording, imaging, data analysis, stimulation, or modulation.
Medical robotics	Neurotechnology engages with robotics on several initiatives including the investigation of human motor control and design-efficient assistive devices. A minimum of a bachelor's degree in computer science, computer engineering, or an equivalent course is required. However, it is an industry standard for the employee to have a specialised master's degree or PhD. There is currently a four-year Bachelor of Science (BSC) degree in the National University of Maynooth (NUIM) in Robotics and Intelligent Devices. However, this course does not currently have a medtech specific subject.

Skill category	Description of skills required
Computational neuroscience	To develop neuro products, companies need employees with a detailed knowledge of the information processing properties of the brain and the structures that make up the nervous system. This highly complicated sector requires a degree in computer science, computational biology, bioinformatics, physics, or a related field. A primary degree is generally supplemented with a master's degree or PhD in neurophysiology or neuromodulation.
Nanotechnology	Neurotechnology, by its very nature, is intertwined with nanotechnology, and has been applied in areas such as neuro-regeneration. Companies require employees in the field to have a primary degree and a follow-on master's degree or PhD in the biosciences, accompanied with some specialisation in nanotechnology. Dublin Institute of Technology (DIT), Trinity College Dublin (TCD), and University College Dublin (UCD) all currently run a nanotechnology or nanoscience-based course or master's degree.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Vascular and minimally invasive solutions

Minimally invasive devices aid minimally invasive surgery. This involves the performance of medical procedures through tiny incisions, allowing for quicker recovery times and less discomfort for the patient. Vascular devices are devices related to or affecting a vessel or vessels, particularly those which carry blood. There is an increased demand for minimally invasive healthcare solutions, which has significant benefits for the Irish medtech sector. Currently, 80% of global stent production is carried out in Ireland. Clearstream Technologies, Medtronic, Boston Scientific, Abbott Vascular, and Harmac Medical are examples of companies operating in the vascular and minimally invasive solutions sector in Ireland. There are a number of sector-specific skills associated with vascular and minimally invasive devices, as set out in the following table.

Table 12: Sample vascular and minimally invasive skill requirements

Skill category	Description of skills required
Balloon engineering	Medical balloons play a major role in several vascular and minimally invasive procedures, and these devices are constantly being improved. A degree in biomedical engineering, chemical engineering, or another related discipline is required, along with a specialised master's degree. Due to the highly regulated nature of the field, experience in process validation (installation qualification (IQ)/operational qualification (OQ) and performance qualification (PQ)) is also desirable. Experience in technical writing protocols to support verification for product commercialisation is also desirable.
Microbiology	Companies within the sector require a detailed knowledge of microbiology to develop minimally invasive products and techniques. Companies often require microbiologists to have an undergraduate degree in microbiology, as well as practical experience working in a regulated GMP environment. It is often desirable for microbiology employees to have experience of product release testing, as well as bioburden/sterility validation experience, to assist with the regulatory framework in place.

Skill category	Description of skills required
Technical sales	It is imperative that the company has the technical sales skills to properly market and sell the product, and can clearly illustrate the benefits of the product. While a bachelor's degree is generally required by most companies, a specific course requirement is generally not outlined. However, a business degree is standard. Companies need employees with a working knowledge of both the devices they sell and the marketplace in which they operate. This knowledge primarily comes from industry experience.
Robotic engineering	Minimally invasive devices and procedures are frequently administered through robotic techniques, so a detailed understanding of robotic engineering is needed. While a bachelor's degree in computer science or electrical engineering is required, it is widely accepted that a master's degree or PhD in these fields is the industry standard for employees in the sector. As well as practical manufacturing skills, programming skills are also required, with C/C++ or Java being widely used in the field of robotics.

Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

A skilled workforce for the future

It is widely recognised within the medtech industry that a skilled and suitable workforce is a core component of a successful hub. While this report covers the specific quantitative figures of where skills shortages exist, some broader future workforce requirements emerged through the industry stakeholder engagements. The following figure lists these requirements.

Blended skillsets

Due to advances in technology, the connectivity of devices, and the increasingly collaborative nature of new products, companies will require employees to have a more blended skillset than what was previously needed. As the lines between departments and sectors continue to be blurred by collaborative initiatives, employees will require, at the very least, an understanding of the other relevant aspects of the product lifecycle and how they may impact upon a device. For example, a product design engineer working on the development of a connected device will need a working knowledge of the IT and software aspects of the product. Ireland's future medtech hub will create platforms for employees to obtain these blended skillsets. These platforms will use strong collaborations with third-level institutions, the establishment of upskilling programmes, and similar initiatives to ensure a suitably skilled workforce exists in the Irish market.

More formalised programmes such as structured graduate programmes and apprenticeship programmes enable new employees to enter the industry in a structured way. In some cases, recent graduates may not understand the wider functions of the organisation they join. By implementing structured graduate and apprenticeship programmes, new employees entering the industry in the future will be trained and exposed to a wider range of functions across the organisation. For example, a graduate product design engineer with a third-level qualification may enter into a two-to-three year structured programme that provides detailed training for the role concerned. Such an initiative can expose graduates to a wide range of functions across the organisation, such as regulation and commercialisation, through timed rotations.

Apprenticeship programmes provide a combination of on-the-job training and academic off-the-job education for those entering the workforce. In 2015, the Irish Government identified 25 apprenticeship proposals that were sustainable and at an advanced stage of planning and design, and ready for development. These included three apprenticeships proposed by the Irish Medtech Association and Plastics Ireland. The Apprenticeship Council, which was launched on 18 November 2014, has played a vital role in advancing these programmes.

Following the approval of proposals submitted to the Apprenticeship Council, The Irish Medtech Association and Plastics Ireland, in collaboration with industry and coordinating Institutes of Technology, have developed industry-led national apprenticeship programmes for roll out in 2017. These programmes are as follows:

- Manufacturing Technician (level 6, 2 years)
- Manufacturing Engineer (level 7, 3 years)
- Polymer Processing Technologist (level 7, 3 years)

The new apprenticeship model offers an opportunity for business and education providers to work together to expand apprenticeship into new sectors of the economy and across a range of qualification levels.

Development of transferable skillsets

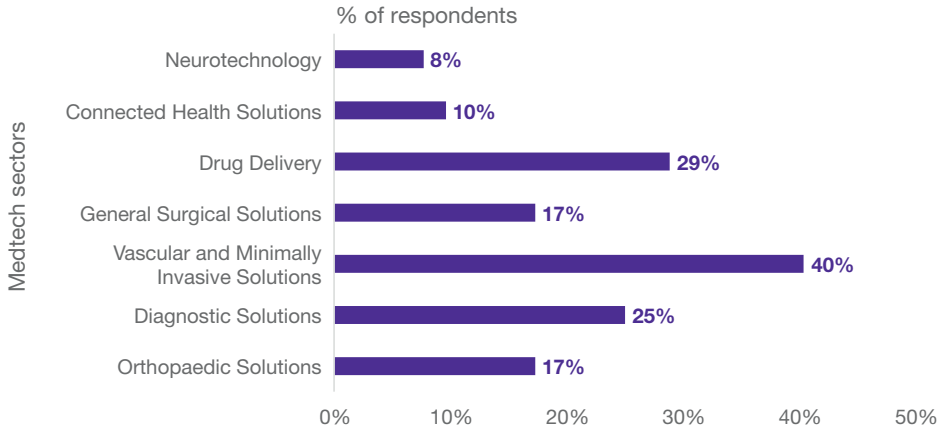
With a skills demand in the Irish medtech industry, the utilisation of transferable skills from other industries is a potential solution. The medtech industry needs to attract skills from other sectors into the medtech industry. Organisations will be required to clearly define the on-boarding approach for employees entering the medtech industry to utilise their skills effectively.

Section 4: Future medtech skills needed for 2020

To develop an insightful understanding of the key skills needed by the Irish medtech industry, a detailed survey was carried out of 52 Irish Medtech Association members. A breakdown of the medtech sector(s), within which the respondent's organisations operate, is outlined in the following figure.

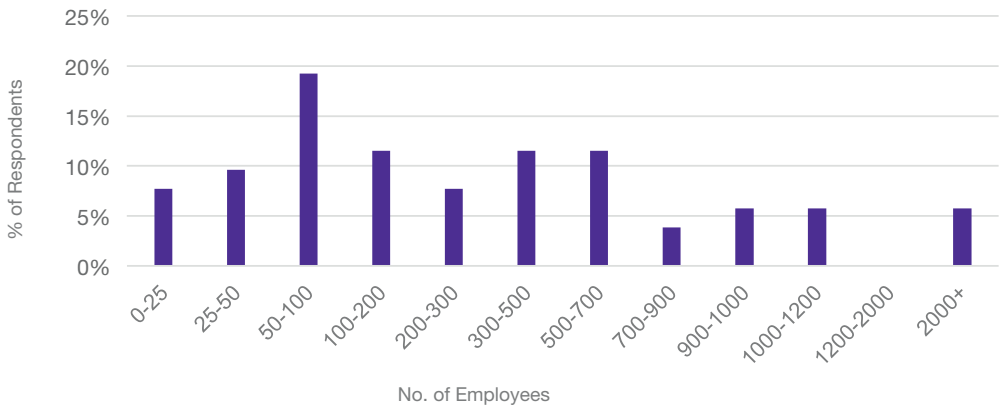
The size of the respondent organisations vary, as illustrated in the following figure. This figure provides an overview of the employment figures of the participant companies inclusive of permanent and contract resources. It also indicates that most respondents employ 50–100 employees.

Figure 13: Breakdown of medtech sectors within which respondent organisations operate



Source: Irish Medtech Association Skills Needs Assessment Survey

Figure 14: Number of employees by survey respondents



Source: Irish Medtech Association Skills Needs Assessment Survey

Current skills demand

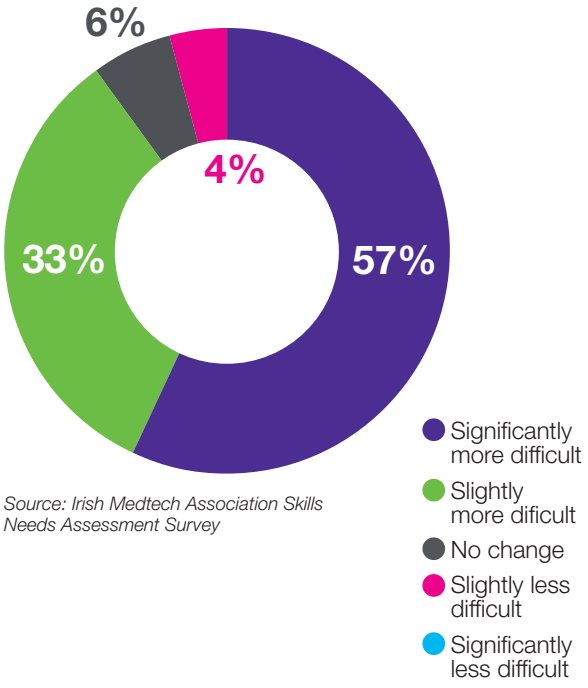
Skills demands have been identified within the medtech industry in Ireland. As outlined in figure below, over 89% of survey respondents highlighted that it is more difficult (significantly or slightly) to fill vacant positions in their organisations over the past five years. We need to understand the adverse effects of skills shortages on the medtech industry, the impact this has on individual organisations, and what it means for the future of the industry.

Survey respondents indicated that they have addressed their current skills demands. Over 78% of survey respondents have transferred staff internally and 78% of organisations have provided internal upskilling programmes. A further 50% of survey respondents stated that they had to pay a wage premium to attract suitable employees. In turn, this increased costs for the Irish medtech industry.

A total of 27% of respondents highlighted that they had to adjust their business strategy to adapt to the changing skills needs and the skills available within the Irish medtech industry.

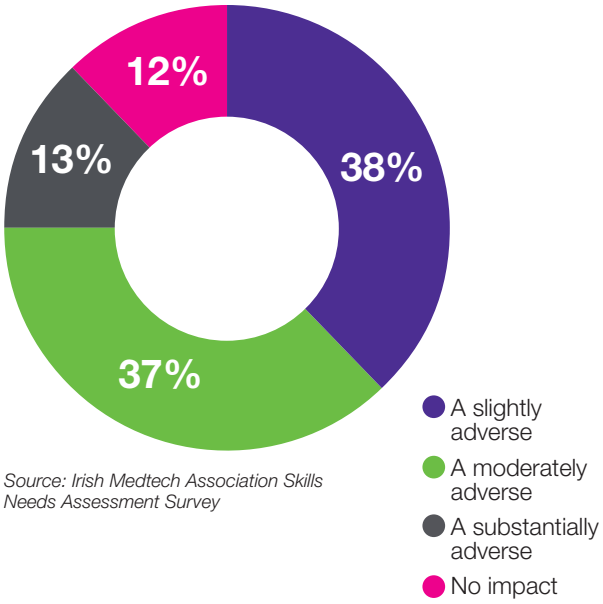
As highlighted in figure 16, respondents said that skills demands have an adverse effect on the growth of the organisation. Less than 12% identified no impact. The survey results are consistent with the feedback provided in the one-to-one interview and workshop processes conducted.

Figure 15: Difficulty filling vacant positions over the last 5 years



Source: Irish Medtech Association Skills Needs Assessment Survey

Figure 16: Impact of skills shortage on growth



Source: Irish Medtech Association Skills Needs Assessment Survey

Future skills demand

Respondents were asked to identify the number of employees required to meet their current skills demand as well as the forecasted number of employees required in each business function up to 2020. The table below outlines the breakdown of the current and forecasted figures based on 52 survey respondents, which represents approximately 20,411 employees. This accounts for 70% of the 29,000 people employed in the Irish medtech industry.

Table 13: Future skills gaps by function up to 2020

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Operations	11,160	13,193	2,033 (18%)
Engineering	1,660	2,036	376 23%)
Research and development (R&D)	713	1,076	363 (51%)
Supply chain	574	738	164 (29%)
Regulatory	127	181	54 (43%)
Quality	1,717	2,004	287 (17%)
Finance/procurement	366	401	35 (10%)
Sales/marketing	183	273	90 (49%)
Human resources (HR)	169	189	20 (12%)
Business excellence	128	228	100 (78%)
Commercialisation	44	54	10 (23%)
Data analytics	54	84	30 (56%)
Scientists	138	240	102 (74%)
Other	3,378	3,698	320 (9%)
TOTAL	**20,411**	**24,395**	**3,984**

Source: Irish Medtech Association Skills Needs Assessment Survey

Each of these business functions is analysed in further detail in the following sections.

Operations

Table 14: Key facts about the operations business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Operations	11,160	13,193	2,033 (18%)

The scope of operations covers a broad range of roles within medtech companies as there is considerable diversity among medical devices production processes. The survey data highlights significant skills opportunities within the general operations function, as an additional 2,033 employees are forecasted to be required up to 2020. The 18% increase in forecasted operations roles serves to highlight further the predicted growth in medtech manufacturing in Ireland.

Engineering

Table 15: Key facts about the engineering business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Engineering	1,660	2,036	376 (23%)

The forecasted skills opportunities are significant across all engineering fields up to 2020. The survey data has highlighted a need for approximately 23% additional engineering positions up to 2020. The need for additional engineering expertise was raised repeatedly throughout the stakeholder engagement process.

Research and development (R&D)

Table 16: Key facts about the R&D business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
R&D	713	1,076	363 (51%)

As outlined in both the operations and engineering data, there is a high demand for R&D staff predicted within the medtech industry up to 2020. An example of the additional emphasis being placed on R&D within the Irish market was highlighted in September 2016, with the opening of the Centre for Research in Medical Devices (CÚRAM) in Galway. The centre, which was opened by Science Foundation Ireland (SFI) and leading industry stakeholders, represents a €68 million investment in chronic disease research. Medtech R&D facilities such as the CÚRAM Centre serve as an example of the importance of addressing R&D skills shortages.

Supply chain – materials planning

Table 17 Key facts about the supply chain-material planning business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Supply chain	574	738	164 (29%)

Medtech industry trends such as cost containment, technological advancements, and increased regulatory scrutiny are impacting how companies manage their supply chain operations. Throughout the interview and workshop processes, many stakeholders highlighted the need for companies to successfully meet these challenges under increased cost pressure. In particular, companies communicated a need for employees with expert knowledge of risk management, inventory optimisation, as well as lean and six sigma manufacturing principles. These employees would offer a more blended skillset while still maintaining the supply chain speciality required for the company.

Regulatory

Table 18: Key facts about the regulatory business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Regulatory	127	181	54 (43%)

The demand for regulatory skills within the Irish industry was highlighted as a priority area for a large number of stakeholders engaged throughout the interview and workshop processes. While the number of additional regulatory employees is expected to be relatively small, recruiting experienced regulatory professional is challenging. Steps have been taken to address this forecasted skills shortage with the launch of the Master's in Medical Technology Regulatory Affairs by the Irish Medtech Association Skillnet. This master's degree is a collaboration between the Irish Medtech Association Regulatory Steering Committee, Institute of Technology, Sligo (IT Sligo), the National University of Ireland Galway (NUIG), and the Fundamentals in Regulatory Affairs Programme in conjunction with University of Limerick (UL). These programmes will help develop more regulatory professionals within the medtech sector in Ireland meet up to 2020.

Quality

Table 19: Key facts about the quality business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Quality	1,717	2,004	287 (17%)

The demand for employees with quality skills was identified by a significant number of stakeholders as their primary employment area to be addressed up to 2020. The evolving global medtech regulatory and quality landscape will demand additional expertise across the industry. The Irish Medtech Association Skillnet and Irish Medtech Association Springboard programmes have prioritised the establishment of quality assurance programmes over the past five years to keep pace with the demand. The group have also prioritised quality assurance skills development under its current submission under the new Springboard+ framework, with the upskilling of 200 professionals should the application be successful.

Finance/procurement

Table 20: Key facts about the finance/procurement business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Finance/procurement	366	401	35 (10%)

While there is a forecasted skills gap within the finance and procurement sectors, the survey data highlights that it is relatively small in comparison with other business functions of the industry. In total, 35 additional employees in the finance and procurement sectors are expected to be required up to 2020. Organisations have expressed a distinct preference for employees with some working knowledge of the various other functions and departments within a medtech company. Again, a demand for a blended skillset was highlighted.

Sales/marketing

Table 21: Key facts about the sales/marketing business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Sales/marketing	183	273	90 (49%)

The commercialisation of medtech products was identified by stakeholders as a key area to be addressed, with sales and marketing employees playing a major role in the successful delivery of medtech products to market. Throughout the consultations that were part of this study, the primary issue highlighted was the difficulty in attracting employees with strong sales and marketing skillsets who also have a working knowledge of the clinical aspects of medtech devices. As employee numbers with these skillsets are in short supply, medtech companies are often required to employ sales and marketing employees without medtech expertise and subsequently provide upskilling platforms to improve clinical knowledge within these roles. The development of commercial skills, sharing best practice and benchmarking are key priority of the Irish Medtech Association under its strategy to 2020.

Human resources (HR)

Table 22: Key facts about the HR business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
HR	169	189	20 (12%)

While there are approximately 20 additional HR jobs expected in the medtech industry up to 2020, the figures are relatively small when compared to other business functions within medtech companies. This is because companies tend to outsource HR roles. Industry stakeholders did not identify HR as an area of concern during the consultation process.

Business excellence

Table 23: Key facts about the business excellence business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Business excellence	128	228	100 (78%)

The demand for business excellence skills is expected to grow up to 2020 with an additional 100 employees required in this function. There are numerous trends driving the need for high-level business excellence in medtech organisations, with cost containment and the growth of emerging markets having a particularly strong impact.

Commercialisation

Table 24: Key facts about the commercialisation business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Commercialisation	44	54	10 (23%)

While the data for commercialisation skills requirements shows a relatively low expected demand, the business function was highlighted as a key area to address by numerous stakeholders throughout the consultation process. In particular, companies are seeking platforms for employees from other functional areas to gain a better understanding of the commercialisation processes for medtech devices. Commercialisation was also described as being an extremely difficult process for medtech start-up companies in Ireland because the expertise required to bring a device successfully to market is in short supply. BioInnovate Ireland was identified as a key contributor to the development of a pipeline of talented professionals with niche commercialisation skills for the medtech sector. The Irish Medtech Association is currently conducting a commercialisation-focused survey with its members. The survey aims to highlight further the skills needs within the commercialisation sector, while also identifying the key challenges for organisations in bringing medtech devices to market.

Data analytics

Table 25: Key facts about the data analytics business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Data analytics	54	84	30 (56%)

Over 43% of survey respondents identified big data as being one of the top three technological trends that will impact the medtech industry in Ireland up to 2020. Companies have highlighted challenges in hiring employees with an expert working knowledge of data analytics. They also highlighted as a key issue the fact that they are competing with companies from several other industries. Big data can provide major benefits in terms of product development, risk management, and innovation, and organisations are struggling to meet the employment requirements to meet these needs. Given the need for data analytics across a number of sectors, a significant number of Masters programmes in data analytics have been launched in Ireland in recent years. These programmes will help the industry secure the future skills needed in this area.

Scientists

Table 26: Key facts about the scientists business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Scientists	138	240	102 (74%)

Survey respondents predicted a significant need in the future for science skills in the medtech industry. As the collaboration between pharmaceutical and medtech companies continues to increase, the need for science skills also continues to increase. A total of 17% of survey respondents are currently in collaborative partnerships with pharmaceutical companies. Many other companies identified it as a possible area for future collaboration through the interview and stakeholder process.

Other

Table 27: Key facts about the other business function

Business function	Current number of employees	Forecasted no. of employees up to 2020	Differential
Other	3,378	3,698	320 (9%)

The respondents input data relating to skills needs in business functions which were not listed directly in the survey question under the heading of 'Other'. The majority of the data related to employment figures for the following business areas:

- Administration
- Internal IT
- Clinical

The survey data highlights a requirement for 320 additional employees in 'other' business functions up to 2020.

Further analysis of future skills demand in operations roles

While the production of some medical devices 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, which is highlighted by the range of positions outlined below. It should be noted that the individual operations roles referenced may span across a range of business functions, including operations, engineering, quality etc.

Operations roles may also vary in relation to the required levels under the National Qualification Framework (NQF). Operators depending on the particular scope of their roles, can be from level 5-7 on the NQF. While it is anticipated that industry 4.0, among other trends, will reduce the number of employees required in operational functions in the future, the survey results have highlighted that this will not be the case up to 2020. The survey has highlighted a 14% increase in the number of operations employees required. A breakdown of the increases identified, by specific operational functions, is outlined in table below.

Table 28: Future skills gap of operations roles up to 2020

Operations role	Current number of employees	Forecasted no. of employees up to 2020	Differential
General operatives	10,488	11,746	1,258 (12%)
Machine operators	1,015	1,085	70 (7%)
Operations managers	563	607	44 (8%)
General manufacturing technicians	1,419	1,843	424 (30%)
Quality control/assurance	849	993	144 (17%)
Scientific technicians	153	199	46 (30%)
Additive manufacturing	20	93	73 (365%)
TOTAL	**14,507**	**16,566**	**2,059**

Source: Irish Medtech Association Skills Needs Assessment Survey

The survey data forecasts skills opportunities across all operational roles up to 2020. Most notably, the data serves to further highlight the emergence of additive manufacturing as an industry trend, with a 365% increase in resources required in this subsector up to 2020.

The most significant difference identified in terms of number of employees is in the 'General Operatives' category. This challenges the predicted industry 4.0 and other lean manufacturing trends as well as the stakeholder engagement feedback that has indicated a reduced need for general operatives in the future.

Further analysis of future skills demand in engineering roles

There are a broad range of engineering roles utilised in the medtech industry. The table below details the skills demands for individual engineering roles up to 2020 which may span across a number of business functions, including engineering, operations, R&D, etc. The survey data has highlighted a requirement for approximately 36% additional engineering roles up to 2020. The need for additional engineering expertise was a concern raised repeatedly throughout the stakeholder engagement process.

Table 29: Future skills gap of engineering roles up to 2020

Engineering field	Current number of employees	Forecasted no. of employees up to 2020	Differential
Biomedical Engineers	40	65	25 (63%)
Production Engineers	240	301	61 (25%)
Industrial Engineers	42	50	8 (19%)
Manufacturing Engineers	518	648	130 (25%)
Validation Engineers	121	160	39 (32%)
Automation Engineers	92	168	76 (83%)
Product Design Engineers	66	109	43 (66%)
R&D Engineers	455	637	182 (40%)
Quality Engineers	572	676	104 (18%)
Software Engineers	76	150	74 (97%)
Electronic Engineers	92	147	55 (60%)
Biomechanical Engineers	7	13	6 (86%)
Bioelectronic Engineers	1	3	2 (200%)
TOTAL	**2,376**	**3,234**	**858**

Source: Irish Medtech Association Skills Needs Assessment Survey

The survey data illustrates a skills opportunities across all engineering fields up to 2020. As previously highlighted in the operations data, the requirement for manufacturing employees is forecasted to be significant, with approximately 130 additional manufacturing engineers required up to 2020. This figure emphasises the strong predicted growth of the medtech manufacturing sector in Ireland.

'R&D' and 'Quality' engineers have also been identified as the positions in high demand up to 2020.

The engineering future skills data also serves to reaffirm the requirement for a high level of ICT related engineering employees up to 2020, which was a primary concern for medtech stakeholders throughout the engagement process. The emergence of trends such as connected health, the interoperability of devices and IOT has led to a demand for software engineers, with an additional 74 required by 2020.

The demand for R&D engineers is also forecasted to be high with many industry stakeholders indicated that their organisation would be putting an additional emphasis into R&D over the coming years. The forecasted skills opportunities are significant across all engineering fields up to 2020.

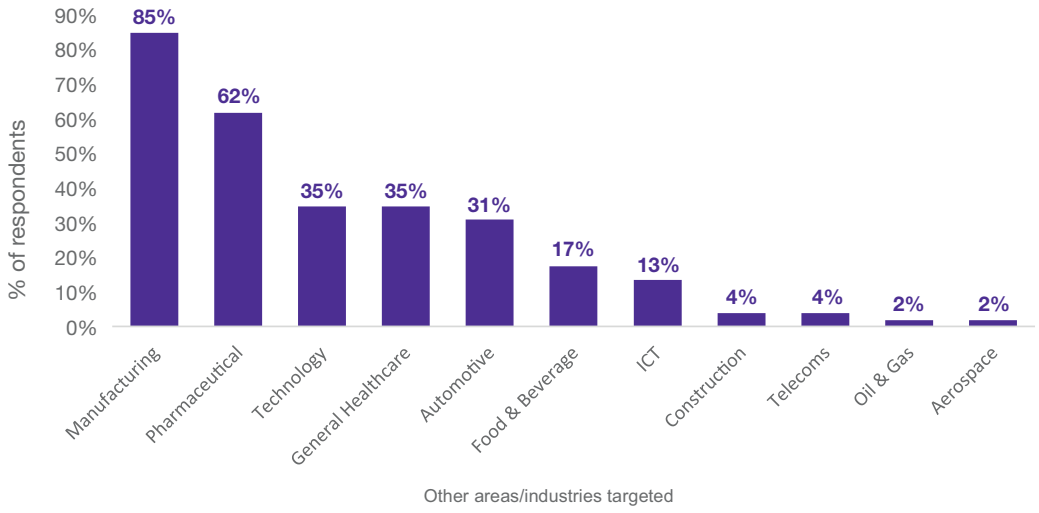
Other target industries of medtech skills

Other areas/industries

Respondents were asked to identify the specific areas or industries that their organisations target for new skills. The following figure outlines the data from 52 survey responses. The selected respondents represent approximately 20,411 employees, which accounts for 70% of the 29,000 people employed in the Irish medtech industry. It should be noted that respondents were permitted to make multiple selections.

The Central Statistics Office (CSO) has identified manufacturing as the second largest employment sector in Ireland. As such, it is unsurprising that a large proportion of respondents target this sector. The significant number of companies targeting the pharmaceutical and technology sectors highlights the increasingly collaborative nature of medtech companies with these areas.

Figure 17: Other areas/industries that respondents target to hire from



Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Steps to meet skills demands

This report provides a number of recommendations and steps required in order to meet the skills demand. Collaboration with third level institutions and evolution of models for collaboration was highlighted on a number of occasions throughout this study.

Collaboration with third-level institutions

Throughout the course of this study, several medtech industry and academic stakeholders were consulted through one-on-one interviews and interactive group workshops. The consensus among most stakeholders was that more collaboration between the medtech industry and academic institutions is required for Ireland to progress as a medtech hub. While willingness was expressed on both sides to engage in further collaboration, the feedback on how to facilitate combined endeavours in the future was inconclusive.

Throughout the stakeholder engagement process, participants highlighted the need for more engagement in work placement, apprenticeship, and co-op programmes. This was considered a key part of the solution to any current and future skills gap. The following figure shows that a total of 12% of respondents do not engage in these programmes but have identified that they would like to be involved.

More communication is needed between the industry and academic institutions to build the platforms required to strengthen the links between the two sectors, and to fully utilise factors such as third-level course content and work placement programmes. In the future, the medtech hub in Ireland will require this communication to be facilitated through platforms such as regional joint committees or steering groups, to ensure effective collaboration.

One example of effective collaboration was highlighted. The Irish Medtech Skillnet and Galway Mayo Institute of Technology (GMIT) offers modules as part of the Higher Certificate in Mechanical Engineering. This uses a blended-learning approach of both online lectures and practical workshops in which students learn workshop skills, mill turning, electrical skills, computer aided design (CAD), pneumatics and hydraulics metrology, and so on. Ten students will graduate in 2017 with a Higher Certificate in Mechanical Engineering (120 credits).

Input into third-level course content

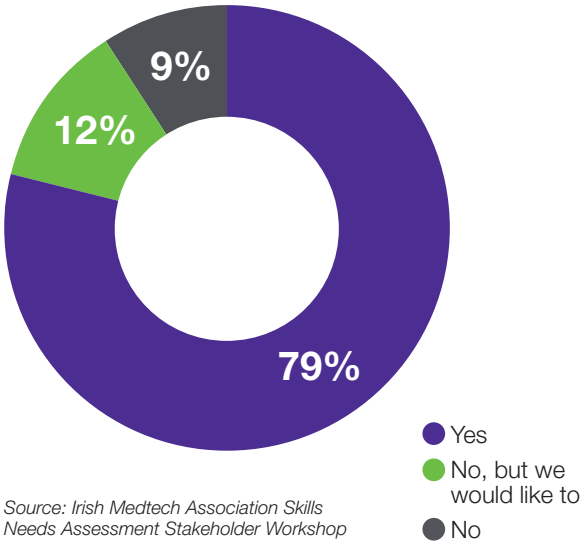
Throughout the engagement process, stakeholders expressed the importance of ensuring that there is a balance between the content taught in third-level courses and what is expected from graduates entering the medtech workforce. Respondents were asked to identify whether their organisation provides input into third-level course content. The following figure highlights that most respondents do not currently collaborate with academic institutions in relation to content taught.

Collaboration with other industries

As outlined previously in this report, a key component of many established and emerging medtech hubs is the infrastructure, and, in particular, the platforms for collaboration between medtech companies and organisations from other sectors. Medical devices are becoming increasingly collaborative in nature. For example, many devices have pharmaceutical or ICT components, and companies are seeking to collaborate with organisations to design and develop products. Biopolis, the international research and development centre for biomedical sciences in Singapore, was identified as an example of how a hub can facilitate and promote collaboration between different sectors.

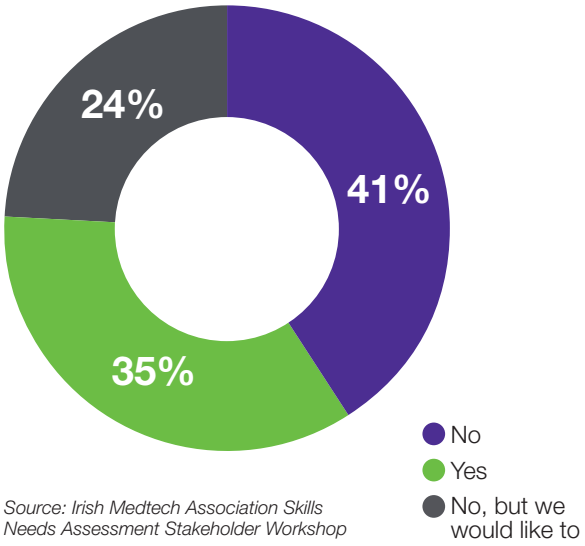
Collaboration is encouraged and easily facilitated through the proximity of different biomedical and ICT companies to each other and their use of a range of shared facilities. Currently, 9 of the top ten global biopharma companies and 18 of the world's top 25 medtech companies are located in Ireland. The presence of these companies in Ireland should be used to sell the country as a unique healthtech hub. A collaborative framework, such as that used by Biopolis, would be a good platform to encourage this.

Figure 18: % of respondents engaged in work placement, apprenticeship or co-op programmes



Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Figure 19: % of respondents who provide input into third-level course content



Source: Irish Medtech Association Skills Needs Assessment Stakeholder Workshop

Level of education required in medtech roles

To suitably address skills gaps in the industry, it is necessary to understand the varying educational requirements for certain roles. Survey respondents were asked to identify the level of education generally required by employees in each business function of their organisation. The levels of education needed are categorised according to function in the following table.

Table 30: Level of education generally required by employees in each business function

Business Function (by percentages)	None	Leaving Certificate	Trade Certification	3rd Level Degree	Master's Degree	PhD
Operations	8%	58%	10%	21%	2%	0%
R&D	6%	0%	0%	67%	17%	8%
Supply chain	6%	13%	8%	69%	4%	0%
Regulatory	4%	0%	0%	83%	12%	0%
Quality	0%	4%	2%	90%	4%	0%
Finance	2%	4%	6%	81%	2%	0%
Engineering	2%	0%	2%	90%	6%	0%
Marketing	21%	4%	2%	63%	6%	0%
HR	4%	4%	4%	83%	4%	0%
Business excellence	10%	4%	4%	65%	13%	0%
Sales	21%	6%	4%	62%	4%	0%

Source: Irish Medtech Association Skills Needs Assessment Survey

Apart from operations, a third-level degree is required for most roles within the medtech industry. R&D was the only role identified for which a PhD qualification is required.

Appendices

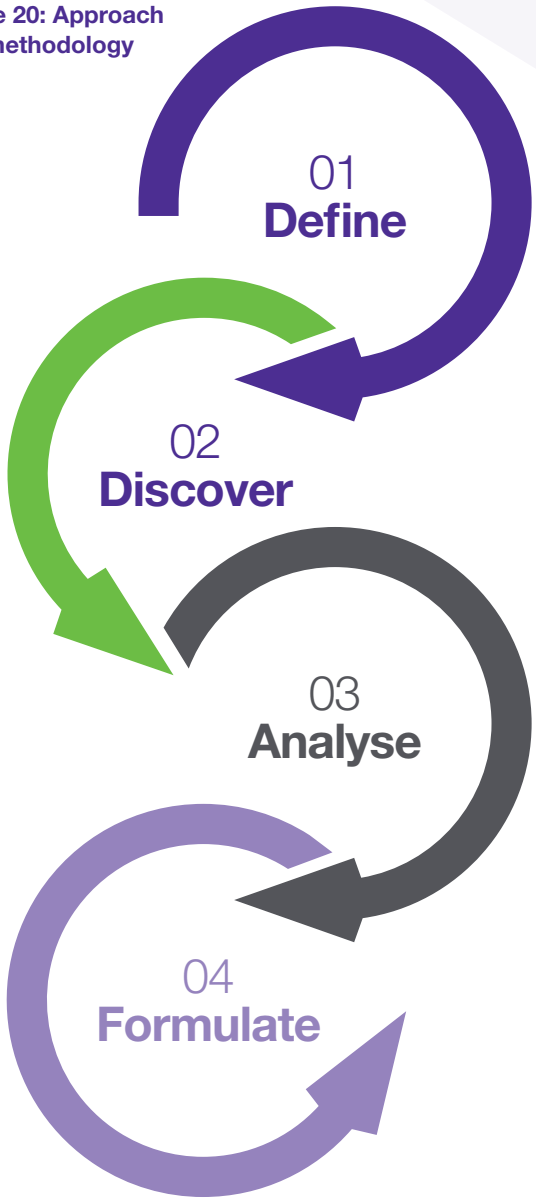
Appendix A Approach and methology

Grant Thornton
An instinct for growth™

Our approach

Grant Thornton adopted a four-phased approach that was tailored to meet the specific needs of the Irish Medtech Association. The approach is illustrated in the following figure.

Figure 20: Approach and methodology



Phase 1: Define

In this phase, the project scope was articulated and agreed with all parties. This phase ensured that there was a common understanding of the expectations and overall goals of the assignment.

Phase 2: Discover

The second phase of the assignment involved gathering information from multiple sources through several outlined methodologies, including the following:

- Extensive desk research
- Industry and academic stakeholder consultations (one-to-one interviews)
- Interactive regional workshops
- A detailed questionnaire-based survey sent to all Irish Medtech Association members

Phase 3: Analyse

This phase included the analysis of large amounts of both quantitative and qualitative data related to the skills needs of medtech companies across a broad range of areas within the medtech industry. The findings from this analysis identified specific skills shortages as well as the impact that these shortages were having on companies within the industry.

Phase 4: Formulate

This phase involved the production of a final report to the Irish Medtech Association Skillnet. A draft report was initially presented and following feedback from the Irish Medtech Association and its Board, this report was finalised.

Information gathering techniques

Three forms of information gathering, which supported the approach, are outlined in more detail as follows.

Desktop research

A key research method for this report was desktop research of best practices used by medtech hubs internationally. This research also identified the industry trends, challenges, and opportunities throughout the medtech industry. The scope of this included a paper review of international medtech hubs in the US and Europe, in Ireland, and, at a high level, the industries comparable to medtech.

Interview and questionnaire-based surveys

One-to-one interviews with 27 medtech industry and academic stakeholder institutions were held, through conference calls and face-to-face meetings. Through these consultations, specific skills needs and challenges that were being faced by companies in Ireland on an operational and future strategic level, as well as the steps being taken to address these needs and challenges, were identified and discussed.

Following the stakeholder consultations, the team worked in coordination with the Irish Medtech Association to develop a questionnaire-based survey to provide hard data to support any findings of this report. The survey provided information on industry trends and factors contributing to a skills gap, as well as quantitative data on the specific skills shortages that companies within the medtech industry were experiencing.

Interactive regional workshops

Interactive regional workshops were undertaken to engage with key stakeholders in a group format with other industry stakeholders. These provided a means of creating a shared understanding of the medtech future skills requirements and an opportunity to validate the findings.

The workshops focused on several specific sectors grouped under the broader medtech umbrella, set out as follows:

- Advanced manufacturing
- Connected health
- Diagnostics
- Smart drug delivery
- Neurotechnology
- Orthopaedic solutions
- Vascular and minimally invasive solutions

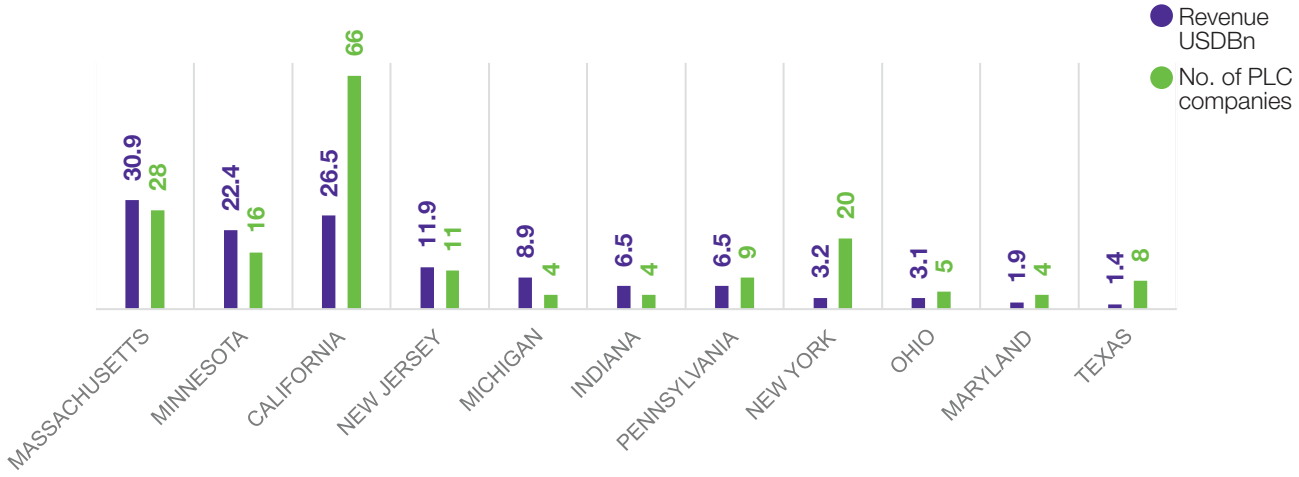
This provided a structured approach to the engagement process. These groupings were agreed with the input of the Irish Medtech Association.

Appendix B
Global medtech hubs

The US

Companies established in the US account for approximately two thirds of the total revenue of the top 40 medical device companies globally. The industry employs more than 400,000 people directly and almost two million people indirectly. Several factors lead to a greater demand for medtech innovation in the US, including a high level of obesity and a growing population of people over 65 years old. There are currently about 7,000 medtech companies in the US, with California, Massachusetts, and Minnesota being the primary hubs. The following figure provides an overview of the primary medtech hubs within the US, both in terms of total revenue generated and the number of public limited companies (PLC) companies located within each area.

Figure 21: US medtech hubs by revenue and number of PLC companies 2014



Source: Pulse of the industry - Medical Technology Report (2013)

US case studies

Minneapolis/St. Paul (Minnesota)

Minnesota was once a world leader in the supercomputer industry with major IT companies including IBM, Univac, Control Data, and Cray Research all having their headquarters in the state. However, this is no longer the case. The skillset of the IT employee base has been transferred to the medtech industry, leading to the area establishing itself as a major hub for both medtech development and manufacturing.

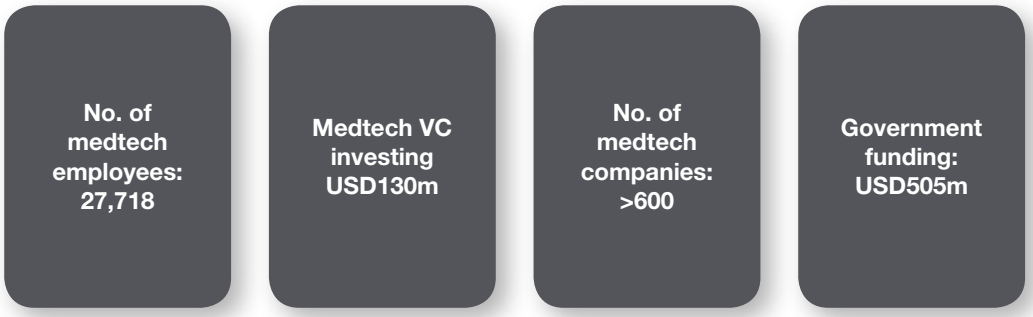
The area benefits from a robust manufacturing supply framework and an experienced pool of job candidates. There have been a number of breakthrough innovations emerging from what are called the 'twin cities'. This includes the first external wearable pacemaker, followed by the first implantable pacemaker, innovative heart valves, the hemodyne blood pump and many others. The cluster of medtech companies and the level of activity based within the twin cities area is high relative to the size of the area, as illustrated in the following figure.

Several factors have contributed to the area becoming a hub for the medtech industry. These factors are highlighted as follows.

Expertise in a specific area

Minnesota is generally regarded as an industry and world leader in the development and manufacturing of cardiovascular and surgical devices. This expertise in specialist products and innovation has filtered down through the industry and into the third-level education system and is considered a major selling point for medtech investment in the area.

Figure 22: Key facts about the Minnesota medtech hub



Source: Qmed - Top 10 US cities for medtech innovation (2015)

Infrastructure

The area has an established medtech infrastructure which facilitates the successful implementation of a full product lifecycle. This includes universities, research centres, and development and manufacturing facilities. The governing authorities of the city have worked hard to create this successful infrastructure. Actions taken include the following:

- Rather than giving tax breaks to medtech companies, as per the traditional approach, the city has directly financed company expansions and partnerships with third-level institutions. For example, the 'Minnesota investment fund' is used as an incentive for companies to expand their workforce, and to finance academic collaboration.
- A number of stakeholders from the sector have formed an industry collaboration group, 'The Minnesota Medical Manufacturing Partnership', which includes members from the private, public, and academic sectors, and has a broad range of responsibilities. These responsibilities include the optimisation of the regional talent base through training and educational programmes. This optimisation is based on medical devices and manufacturing, the establishment of mentoring programmes to educate employees and students in the sector, and the support of events and programmes which heighten the interaction and collaboration between the three sectors.

Addressing skills shortages

Minnesota is experiencing issues with skills shortages, with companies having particular difficulty filling skilled manufacturing roles. To address this shortage, the Minnesota Department of Employment and Economic Development (DEED) has developed a matching grant programme, the 'Minnesota Jobs Skills Partnership'. The programme provides funding for companies to engage with third-level institutions in the design and implementation of four-year and two-year programmes to address specific skills gaps.

For example, Medtronic developed a curriculum with Hennepin Technical College, which educated employees from 359 companies on effective communication with auditors, a skill that the organisation was struggling with. According to a DEED public document, the job skills programme awarded the college $226,089 in funding, while Medtronic contributed $397,778. The college itself provided $9,177.

San Jose/Silicon Valley

California is unparalleled in the US when it comes to the sheer size of industry, with a lot more medtech workers and companies than any other state. The vast economic landscape of the state means that there are several medtech hubs. San Diego has emerged as a leader in the field of wireless medical technologies, while Orange County also has a major cluster of medtech innovation. For this report, the medtech industry in San Jose/Silicon Valley is examined in more detail. Some key facts about this medtech hub are outlined in the following figure.

Figure 23: Key facts about the San Jose/Silicon Valley medtech hub

Source: Qmed - Top 10 U.S. cities for medtech innovation (2015)

Silicon Valley is home to a large number of innovative medtech firms, which benefit from being located in an area that leads the nation in Venture Capital (VC) funding. While there are challenges in operating out of California, primarily the high tax rates, there are also several benefits that are somewhat unique to the area. These benefits are detailed in the following sections.

Innovation in specialist fields
A large number of medtech companies are located in Silicon Valley because of its environment, which favours innovative development of new ideas in the field, coupled with a well-developed support system for the commercialisation of products. Entrepreneurship and innovation are woven into the infrastructure of the region. These factors create an ecosystem that effectively ensures a smooth progression from start-up to commercialisation. Because of this, the area is established as a world leader in the use of information technology (IT) for healthcare-related applications.

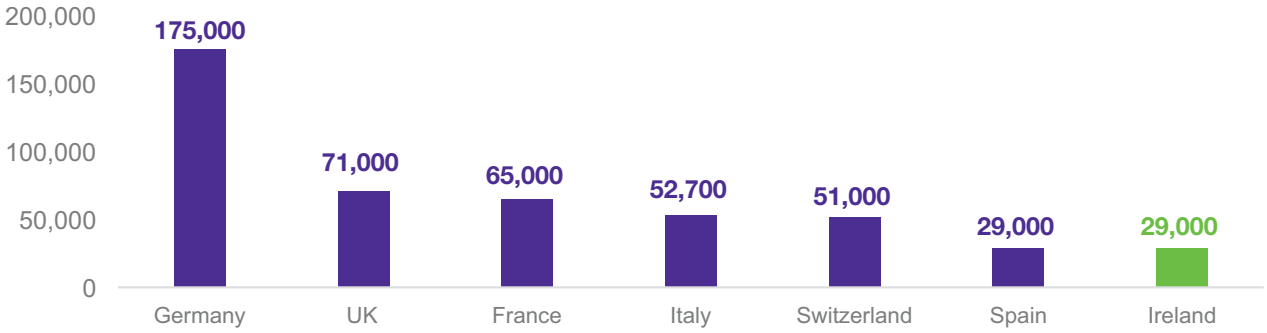
VC funding
Due to its location within the world's most affluent technology hub, the Silicon Valley medtech industry receives the largest amount of VC funding in the US. Many major firms take advantage of the resources in the area to acquire and/or invest in the smaller venture firms. This ensures that the smaller companies, which generally include an elite workforce, have the required economic resources available to commercialise their ideas and innovations.

Workforce
Home to Stanford University, among other top academic and research sites, the region has one of the most highly educated and skilled workforces in the world. Nearly half (46%) of the region's adult population are college educated, which is significantly higher than the national average (29%). The area attracts elite technological minds which aids greatly in the advancement of the medtech industry. The high density of companies in the relatively small area means that demand for medtech employees is high. Because of this, employees in the Silicon Valley medtech industry receive significantly better salary packages than employees in other hubs in the US. The financial incentives, along with the state-of-the-art technology used within the companies, entices the top academic minds.

Europe

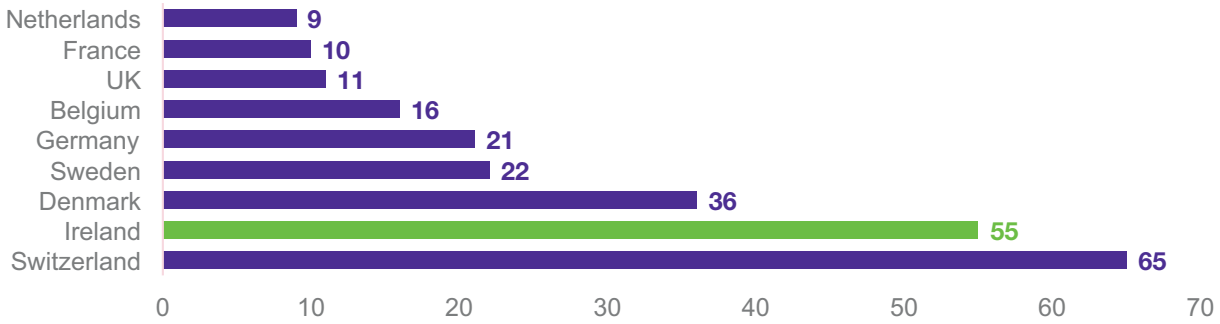
The European medtech market is a traditional stronghold in the global medtech industry. Western Europe represents more than a quarter of the global medical device market, with the European sector being led by Germany, France, UK, Ireland, and Italy. The European market employs more than 575,000 people in the medtech industry. The following figure provides an outline of the employment figures within the major European medtech markets, according to Medtech Europe.

Figure 24: Number of employees employed in the European medtech industry



Source: Medtech Europe – The European Medical Technology Industry in Figures (2015)

Figure 25: Number of people employed in the European medtech industry per 10,000 inhabitants



Source: Medtech Europe – The European Medical Technology Industry in Figures (2015)

The following figure highlights the European medtech employment figures as outlined by Medtech Europe. When employment is considered in relation to a country's size and population, Ireland features prominently in the European medtech industry.

There are currently approximately 25,000 medtech companies in the EU with the total value of the market estimated to be €100 billion. The industry is a hugely innovative and prosperous area of EU business and is considered as somewhat of a 'model' industry within the EU. A major benefit of the European industry is the approval time for new devices coming onto the market. The healthcare industry in Europe is highly advanced and there is a constant demand for cutting edge, high-tech products. A product is generally approved in Europe twice as quickly as it is in the US. With the average global lifecycle of a product being 18–24 months, and more than 12,000 patents being filed annually, this quick turnaround is a major advantage for the European market.

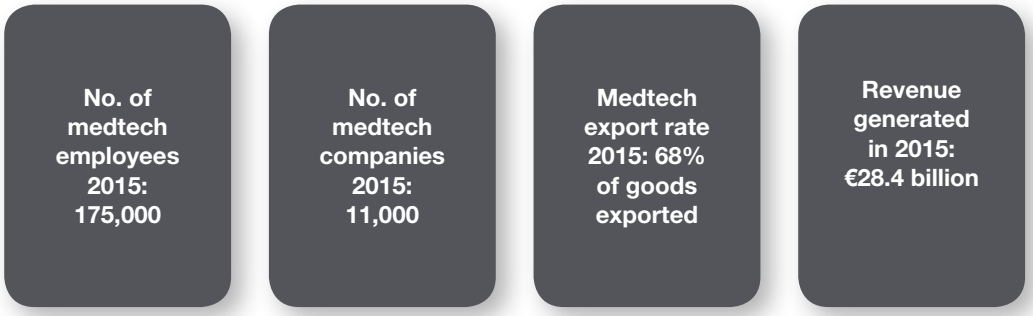
European case studies

Germany

Medtech Europe has reported that the German market is the largest in Europe with approximately 11,000 companies and over 175,000 employees. As with the other established markets analysed, Germany has a highly talented workforce. Well-educated doctors, researchers, and engineers facilitate a high standard of clinical research. The layout of the market differs to that of the US, as it is generally made up of smaller specialist companies rather than larger multinational organisations.

The German federal economic development agency, Germany Trade and Invest (GTAI), identified over 30 specialised cluster networks in Germany. This organisation enables effective collaboration across a range of schemes and projects between private sector companies, hospital research centres, and academia. These technology clusters provide benefits across the entire value chain. Some key facts about the German medtech market are outlined in the following figure.

Figure 26: Key facts about German medtech industry



Source: Germany Trade and Invest - Industry Overview of the Medical Technology industry in Germany (2015)

Several factors contribute to the ongoing success of the German medtech industry.

Specialist companies
As mentioned above, the layout of the German medtech industry consists of small, specialist companies with defined roles and expertise. This allows companies to identify niches in the market and become the specialist in each sector. For example, GTAI outlined that the German industry is renowned for its highly skilled manufacturing of surgical instruments and imaging technology.

Cost to market
Companies in Germany have a major advantage over their US counterparts in relation to the time and cost associated with bringing a product to market. For example, in Germany in 2012, it cost between €8 million and €10 million to bring a new medical device to market. According to the GTAI, it cost about $80 million in the US.

Workforce
The presence of a skilled and well-educated workforce is a common feature of most established medtech markets. Germany's traditional engineering expertise, primarily from the automotive industry, has somewhat transferred to the medtech industry. This coupled with an extremely sophisticated healthcare system that is comprised of world class physicians and talented researchers has resulted in a progressive medtech industry in Germany.

Infrastructure
Germany has a well-functioning infrastructure. It is centrally located in Europe and is a short distance from the most important European markets due to its excellent transport infrastructure. As a result, it can provide a secure supply of medtech-related exports.

The UK

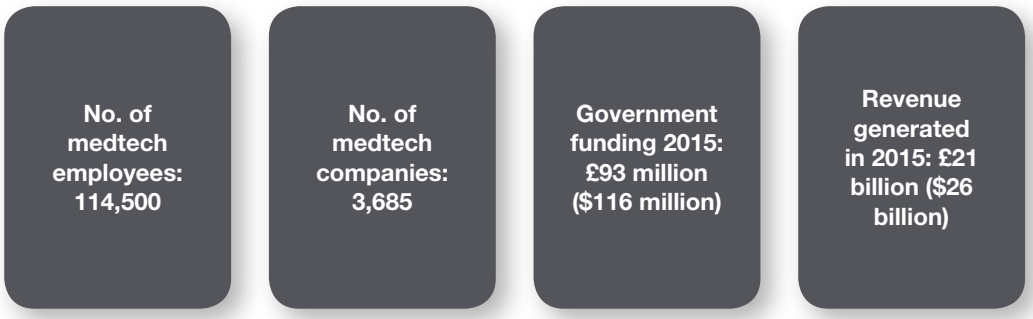
The UK is home to one of the largest medtech markets in the world, and the second biggest in Europe, behind Germany. The industry is primarily made up of small and medium enterprises (SMEs), as opposed to large multinational organisations. According to the UK Government's 2015 annual medtech update report, a total of 82% of medtech companies located in the UK are indigenous. Ireland is similar in this respect, with the Irish Medtech Association reporting that over 60% of Irish medtech companies are indigenous. This section provides an overview of the UK market as a whole. Some key facts about the medtech industry in the UK are outlined in the following figure.

Several factors contribute to the growth and success of the UK medtech industry.

Expertise in manufacturing products
The UK market is primarily a manufacturing market and this is reflected in the product segments that generate the most revenue and account for the highest levels of employment. The production of single-use technology, orthopaedic devices, and in-vitro diagnostic device (IVD) products generates the largest amount of income for the sector and accounts for approximately 29% of all employment in the market.

Marketplace infrastructure
As mentioned previously, the UK market is comprised of a large number of SME clusters rather than smaller groupings of multinational organisations. Almost 98% of companies in the UK industry have revenues of less than £50 million and 2,314 companies employ less than 10 people. While this model causes some inherent difficulties, it also provides a platform for successful specialist companies to flourish.

Figure 27: Key facts about the UK medtech industry



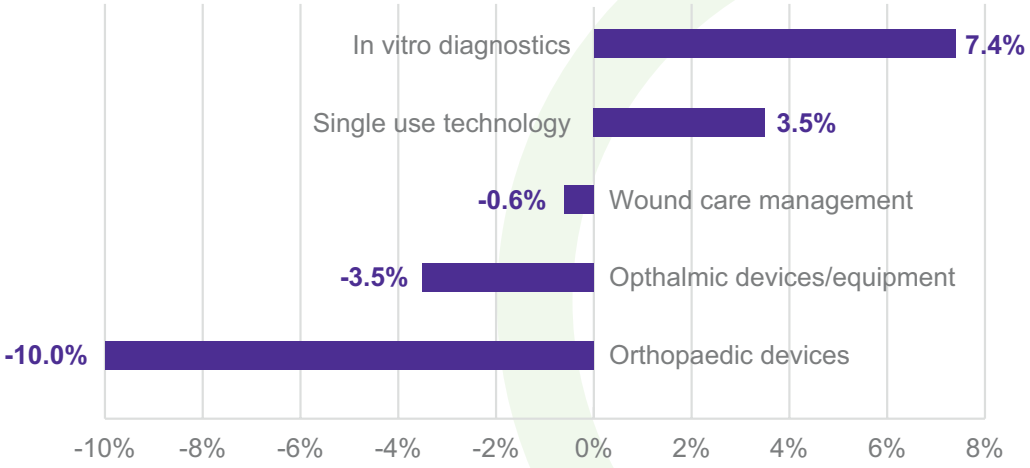
Source: www.gov.uk – Strength and Opportunity UK Medical Technology Infographic (2015)

Healthcare service
The National Health Service (NHS) in the UK is highly regarded globally. According to the NHS 2015/2016 funding plan report, the NHS had expenditure of over £116 billion for 2015-2016. This substantial healthcare spending allows for a high level of care to be provided using the latest medtech technologies. The service is generally provided at little expense to the patient. These factors, coupled with a private health sector worth approximately £35 billion ($44 billion) annually, benefit the medtech industry greatly.

Economic growth
While there is currently some economic uncertainty driven by the Brexit referendum decision, the UK has traditionally had a strong and consistent economy, fuelled by a robust British pound sterling. This economic stability has been the benchmark for growth across several industries, including the medtech industry.

The following figure outlines the medtech segments with the highest compound annual growth rates (CAGR) between 2011 and 2015.

Figure 28: % CAGR turnover UK medtech segments 2011-2015



Source: www.statista.co.uk - Compound annual growth rate of turnover in segments of the medical technology sector in the United Kingdom (UK) from 2011 to 2015

Asia

Asian case studies

China

The Chinese medtech market is currently the second largest market globally, having experienced somewhat unprecedented growth recently. Over the last 10–15 years, the Chinese Government has hugely emphasised healthcare reform and this is reflected in the growth of the medtech industry.

The Chinese medtech industry has traditionally followed trends from international peers in the advancements of new innovations. However, there is now a sense that their platforms, innovations, and services may overtake international competition. As expected, the medtech hubs in China are generally located in the regions around Beijing, Shanghai, and Shenzhen. In this section, the Chinese medtech industry as a whole is analysed. The following figure outlines some key facts about the Chinese medtech industry.

Several factors have contributed to the growth of the Chinese medtech industry in recent years.

Government investment

The Chinese government has made a conscious decision to grow their Chinese medtech industry to compete on a global scale. Previously, most highly technical medtech devices were imported from Japan or the US but as government funding increases for innovation, research, and product development, the Chinese industry is becoming more self-sufficient.

Chinese medtech eco-system

There is a growing trend in the Chinese market to promote the purchase and use of domestic products rather than imports. The Government has put a number of tax and other incentives in place to promote Chinese producers. This is coupled with a commitment from a large number of Chinese hospitals to purchase a full range of domestically developed devices. Many multinationals recognise the significance of this. For example, the Massachusetts Institute of Technology (MIT) Review, April 2010, outlines how American multinational General Electric (GE) recently put forward their 'In China for China' strategy, establishing four research and development centres, as well as six other facilities in China to design and manufacture mid-end products exclusively for the local market.

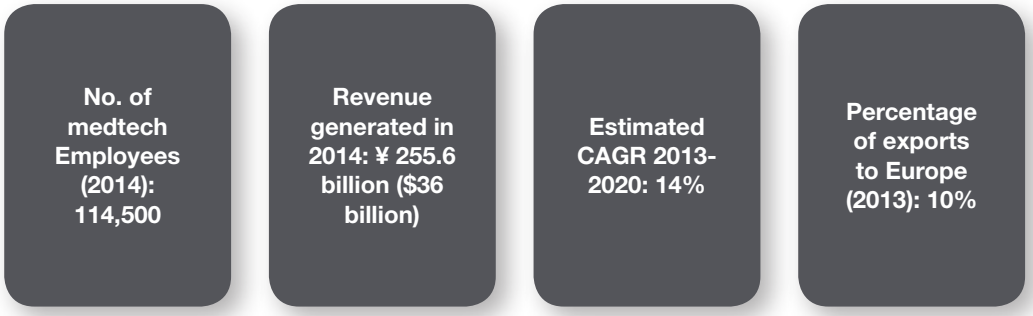
Workforce

Like Ireland, China has a large and highly skilled workforce to support the growing medtech market. The country is home to some of the world's top universities, and as the Chinese middle class continues to grow, a growing number of university graduates are seeking employment in the industry.

Free trade zones (FTZs)

The establishment of FTZs has sparked interest for foreign producers of medtech products. Ireland has benefitted from similar exemptions and freedom of movement rights through its EU membership. Notably, the Shanghai Waigaoqiao FTZ is attracting attention after liberalisation in the hospital sector. As a result, the first wholly foreign-owned hospital from a Hong Kong–German consortium was established. This step exemplifies the willingness to test new business models of healthcare in China. The local Chinese medtech industry can now cater more easily for this because of eased regulations and tax reliefs. On the other hand, it demonstrates the clear need to quickly implement new healthcare centres in an overpopulated and ageing country that is currently medically underequipped.

Figure 29: Key facts about the Chinese medtech industry



Source: Statista – Winning in China's Changing medtech Market (2014)

Japan

Japan's medtech industry is among the world's largest and is continuing to grow and develop. Several factors contribute to the growth of the industry, including a traditionally technologically adaptive infrastructure and a substantial national market, amongst others. In addition, the Japanese Government has recognised that the medtech industry is one of the 'pillars of economic growth' that will play a major role in the future sustainability of the Japanese economy. Because of this, a number of Government-led initiatives were put in place to provide growth platforms to the industry. Some key facts about the Japanese medtech industry are outlined in the following figure.

Several factors have contributed to the growth of the Japanese medtech industry.

Domestic market size

Biomedical Japan Incorporated has identified the Japanese domestic market as the third-largest medical device market globally. It is expected to grow even further due to Japan's large population over the age of 65. This is a huge attraction for foreign companies to establish operations within the country. While the regulation in the Japanese medtech industry is relatively comprehensive, the avoidance of export-related costs on a large percentage of production is also seen as extremely beneficial.

Connectivity of government ministries and industry

The Japanese Government previously identified a clear imbalance between the high level of medtech imports into the Japanese market and the relatively low level of exports in the industry. This indicated a clear inefficiency of getting the conceptualisation phases of a device through to market. To tackle this, the government decided that the three ministries responsible for medtech-related policies had to work closely together. The Ministry of Science and Technology, the Ministry of Economy, Trade and Industry, and the Ministry of Health, Welfare and Labour were all involved in the creation of a medical innovation council. The ministries are joined on the council by advisors from academia, healthcare services, and industry. This collaborative effort ensures that the medtech industry has a single focused strategy, with input from all stakeholders of the industry.

Government incentives for medtech innovation

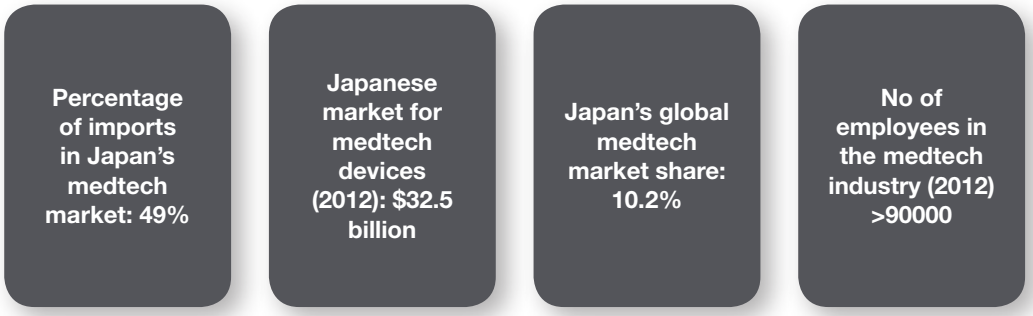
The Japanese Government recognised that the country has a highly capable manufacturing and research infrastructure, but that it is underutilised within the medtech industry. To address this, a number of financial (primarily tax relief) incentives and collaboration efforts have been put in place to encourage companies from other fields to enter the medtech industry.

One such initiative in Japan is the use of a model reminiscent of Japan's automotive and electronics industries. Large companies partner with SMEs to combine the wide marketing and manufacturing reach of the former with the advanced technologies developed by the latter. This collaboration with Japan's auto and electronics industry is a key advantage for the Japanese medtech hub.

Infrastructure

While Tokyo is the largest hub for start-ups in Japan, the medtech industry and the Japanese Government have recognised that there are a number of logistical issues associated with setting up in the city, such as real estate affordability and other associated set-up costs.
As a result, there is now a push to establish 'Tech Hubs' in neighbouring cities. These are purpose built for the advancement and collaboration of technologies. An example of this is the Osaka Innovation Hub (OIH), which is the base of operations for many entrepreneurs in Osaka and the greater Kansai area. The OIH has purpose-built medtech facilities including laboratories and business functions, which act as a plug-in and play facility for medtech companies. It also has a convention centre, a co-working space, an incubator from a Global Venture firm, and a hands-on laboratory that showcases projects by local start-ups and university students.

Figure 30: Key facts about the Japanese medtech industry



Source: Biomedical Japan Incorporated - The Japanese Medical Technology Market (2012)
Source: Epsicom - Medistat World Market Forecasts to 2017 (2012)

South Korea

South Korea's economy is the fourth largest in Asia. The combination of increased insurance coverage, an aging population, and government initiatives to expand the healthcare market, have made South Korea a prime destination for Western medical companies looking to expand into Asia. This also includes Japanese companies looking to grow within an expanding national market. South Korea has traditionally been a hub for technological innovation and development, and this has transferred into the medtech industry. Some key facts about the South Korean medtech industry are outlined in the following figure.

Several factors have contributed to the growth of the South Korean medtech industry.

Government initiatives

The South Korean Government has invested almost $3 billion in technology hub centre initiatives in recent years. According to Korean business portal, Business Korea, this financial boost has had a major impact on the medtech industry. A number of initiatives have been put in place, including matching international investment funds and tax incentives for foreign medtech investors. In addition, safety nets have been provided through funding programmes for scientists who are not successful on their own. The country is trying to lose the stigma previously attached to being an entrepreneur in South Korea, and the benefits are being seen within the medtech industry.

Specialisation in medtech IT

South Korea is a world leader in IT infrastructure and there has been a major push by Korean medtech companies to focus on the advancement of big data development in the medical industry. The infrastructure of the medtech industry is notably changing and there is going to be a shift towards remote and personable patient treatment.
For instance, Seoul National University Bundang Hospital (SNUBH) introduced a Hospital Information Exchange System developed by Korean companies for the easy sharing of patient records through big data system developments. SNUBH has shared its digitised medical records up to 2014 with more than 50 primary clinic hospitals. Given the already advanced IT infrastructure in place in Korea, many medtech companies see this style of data technology as being the future foundation of the Korean industry, with strong export potential in the future.

Collaborations

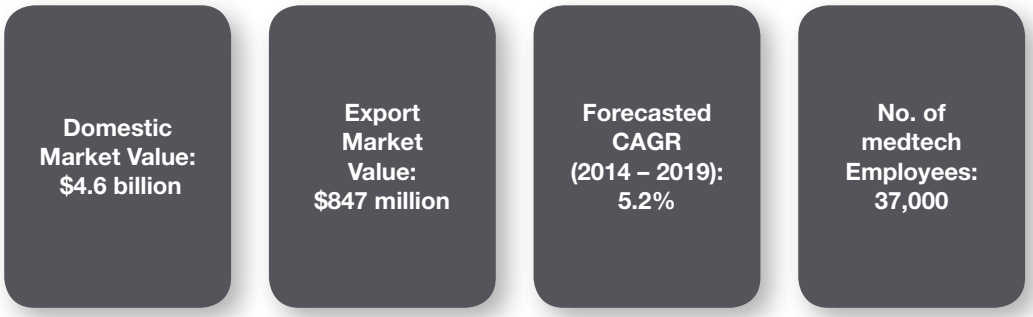
Several medtech collaborations, primarily through Government-led initiatives, have been hugely beneficial to the Korean medtech industry. This is similar to the expansion approach effectively adopted by Ireland. An example of this is a recent agreement that has allowed medtech companies to hire an engineer to serve their two-and-a-half-year compulsory military service in the research and development (R&D) department of medical companies. After two months of basic army training, people are incentivised to join the medtech workforce instead of completing their obligation in the military.

In addition, several international medtech entrepreneurship programmes have been established between Korean and foreign universities. For example, Singapore-Stanford Biodesign (SSB) and Dongguk University (DU) signed a three-year 'SSB-Korea Innovation Partnership' (SKIP) in 2015, that aims to develop talent in medical technologies innovation and gain insights into the medtech ecosystem in Singapore, Korea, and the region.

Highly skilled workforce

According to the OECD, approximately 66% of 25–34 year olds in South Korea are university graduates and the country is renowned for having some of the most technical and advanced academic institutions in the world. This is similar to Ireland, which has a highly educated workforce with approximately 38% of the population holding third-level qualifications. Currently, more than 400,000 Koreans work in the field of R&D and the country has a significantly lower staff turnover than China or Hong Kong.

Figure 31: Key facts about the South Korean medtech industry



Source: Business Korea - Medical Devices Korea Nurture Medical Device industry (2014)

Israel

Israel has the largest medical device market in the Middle East. However, much of the market, (just under 83%), is supplied by imports. A significant portion of these imports are high-end products, falling into the diagnostic imaging apparatus category. In 2015, there were over 200 new medtech companies registered in Israel, making it the second fastest growing market in the world. This section cover the Israeli medtech industry as a whole. Several key facts about the Israeli medtech industry are listed in the following figure.

Medtech eco-system

The growth of the Israeli medtech industry is largely due to the successful eco-system in place in the country. This includes first-rate academic and medical institutions, enlightened government support, successful incubators and accelerators, and the active presence in Israel of global medtech companies.

Most of the highly technical academic institutions have active 'technology transfer offices'. These are engaged full time in the commercialisation of technological inventions developed by their respective institutions, using sophisticated licensing and start-up practices. These transfer offices bridge the gap between the development and commercialisation phases.

Innovation in R&D

In 2015, the Israeli industry lodged more patents per capita than any other medtech industry in the world and it is widely accepted that Israel is a global innovation hub when it comes to new healthcare solutions. This innovation is inevitably intertwined with the eco-system outlined above, with several factors helping to facilitate the development and manufacturing of new advancements.

Government assistance

The Israeli Innovation Authority provides financial support for R&D in the medtech industry. In fact, R&D forms a substantial part of the Authority's overall budgets. Most medtech companies in Israel are SMEs, with over 50% of companies having less than five employees. These companies are assisted further through State incubators such as 'Mindup' and 'MedXelerator'.

Workforce

As in Ireland and other medtech strongholds, the Israeli industry has a very skilled and suitable workforce at its disposal for medtech R&D. As mentioned previously, Israel is home to highly regarded academic and medical institutions that work to develop the skills of the innovative workforce. It is also worth noting that almost all Israeli citizens are conscripted and must spend a certain amount of time in the Israeli army after reaching 18 years of age.

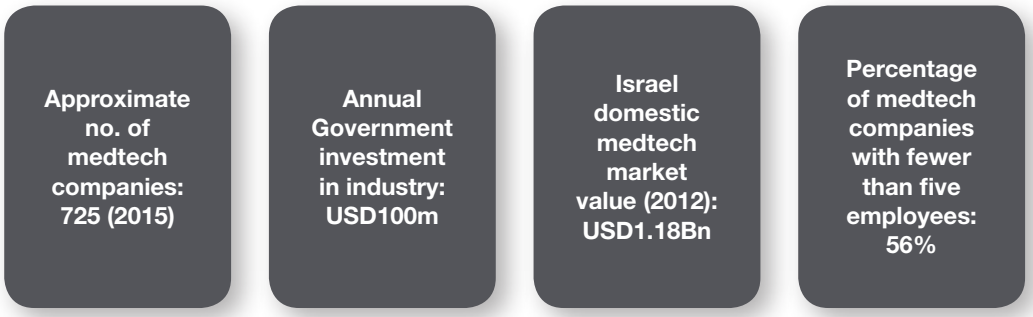
This time served provides the workforce with a range of skills, including an understanding of engineering principles, which influences the career paths chosen post conscription, as well as being very beneficial to those who choose to move into the medtech industry.

US/Israel relations

The US and Israel have extremely strong political and economic ties, which has benefitted the Israeli medtech industry. Most large US multinational organisations have operations in Israel and there have been frequent acquisitions of smaller Israeli start-ups by these firms. US companies have also invested greatly into the industry.

According to a report from the research firm, Israeli Venture Capital (IVC) Research Centre, more than $400 million was invested between 2010 and 2014 by American organisations into the Israeli digital health industry alone. US companies also benefit from Israeli government grants, which are considered to be incentives to operate within the Israeli market.

Figure 32: Key facts about the Israeli medtech industry



Source: Knowledge, Wharton, Medical Device and Diagnostic Industry (2014)
Source: Israel Advanced Technology Industries – Israel's Life Sciences Industry Annual Report (2015)

Singapore

The medtech industry was identified by the government of Singapore as a potential area of growth in the early 2000s, and the industry has seen substantial progress since. This has largely been due to several government-led initiatives. While Singapore had traditionally been used as a manufacturing or distribution site for medtech companies, there has been a recent shift of focus towards R&D.

The market has seen a surge of domestic SMEs coming into the industry, while several large Multinational Corporations (MNCs) have also set up operations in the purpose-built medtech hubs in the country. According to Singapore's Agency for Science, Technology and Research, the successful growth of the industry has led to Singapore's medtech industry contributing $5.5 billion in output and having more than 10,500 jobs in 2014 This is compared to an output of $1.5 billion and 4,000 jobs in 2000. Some key facts about the Singaporean medtech industry are outlined in the following figure.

As with any emerging market, there are positive factors which contribute to the prosperous nature of the industry, but there are also barriers that affect future growth.

Medtech hub infrastructure

The Singaporean Government have put in place an extremely beneficial and progressive medtech infrastructure for both incoming global MNCs and domestic SMEs. 'Future Ready Singapore' describes the financial support systems in place along with the Government-built, state-of-the-art, design-led medtech facilities or communities, such as 'Biopolis' and the 'Medtech Hub'.

These hubs facilitate the development of the entire chain of medtech activities, from R&D to manufacturing and healthcare. The hubs essentially provide a 'plug-and-play' environment for the medtech community, which means that they connect and work perfectly at first use. Companies can also tap into innovative ideas from partnerships with public-sector researchers and clinicians, advanced technologies from global industry leaders and academic centres, and can test bedding infrastructures in hospitals, all of which are available within the purpose-built medtech hubs.

Specialisation

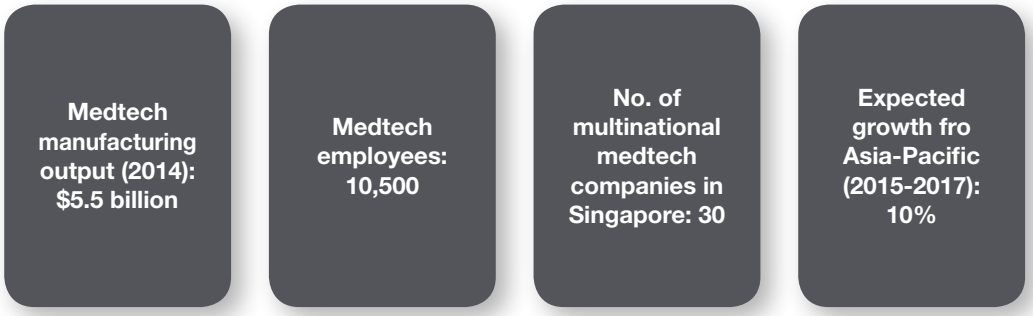
Singapore has used the medtech infrastructure outlined above to become specialists in the production and development of several specific medical devices. The market has seen recent substantial growth in several medtech sectors including cardiovascular, eye care, diagnostic, imaging, research tools, scientific instruments, and orthopaedics.

To put this into perspective, the 2016 Association of Southeast Asian Nations (ASEAN) briefing report stated that 10% of the world's contact lenses, over 70% of microarrays, and 50% of the world's thermal cyclers and mass spectrometers are currently produced in Singapore. This core specialist product market ensures that the industry has a solid foundation, while ongoing research, development, and growth efforts are continued.

Intellectual property (IP)

According to the World Economic Forum's (WEF's) 'Global competitiveness report 2015-2016', Singapore ranks fourth out of 114 countries globally in terms of its security of IP protection. Traditionally, some concerns were raised in relation to IP protection in several Asian markets. For example, China ranked sixty third on the same WEF report. With R&D being a primary focus of the medtech industry, it is imperative for companies to make sure that their ideas are secure and that their patents are legally sound. Singapore's strict IP protection policies allow medtech companies based in the country to have relative peace of mind in this respect.

Figure 33: Key facts about the Singaporean medtech industry



Source: Singapore Business Review - Singapore's 6 Key Growth areas (2016)
Source: Future Ready Singapore – Medical Technology (2015)

Emerging markets

Brazil

Brazil's medtech industry is considered the top market in the Latin American region and is among the top 10 medtech markets in the world. The medtech market is dominated by the subsidiaries of the big multinational companies, with the independent national companies generally being small to medium in size.

To develop and be competitive within the Brazilian medtech industry, there is a general trend towards industry consolidation in the sector. Many companies resist the expansion of operations in Brazil past a certain threshold, due to the country's gaping fiscal deficit, political dysfunction, deep economic recession, and ongoing socio-economic unrest. Some key facts about the Brazilian medtech industry are outlined in the following figure.

As with any emerging market, there are positive factors which contribute to the prosperous nature of the industry but there are also barriers that affect future growth.

Strengths

Market focus on medical consumables

The Brazilian medtech market is generally a manufacturing market for nationwide use or for export to other emerging international markets or Latin America. Companies are aware that they cannot compete with most established medtech industries in research, or in the manufacturing of highly technical devices. This results in a strategy towards the production of consumables such as surgical gloves, syringes, needles, catheters, cotton, sealants, glues, sutures, staples, anti-adhesion, and tapes, to name a few. While the value of these products is undoubtedly lower than more technical products, it does ensure a steady turnover for Brazilian medtech companies.

Government initiatives

The sheer size of Brazil's healthcare market makes it an attractive export avenue for many multinationals. The Brazilian Government has recognised this and has launched several stimulus packages to encourage higher levels of domestic production, especially in relation to highly technical medical equipment. Various policy channels are used, such as taxation, financing of modernisation and innovation, public purchasing and public-private productive development partnerships.

Barriers to future growth

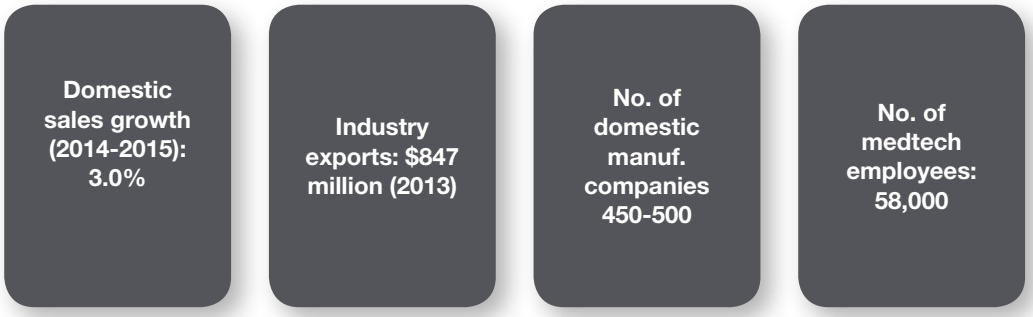
Workforce

The Brazilian medtech industry does not have access to the highly skilled workforces that are available to other established medtech hubs. This is a critical factor across all market leaders in the medtech industry and one in which Ireland has seen a huge return on its investment. It is tough to envisage the Brazilian medtech industry being a major established market without tapping into the more profitable sectors of production and innovation. This is extremely difficult to do without a suitable labour market.

International market uncertainty in Brazil

For the industry to move forward and compete with established markets, Brazil needs a higher number of multinationals to be based in the country. This would bring the skills, expertise, and funding required for growth. As outlined above, several factors, both social and economic, make Brazil an uncertain location in which to invest.

Figure 34: Key facts about the Brazilian medtech industry



Source: Switzerland Global Enterprise - Brazil's Market for medtech Products (2014)

India

The Indian medtech industry is the fourth largest in Asia (behind China, Japan, and South Korea), and many industry forecasters are predicting that it is a market that will experience substantial growth up until 2020. The marketplace has been traditionally dominated by imported products, which currently comprise around 75% of total medtech sales domestically. Multinational organisations based in the marketplace tend to limit their activity to distribution, with relatively few committing to setting up manufacturing operations.

The medtech industry hubs are, for the most part, located in the states of Andhra Pradesh, Maharashtra, and Gujarat. Some key facts about the Indian medtech industry are outlined in the following figure.

As with any emerging market, there are positive factors which contribute to the prosperous nature of the industry but there are also barriers that affect future growth.

Strengths

Large manufacturing infrastructure for medical consumables

India has a population of 1.25 billion people, so its markets and industries operate at scale. The medtech industry has created a large manufacturing infrastructure that produces large quantities of low-tech medical consumables and disposable devices. These devices have low markup values but are produced on such a large scale, they contribute greatly to the industry.

Government initiatives

According to India's Department for Science, Technology and Earth Sciences, the Indian medtech industry was valued at $6.3 billion in 2013. The Indian Government has identified the medtech industry as a potential growth area and have increased investment in an attempt to establish India as a medtech hub. The Indian Government has established a federal National Medical Device Authority to promote its medtech industry through industry-friendly measures such as the creation of medtech specific industrial parks, tax concessions, and direct state funding of medtech startups.

Barriers to future growth

Technical high-spec infrastructure

While the infrastructure is in place for large-scale, low-tech manufacturing in India, the eco-system that allows for the development and production of highly technical medical devices is currently not in place. For many companies within the industry, there is a perception that the best approach for producing big ticket items within the Indian market is to eliminate technical features from the templates of similar devices sold in Western markets. This has resulted in the production of lower quality versions of established devices. This is considered to have had a deeply negative effect on the export capabilities of the Indian medtech industry.

Taxation

The tax rates for importing components of medical devices to manufacture are disproportionately high in comparison to the rates for importing the finished product itself. As a result, multinationals use India primarily as a distribution route, rather than as a manufacturing hub for more technical devices.

Figure 35: Key facts about the Indian medtech industry

Source: US-India Business Council (2014)
Source: Medical Device and Diagnostic Industry - Emerging medtech Hubs Around the Globe (2016)

Glossary

Glossary Term Style	Glossary Meaning Style
3D	3 Dimensional
AdvaMed	Advanced Medical Technology Association
AI	Artificial Intelligence
AMBER	Advanced Materials and Bioengineering Research
ARCH	Applied Research for Connected Health
ASEAN	Association of Southeast Asian Nations
ASTM	American Society for Testing and Materials
CAD	Computer Aided Design
CAGR	Compound Annual Growth Rates
CISSP	Certified Information System Security Professional
COPD	Chronic Obstructive Pulmonary Disease
CSO	Central Statistics Office
CÚRAM	Centre for Research in Medical Devices
DEED	Department of Employment and Economic Development (Minnesota)
DOC	Department of Commerce (US)
DIT	Dublin Institute of Technology
DU	Dongguk University
EKG	Electrocardiogram
FDA	Food and Drug Administration (US)
FDI	Foreign Direct Investment
FTZ	Free Trade Zone
GAMP	Good Automated Manufacturing Processes
GE	General Electric
GMDN	Global Medical Devices Nomenclature Agency
GMIT	Galway Mayo Institute of Technology
GMP	Good Manufacturing Practice
GNP	Gross National Product
GTAI	Germany Trade and Invest
GxP	Good Practice
HBS	Harvard Business School
HCI	Human Computer Interface
HEA	Higher Education Authority
HETAC	Higher Education and Training Awards Council
HIHI	Health Innovation Hub Ireland
HSE	Health Service Executive
ICT	Information Communications Technology
IDA Ireland	Industrial Development Authority of Ireland
IOT	Interoperability Test
IP	Intellectual Property
IQ	Installation Qualification
IT	Information Technology
IT Sligo	Institute of Technology, Sligo
IVC Research Centre	Israeli Venture Capital Research Centre

IVD	In-Vitro Diagnostic Device
JSSP	Job Seeker Support Programme
MDDI	Medical Device and Diagnostic Industry
Medtech	Medical Technology
MIT	Massachusetts Institute of Technology
MNC	Multinational Corporation
MRI	Magnetic Resonance Imaging
NHS	National Health Service
NIBRT	National Institute for Bioprocessing Research and Training
NIH	US National Institutes of Health
NFQ	National Qualification Framework
NUIG	National University of Ireland Galway
NUIM	National University of Maynooth
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturers
OIH	Osaka Innovation Hub
OQ	Operational Qualification
PLC	Public Limited Company
PQ	Performance Qualification
PQA	Personal Qualities and Attributes
QMS	Quality Management System
QS	Quacquarelli Symonds
SFI	Science Foundation Ireland
SKIP	SSB-Korea Innovation Partnership
SME	Small and Medium Enterprises
SNUBH	Seoul National University Bundang Hospital
SOLAS	Seirbhís Oideachais Leanúnaigh agus Scileanna
SSB	Singapore-Stanford Biodesign
STEM	Science, Technology, Engineering, and Maths
TCD	Trinity College Dublin
UCD	University College Dublin
UL	University of Limerick
VC	Venture Capital
WEF	World Economic Forum
WHO	World Health Organisation

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