

# Medical Device Sectoral Overview



**Galway City and County Economic  
and Industrial Baseline Study**

# **MEDICAL DEVICE SECTORAL OVERVIEW**

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## Our Approach<sup>1</sup>

Our approach in undertaking this overview of the medical device sector was to take a global and national perspective before focusing on the regional and local level. One of the main limitations we faced preparing this sector review is the lack of quality and reliable data at the local level. The framing of the global and national level overviews against publicly available local data provides a basis and context to consider the future of the in Galway City and County.

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<sup>1</sup> The information contained in this overview has been compiled from many sources that are not all controlled by the Whitaker Institute. While all reasonable care has been taken in the compilation and publication of the contents of this resource, Whitaker Institute makes no representations or warranties, whether express or implied, as to the accuracy or suitability of the information or materials contained in this resource.

## Executive Summary Overview of the Medical Device Sector

### Global Overview

- The current global market is valued at \$228 billion, up from \$164 in 2010 and projected to reach \$440 billion by 2018.
- The global market is growing at approximately 4.4% compound annual growth rate per year.
- The US market value is 38% of the global total and China has become the third largest medical device market valued at \$48 billion.
- Johnson and Johnson, GE and Medtronic are the top 3 medical device companies.
- There are 7,000 medical device companies in the US and the market is anticipated to grow at 6.1% compounded annual growth rate.
- Some 400,000 individuals are directly employed and 2 million indirectly employed in the US with Massachusetts generating the most revenue.
- Western Europe represents approximately 25% of the global medical device market, with Germany leading the market followed by France, the UK and Italy.
- In Western Europe, 3.7% is the current compounded annual growth rate for the sector and Northern Europe is forecasted to have a 5.1% compounded annual growth rate in the next five years.
- There is a 20% average annual growth rate for the Chinese medical device market.
- Hospitals account for the largest distribution channel for medical devices in the Chinese market at 79% followed by pharmacies at 17%.
- Diagnostic imaging devices have a 40% market share.
- Cost containments, pricing and reimbursement controls and regulatory issues are key drivers for the medical device sector.

## National Overview

- Export value is €10.6 billion, up 8% since 2011.
- Medical devices and diagnostic products represent 8.5% of Ireland's total merchandise exports.
- There have been 338 notifications to the Irish Medicines Board to their medical device register relating to class 1 in-vitro diagnostic and custom made devices.
- There were 48 new medical device manufacturers registered in 2012 with the Irish Medicines Board.
- 15 of the top 20 global medical device companies have operations in Ireland.
- There are 300 medical device companies employing more than 25,000.
- 90% of companies in this sector are SMEs.
- 94% of Irish medical device companies are expressing confidence about their business.

## Regional and Local Overview

- Galway employs one third of the country's 25,000 medical device employees and the West accounts for 39% of regional distribution of medical device.
- There is a significant cluster of medical device companies with Medtronic and Boston Scientific being the largest MNC employers.
- Boston Scientific Ireland Ltd employs 2,800 individuals and Medtronic Vascular Galway Ltd. employs 1,882 individuals.
- The medical device cluster in Galway occurs through university-industry linkages, a continuous development of a skilled labour pool, international reputation through the success of Boston Scientific and Medtronic, the growth of supplier firms and knowledge transfers establishing new start-ups.
- The medical device companies within this cluster are supported by such organisations as Enterprise Ireland, IDA Ireland, Udaras na Gaeltachta, Local Enterprise Office Galway, GMIT and NUI Galway.
- Galway has become recognised for its specialisation in coronary devices.
- The Department of Mechanical and Biomedical Engineering has given rise to an average of 22 graduates per year since 2003.

- A BioInnovate team recruited in Galway, focusing on cardiovascular disease identified the need for a vascular support device and technology to improve vascular embolism.
- REMEDI has recently received €47 million in funding grants for pioneering research initiatives for 36 research projects involving over 200 researchers.
- GMedTech has obtained over €3.5 million worth of funding for an applied biomedical research project and has developed three cardiovascular type simulators for assessing heart attacks, stroke and aortic aneurysms.



# Global Overview of the Medical Device Sector

## Global Overview

### Introduction

Billions of patients worldwide depend on medical device products and technologies. These products are used in the diagnosis, prevention and treatment of diseases. Medical technologies include wheelchairs, defibrillators, contact lenses, pregnancy tests and plasters (smartfutures, 2014).

## 1 Global Overview

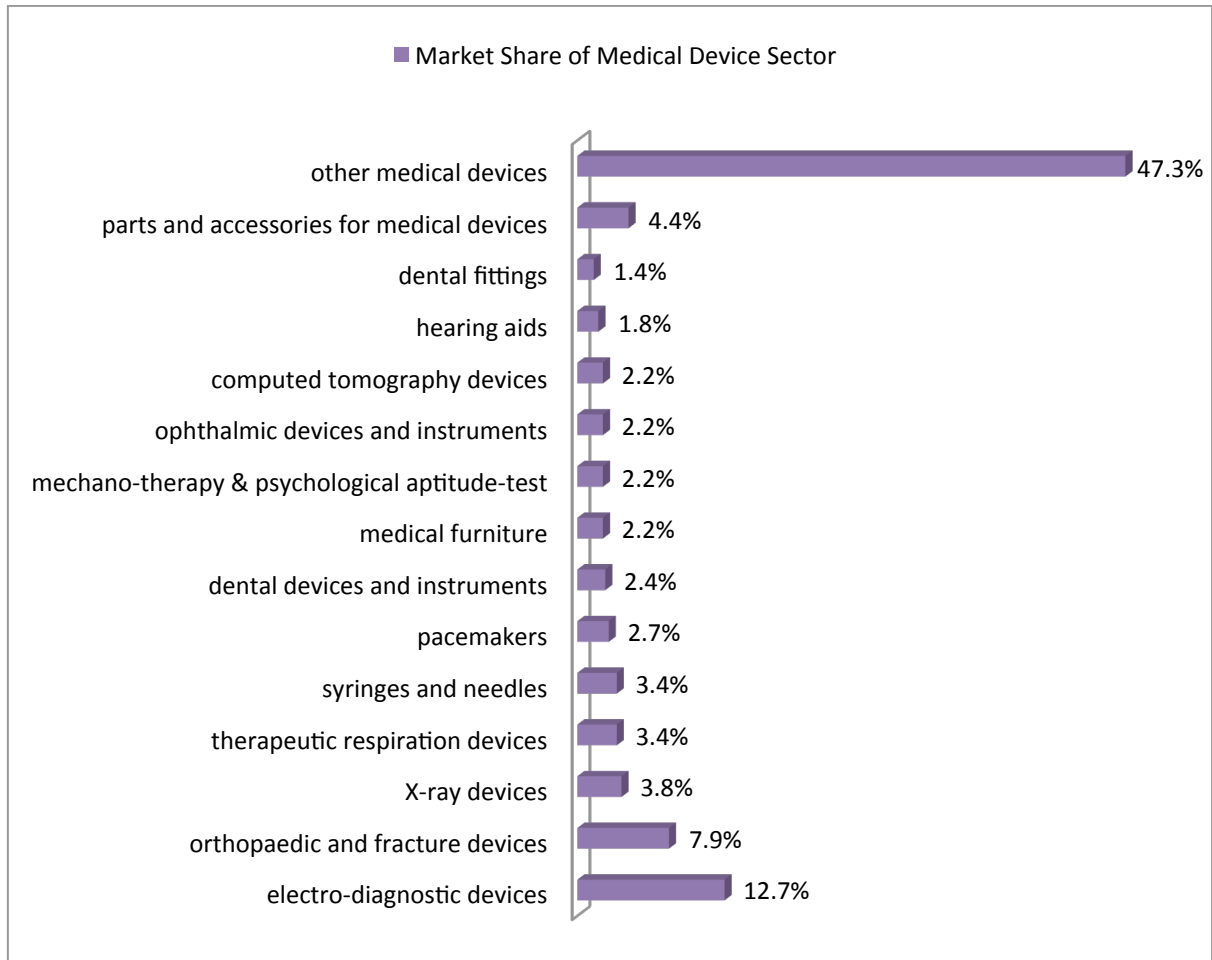
### 1.1 Global Market Size

The global medical device market is currently valued at \$228 billion, up from \$164 billion in 2010 and projected to reach \$440 billion by 2018. It is growing at an approximate 4.4% compound annual growth rate per year. This growth is expected to outpace the prescription drug market by 2018, which is in comparison growing at a rate of 2.5%. Diagnostics are predicted to be the industry's top segment, achieving global sales of \$54.5 billion. Neurology devices are expected to grow the fastest, expanding by 6.1% annually while orthopaedics will grow the slowest at 3.1% (Garde, 2012).

The largest medical device market is the United States, valued at \$125.4 billion (espicom, 2015). The U.S. market value represented approximately 38% of the global medical device market in 2012. The European medical devices market is the second largest, valued at €58 billion. The leading EU markets are Germany, France, Italy, the United Kingdom and Spain (Klass Consulting, 2015). China has recently become the third largest medical device market, growing at an average of 20% annually since 2009 and valued at over \$48 billion (export, 2014).

The global market share of medical devices is illustrated in Figure 1, with electro-diagnostic devices accounting for 12.7% of the global market share (PRNewswire, 2014). Orthopaedic and fracture devices account for 7.9% of market share while dental fittings account for the smallest share of 1.4%.

**Figure 1:**  
Global Market Share of Medical Devices



(Adapted from PRNewswire, 2014).

## 1.2 Top 20 Medical Device Companies

Johnson & Johnson is the leading medical device company in the world (see Table1), generating revenue of US\$28.7 billion. Johnson & Johnson generates more than US\$10 billion more in revenue than the next leading medical device company. General Electric Company in second place generates US\$18.1 billion followed by Medtronic which makes US\$17.1 billion (see Figure 2). Of the top 20 global medical device companies 15 have operations in Ireland (Thornes, 2014).

**Table 1:**  
Top 20 Medical Device Companies

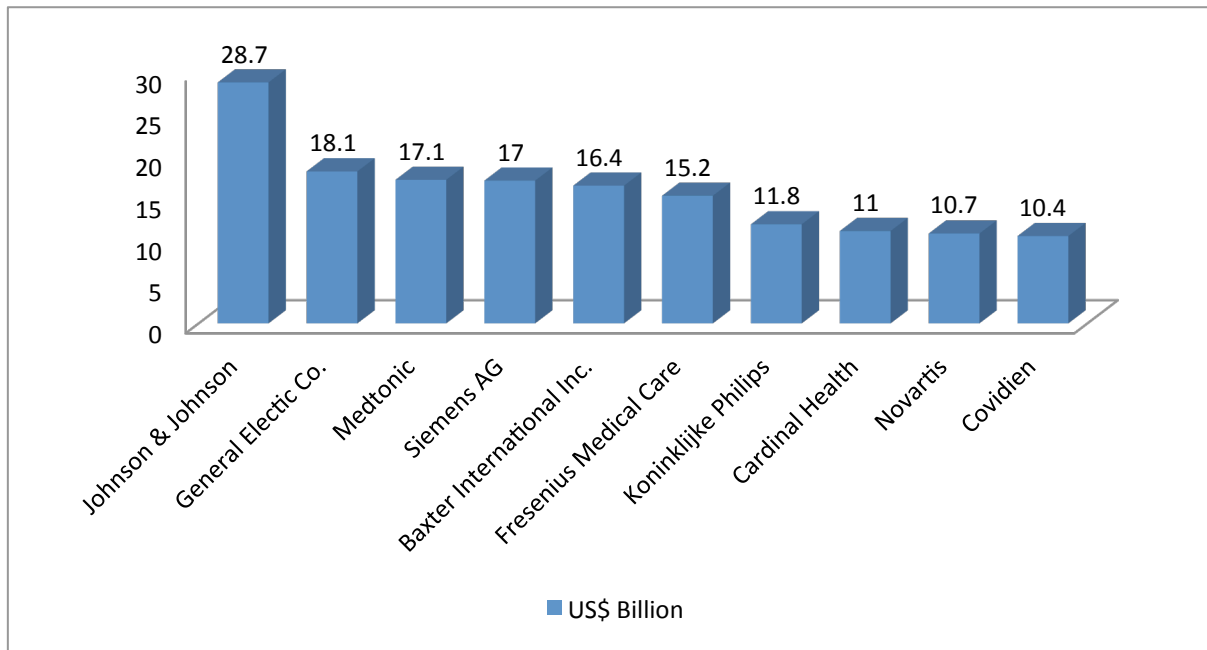
Rank	Company	Rank	Company
1	Johnson & Johnson	11	Stryker Corp
2	General Electric Co.	12	Becton, Dickinson and Co.
3	Medtronic	13	Boston Scientific
4	Siemens AG	14	Essilor International SA
5	Baxter International Inc.	15	Allergan Inc.
6	Fresenius Medical Care AG & Co. KGAA	16	St. Jude Medical Inc.
7	Koninklijke Philips NV	17	3M Co.
8	Cardinal Health Inc.	18	Abbott Laboratories
9	Novartis AG	19	Zimmer Holdings Inc.
10	Covidien plc	20	Terumo Corp.

(Adapted from MDDI, 2014).

Figure 2 illustrates the top twenty leading global medical device companies as of 2014 and their generated revenues. The top twenty leading global medical device companies' combined revenue accumulates to \$156.4 billion (MDDI, 2014).

**Figure 2:**

Leading Global Medical Device Companies and their Generated Revenues, 2014

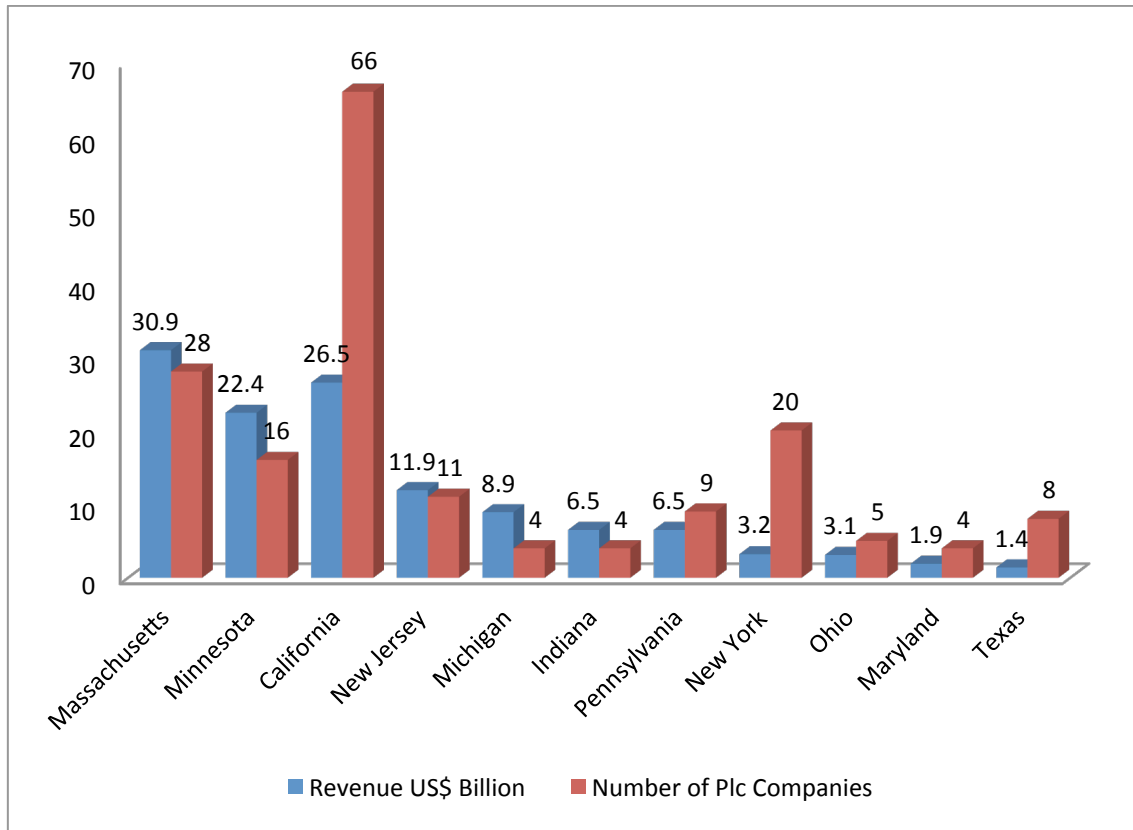


(Adapted from MDDI, 2014).

### 1.3 The United States' Medical Device Market

The United States has more than 7,000 medical device companies, with annual sales of \$106 to \$116 billion per year. The largest concentration of companies is located in California, Massachusetts, New York and Minnesota (Daniel, 2014). The U.S. medical device market is the largest in the world and is valued at US\$125.4 billion. It is second highest in the world per capita expenditure, behind Switzerland. The market is projected to grow at a CAGR of 6.1% over the next three years (espicom, 2014). The medical device sector directly employs 400,000 Americans and indirectly employs almost 2 million. Figure 3 illustrates the locations of the main medical technology public companies in the U.S. California is home to the largest number of companies while Massachusetts generates the most revenue (EY, 2013).

**Figure 3:**  
U.S. Medtech Public Companies



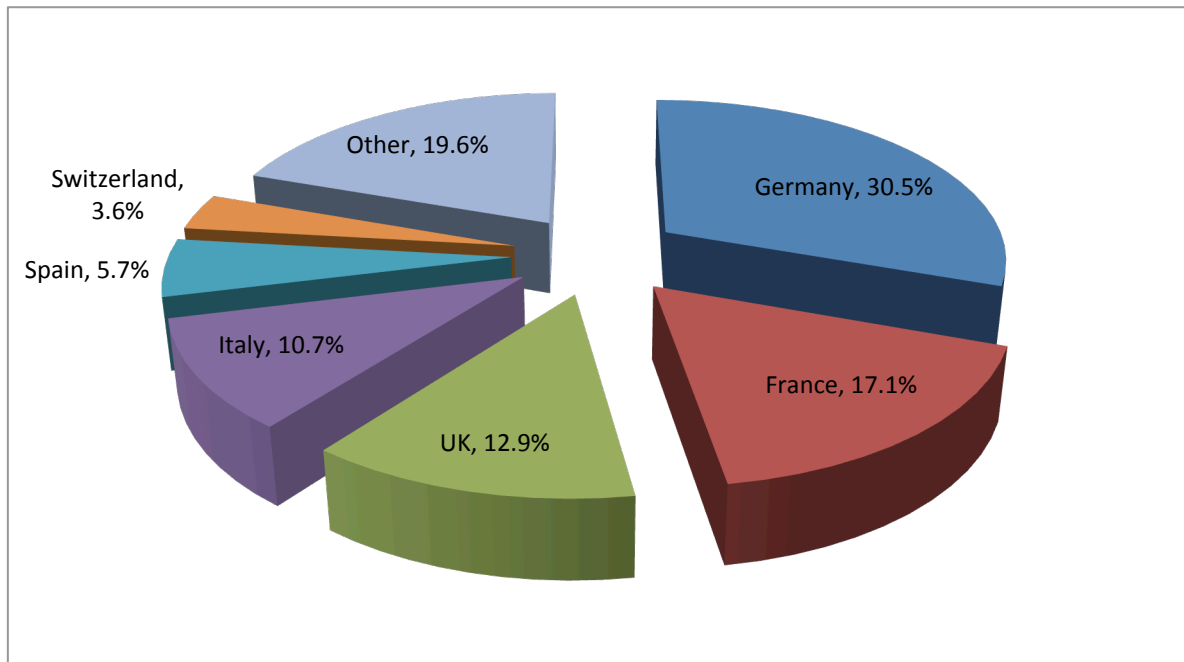
(Adapted from EY, 2013).

Medical Device companies in the U.S. are required to pay a 2.3% tax on their medical device sales as part of the Patient Protection and Affordable Care Act (2013). An estimated \$194 million per month is generated in tax payments by medical device manufacturers. Johnson & Johnson, the largest medical device company in the world, paid \$200 million (Carlson, 2014).

## 1.4 Europe's Medical Device Market

Western Europe represents more than a quarter of the global medical device market. The medical device market within Western Europe is led by Germany, France, the UK and Italy. Figure 4 illustrates Western Europe's medical device market shares (Klein, 2014).

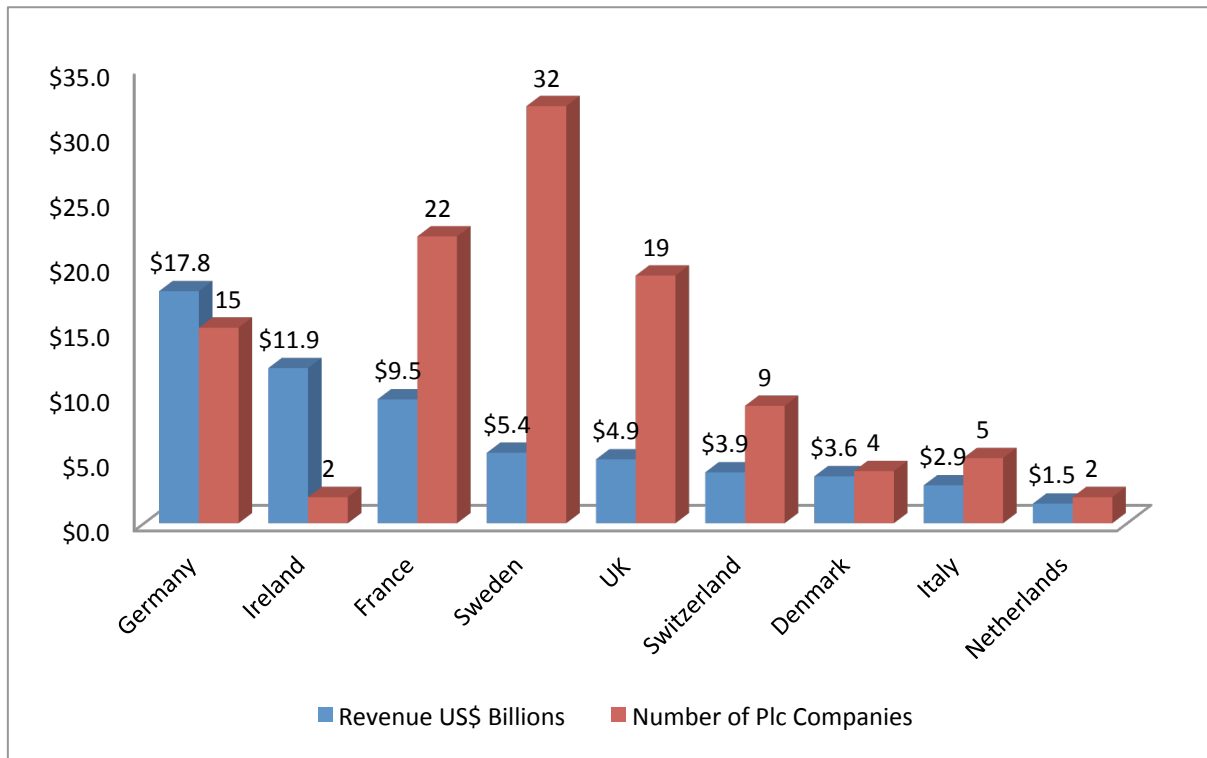
**Figure 4:**  
Western Europe's Medical Device Market Shares, 2014



(Adapted from Klein, 2014).

Figure 5 illustrates the revenue generated by the medical technology pure-play companies within Europe. Germany generates the most revenue, followed by Ireland as of 2012 (EY, 2013).

**Figure 5:**  
European Med Tech Public Companies



(Adapted from EY, 2013).

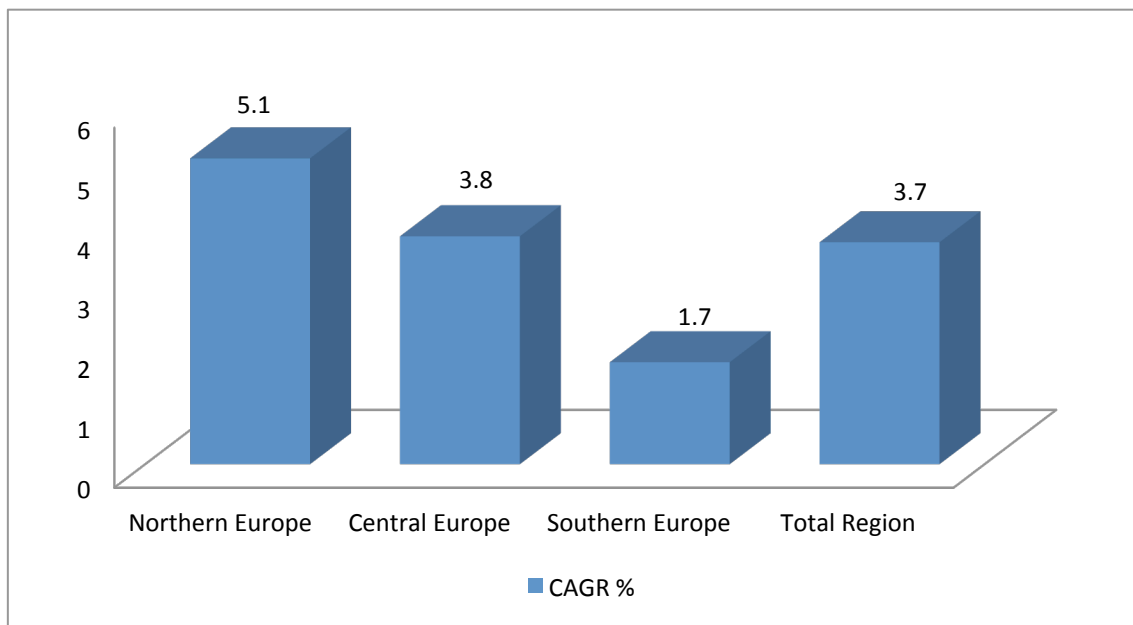
The weakness in the Eurozone is negatively impacting the medical device market in Western Europe. Further threats faced by medical device manufacturers include cost-containment measures, pricing and reimbursement controls as well as a more challenging regulatory and operating environment. Market growth drivers in contrast include a rising elderly population, epidemiology trends focused on chronic diseases and technology innovation. The Eurozone crisis, although beginning to recover requires medical device companies in Europe to further consolidate, focus on core competencies and cut operating costs in order to remain competitive. The Eurozone GDP growth will average 1.3% over the next five years in comparison to the global economic growth of 3.2%. Western Europe is experiencing a compound annual growth rate (CAGR) of 3.7% which is approximately half the global CAGR of 6.6%, indicating a forecasted drop in the global market share over the next five years from a 25% share to 22.6% share (Klein, 2014).

Northern Europe in contrast is set to experience the highest growth rate over the next five years at a CAGR of 5.1%, with the UK leading, followed by Norway, Finland, Denmark, Ireland and Sweden (Klein, 2014).

Central Europe is forecasted to record the second-highest growth in Europe at a CAGR of 3.8%, with Switzerland leading, followed by Germany, Belgium, the Netherlands, France and Austria (Klein, 2014).

Southern Europe is expected to record the lowest growth due to the recession with a CAGR of 1.7%, with Portugal leading, followed by Italy and then Spain (Klein, 2014). Figure 6 illustrates Western Europe's projected medical device market over the next five years.

**Figure 6:**  
Western Europe's Projected Medical Device Market, CAGR, 2014-2019



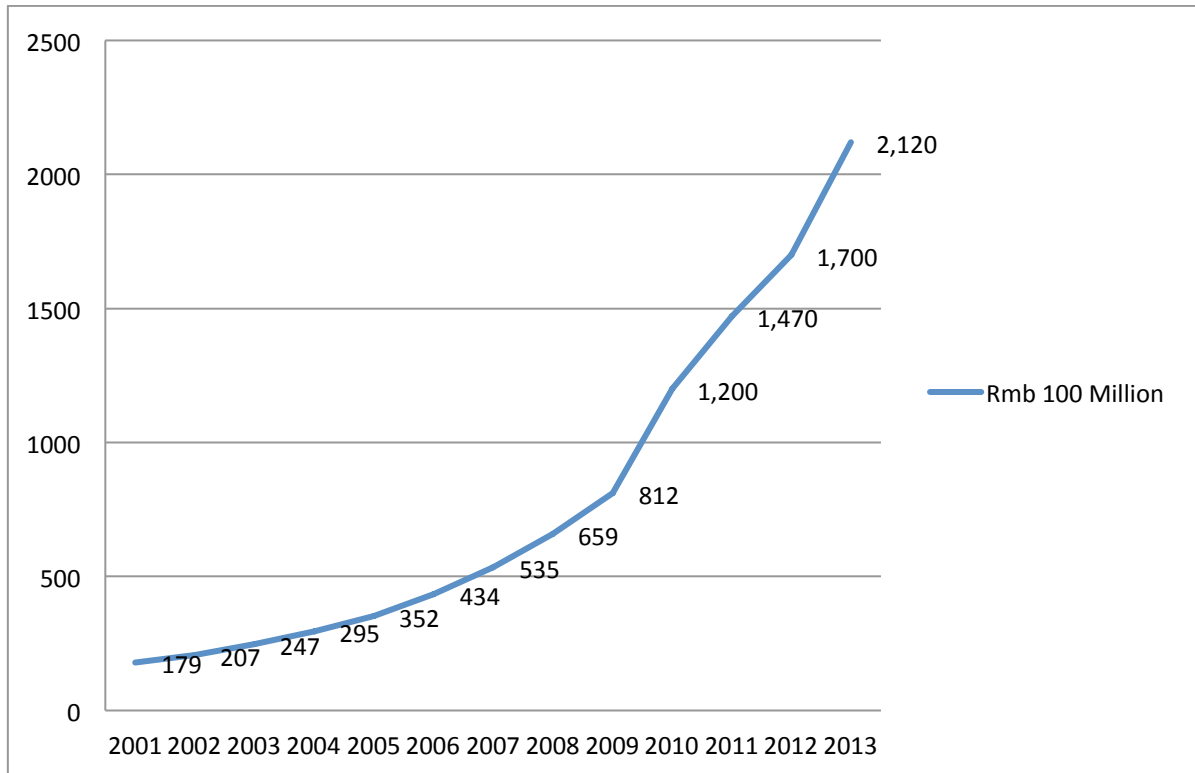
(Adapted from Klein, 2014).

## 1.5 China's Medical Device Market

China has recently become the third largest medical device market, growing at an average of 20% annually since 2009 and valued at over \$48 billion (export, 2014). The medical device market is one of the fastest growing market sectors in China (Elsinga, 2014). Figure 7 outlines the speed at which the Chinese medical device industry is growing.



**Figure 7:**  
Market Scale of China's Medical Device Industry

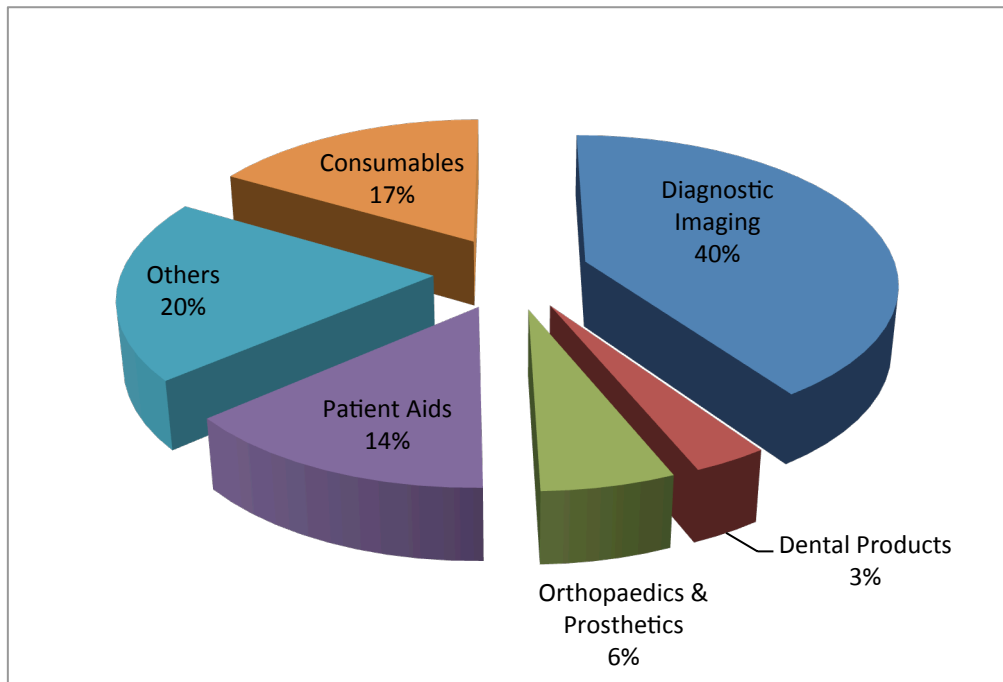


(Adapted from Tsang, 2014).

Like developed countries, a growing share of China's population will soon be over the age of 60 due to its one-child policy. This, along with rising living standards has given rise to the rapid growth in the demand for medical device products. Chinese health care however, has a focus on treatment rather than prevention, leaving a large part of the market underserved. When this side of the market is focused on, there will be an even larger demand for medical device products in China.

China has several thousand local manufacturers of medical devices, of which 90% are focused on the production of low-tech products like syringes and thermometers. The majority of high-tech equipment is imported from such countries as the U.S., Germany and Japan (Elsinga, 2014). Figure 8 illustrates the Chinese medical device market, indicating that diagnostic imaging devices have the largest share.

**Figure 8:**  
Chinese Medical Device Market



(Adapted from Hartford, 2013).

In China, hospitals are the largest distribution channel for medical devices, accounting for 79% of the market share; followed by pharmacies at 17% and other channels at 4%. As of the end of 2013, e-commerce has become an authorised sales channel for medical device in China (Tsang, 2014).

China's number of elderly persons is expected to rise from 194 million to 300 million and its middle class is set to rise to 600 million by 2025, adding value to the upcoming boom prediction for the demand for medical devices in China. Investments in this industry will require product specific licences and regulatory and market entry complexities will need to be addressed (Qian, Freeman & Zito, 2014).

## 1.6 Transforming Trends of the Global Medical Device Industry

### 1.6.1 Aging Global Population

According to the U.S. Department of Health and Human Services the over sixty age bracket is expected to increase from 23% to 32% within developed countries by the year 2050. The

growth of the aging developed world population in turn grows the demand for medical devices, especially diagnostic equipment that focus on disease prevention. This will however reduce the profit margins of medical devices companies as a large part of medical device spending will come from government-subsidised health care (Master Control, 2014).

### **1.6.2 Growth of Emerging Markets**

Medical device manufacturers in developed countries are expected to continue to pursue a greater share of their sales revenue from emerging markets like China, India and Brazil. These emerging markets are expected to drive the medical device industry for the next fifty years. Although consumer confidence still lies with western brands, this trend will inevitably shift towards brands from these emerging economies (Master Control, 2014).

### **1.6.3 Increasing Regulations**

Due to the increasing demand for better, safer products, regulators are compelled to increase regulations. China has proven to be the most challenging region for medical device companies, with 41% of firms stating that device registration has become more difficult in 2014 than in 2013, while 35% of firms rated the U.S. market more difficult. New regulations impacting the medical device market include, The Patient Protection and Affordable Care Act, FDA's 510(k) submissions process and the recent Unique Device Identification legislation (UDI) (Master Control, 2014).

European legislation states that a medical device must have a CE Mark. A CE Mark grants access to all EU and EEA markets as well as any other international markets where CE Marking is accepted. CE Marking is the medical device manufacturer's claim that a product meets the essential requirements of all European Medical Device Directives. Achieving the CE Mark grants access to the European market, allowing manufacturers to freely circulate their products instead of having to adapt products to each national market according to specific regulations. Stricter regulations to begin in 2015 include a scrutiny process which will allow authorities to make a further pre-market assessment of safety and performance of all medical devices to be marketed in the European Union (Packard, 2014).

#### **1.6.4 Healthcare Consolidation / Mergers & Acquisitions**

Patient care delivered by physicians and hospitals is being transformed due to the increased number of hospital mergers and acquisitions. Large health systems are acquiring independent hospitals in an attempt to pursue economies of scale. Medical device manufacturers as a result will need to invest in commercial software tools to help reduce business risk and to help better illustrate the clinical value of their devices (Master Control, 2014).

#### **1.6.5 ‘Consumerisation’**

The main drivers behind the topic of ‘consumerisation’ or the ‘medicalization of consumer devices’ is the emergence of new technologies like smartphones and social media, an increased focus on costs and elevated customer expectations. These drivers are prompting medical device manufacturers to increase their investment in developing patient-empowering technologies such as the AliveCor ECG Heart Monitor. This can be used with AliveCor’s free app, offering patients with heart conditions the ability to record and store single-channel ECGs (Master Control, 2014).

#### **1.6.6 Value-Orientated Customers**

As established medical device products such as wound care, coronary stents and orthopaedic devices are becoming more crowded and as high-impact innovation in these products are becoming harder to identify, smaller companies are gaining market share by offering low prices and innovative business models. These trends are combining to create demand for medical products that are “good enough” and competitively priced. It is estimated that this low cost product segment is growing twice as fast as the industry as a whole in some categories. Difficulties arise around building a sustainable business while protecting the businesses premium offering as offering heavy discounts can lead to percentage annual declines (Llewellyn et al., 2015).

There has been a rise in value orientated customers who seek products that are “good enough” and competitively priced. These customers are willing to sacrifice a degree of innovation, quality and service in return for a lower price. The value-orientated customer, although concerned about price, also has standards for quality, efficacy, safety and service once expectations of a product have been satisfied. New market entries that are highly innovative products will fall into the premium-differentiated category and will still have high prices, but as

competitors emerge and offer similar products at lower prices, customers then view the products as commodities (Llewellyn et al., 2015).

In order for companies to implement this strategy, cost reducing business models are necessary. This may be achieved by designing the least expensive sales model possible and by limiting service support, thus enabling lower prices. Medtronic for example launched its spinoff NayaMed to sell online end-of-life-cycle pacemakers and defibrillators. Costs can be saved by reducing distribution and clinical support or by removing high-end features to make the product cheaper to produce (Llewellyn et al., 2015).

### **1.6.7 Medical Device Reimbursement Policies**

In Europe, coverage and reimbursement of medical devices typically occurs through publically financed national health care systems. Before a coverage decision can be made, jurisdictions require that high-risk, innovative or costly devices undergo a health technology assessment. Although health technology assessment may differ in each European country, it is commonly required that a device demonstrate therapeutic benefit. Once coverage is determined, most European countries use prospective payment systems to determine reimbursement rates. As payment systems in many countries are infrequently updated it can lead to inadequate reimbursement of new technologies which can act as a disincentive for hospitals to adopt and use new medical devices. To address this issue, Germany, the UK, France, Italy, Spain and Sweden have introduced supplementary payments to provide partial or total reimbursements for potentially beneficial technologies until they are fully captured by the payment system (Sorenson et al., 2013).

In the United States, coverage and reimbursement for devices are the responsibility of both public and private payers. The Centres for Medicare and Medicaid Services (CMS) are the largest public payer and provide coverage for a large number of devices once they get approved by the Food and Drug Administration. For a limited number of devices, CMS conducts a national coverage determination which is prompted by new technologies with major clinical or economic impacts, variation in coverage decisions or concerns about inappropriate use. All other coverage decisions are made locally by private insurance carriers which CMS contracts to administer Medicare coverage. Private payers cover about two-thirds of all the US population (Sorenson et al., 2013).

Unlike processes in some European countries, national coverage determinations do not explicitly require evidence of cost-effectiveness. European countries have more centralised

processes for making coverage determinations within the United States. Europe considers more value in determining which medical devices to cover while in the US a limited number of devices undergo a formal value assessment, especially within the public sector (Sorenson et al., 2013).

# National Overview of the Medical Device Sector

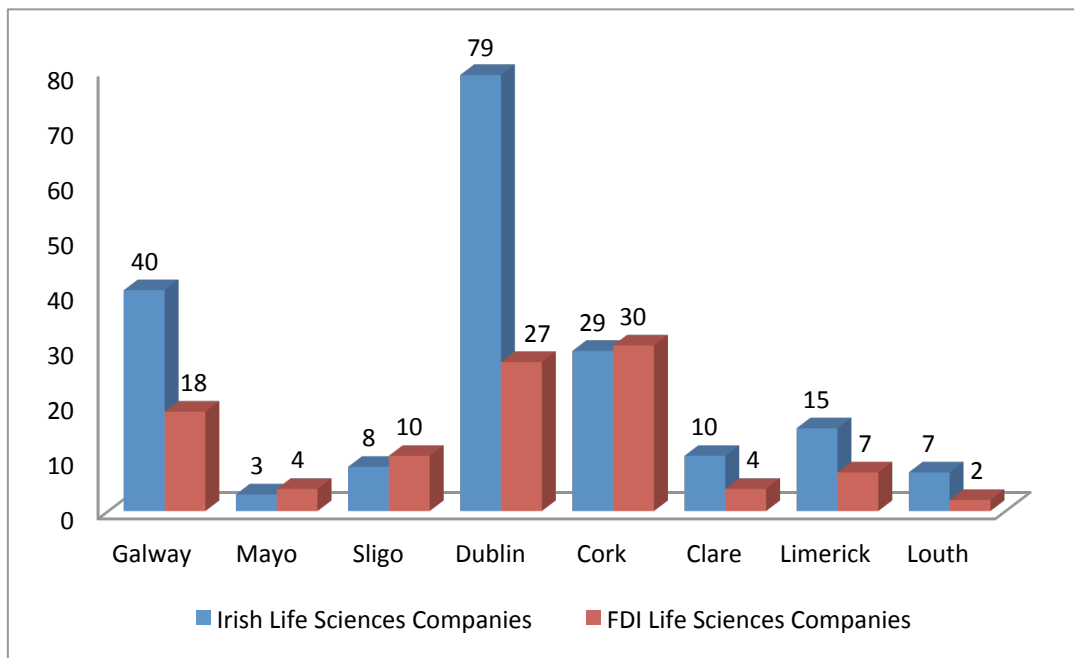
## National Overview

### Introduction

Ireland's medical device industry is growing from strength to strength. It has contributed to rising high-tech exports and knowledge-based employment (CISC, 2010). Overseas orthopaedic companies are attracted to Ireland due to its young, dynamic and well educated workforce; its low corporation tax and its innovative and entrepreneurial spirit (Thornes, 2014). The progressive investment into Ireland has stimulated the development of a domestic cluster of over 100 innovation-led companies along the entire medtech value chain, positioning Ireland as a world-class centre of excellence for medical devices (Enterprise Ireland, 2010).

There are 50,000 individuals directly employed in the life sciences industry which includes pharmaceutical companies as well as medical technology companies. Figure 9 illustrates the number of life sciences companies in Ireland (Enterprise Ireland, 2013).

**Figure 9:**  
Life Sciences Companies in Ireland



(Adapted from Enterprise Ireland, 2013).

## 2 National Overview

### 2.1 National Market Size

CSO figures show exports to the value of €10.6 billion, which is up 8% from 2011. Exports of medical devices and diagnostic products represent 8.5% of Ireland's total merchandise exports (Bioinnovate, 2015). Ireland is the second largest exporter of medical devices after Germany (FORFÁS, 2013). Ireland, per capita, employs the highest amount of people in the European Union, employing 25,000 individuals and has the highest industrial output per capita (Thornes, 2014). In 2012, the Irish Medicines Board (IMB) processed 388 notifications to the medical device register, relating to class I, in-vitro diagnostic and custom made medical devices. In addition, the number of new medical device manufacturers registered in 2012 was 48, up from 32 in 2011, authenticating the growth in this industry (IMB, 2012). Due to the rapid growth within this industry, continuous safety and compliance monitoring is performed by the IMB in order to insure the health and safety of patients and other users of medical devices. Constant monitoring of adverse incidents and correction of product problems ensures this safety. In 2012, a total of 2,225 medical device vigilance reports were received and assessed and a total of 725 compliance cases were investigated with 11 prosecutions and court proceedings being made (IMB, 2012).

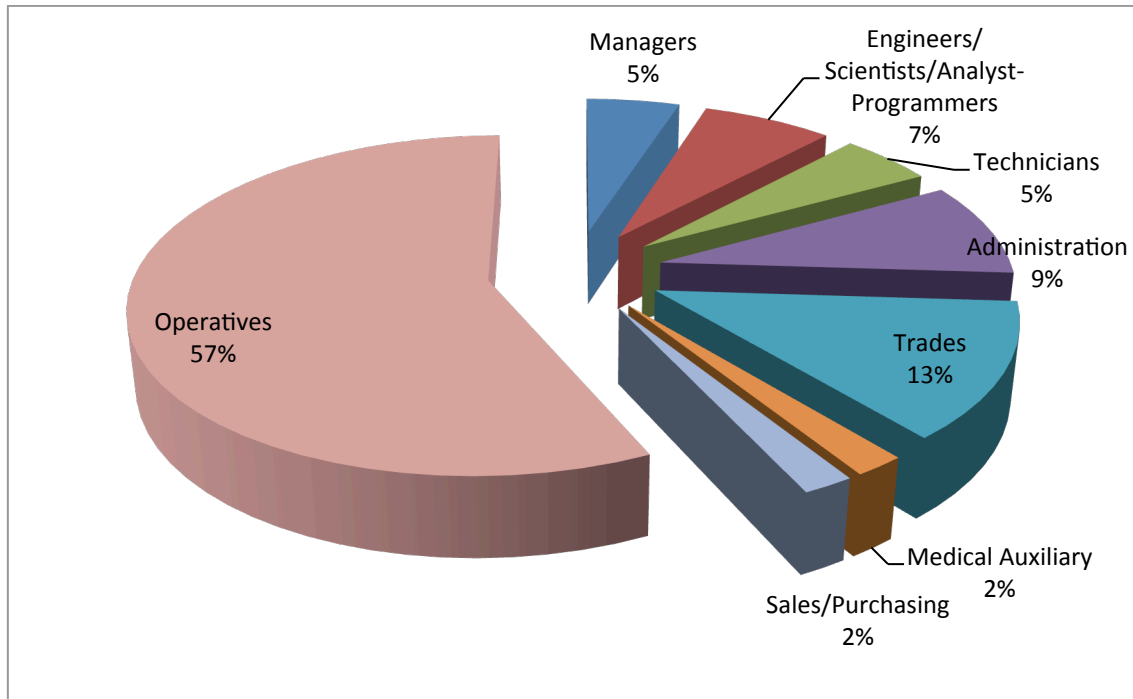
### 2.2 National Medical Device Occupations

Ireland's medical device sector is composed of eight different groups of professions. Figure 10 illustrates the range of occupations in this sector. As can be seen from the chart, over half of the medical device sector is composed of operatives (careers portal, 2015).



**Figure 10:**

Various Occupations within Ireland's Medical Device Industry



(Adapted from careers portal, 2015).

### 2.3 Top 20 Medical Device Companies in Ireland

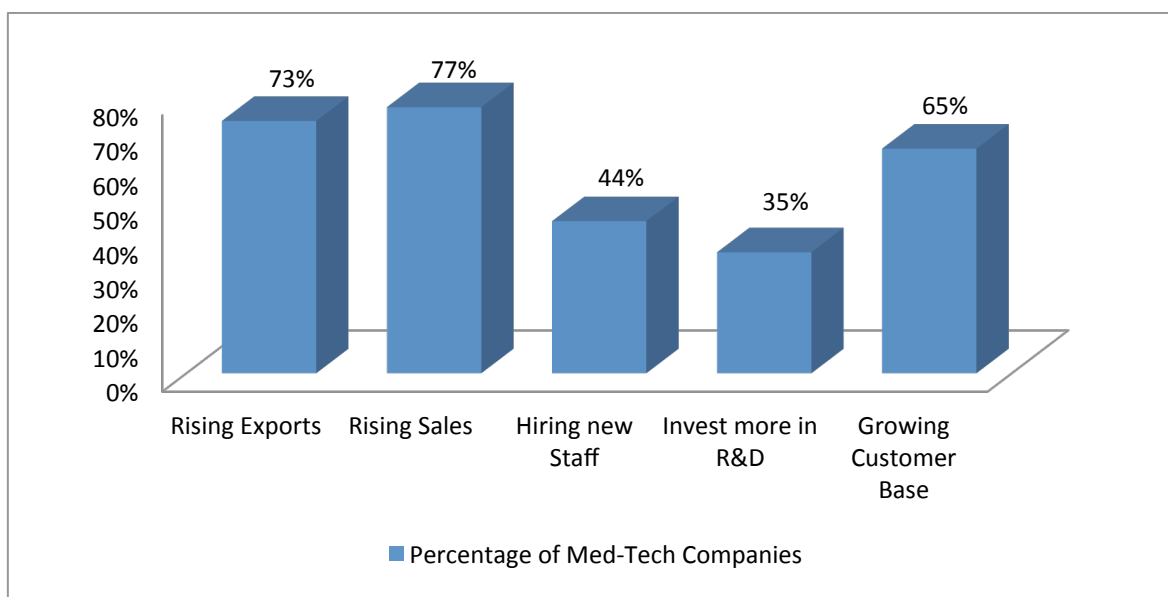
Of the top 20 global medical device companies, 15 maintain operations in Ireland (Thornes, 2014). Johnson & Johnson, the leading global medical device company has been in operation in Ireland since 1935. It has an annual turnover of €59.7 million, employing 100 employees. Medtronic has been in Ireland since 1999 and has an annual turnover of €1.2 billion, employing 1,882 individuals (CRO, 2015). Siemens employs 247 in Ireland and has a healthcare diagnostics manufacturing plant in Dublin and has a turnover of €120.4 million. Abbott Laboratories Ireland is responsible for the sales, marketing and distribution of a wide range of medical device products employing 115 people with a turnover of €82.8 million. Other examples of global medical device companies in Ireland include Bayer, Becton Dickinson, Boston Scientific, Guidant and Stryker.

### 2.4 National Med-Tech Companies

There are over 300 medical device companies in Ireland, employing in excess of 25,000 people. Half of the companies in this sector are indigenous with Ireland's largest indigenous medical

device company being Creganna/Tactx headquartered in Galway. It employs over 800 individuals worldwide and provides a range of contract manufacturing and contract R&D services to start ups and global companies (Enterprise Ireland, 2015). According to a recent survey conducted by The Irish Medical Devices Association (IMDA) on the success and confidence of indigenous medical device companies, 94% of Irish medical device companies are expressing confidence about their business. It concludes that 73% of companies are expecting rising exports, 77% expect rising sales and nearly one half of companies expect to hire more staff. Figure 11 shows the primary results of this survey (IBEC, 2014).

**Figure 11:**  
Results of IMDA Survey of Irish Medical Device Companies



(Adapted from IBEC, 2014).

## 2.5 National R&D and Innovation

The Irish Government has invested €8.2 billion into science and technology research up until 2013. This investment helped to fund centres of excellence such as the €15 million Regenerative Medicine Institute (REMEDI) as well as a world-class biomedical research centre and the Biomedical Diagnostics Institute (BDI). There has been significant growth within the cardiovascular sector with 80% of global stent production being carried out in Ireland, financed by such companies as Abbott, Boston Scientific, Guidant and Medtronic. Ireland hosts orthopaedic manufacturing facilities by industry leaders Stryker, Johnson & Johnson, DePuy and Zimmer. In addition seven global diagnostics companies are located in Ireland including Abbott Diagnostic and Beckman Coulter (Enterprise Ireland, 2010).

An Irish software company recently received CE certification for an app designed to assist oncologists. This innovative medical device is called 'ONCOassist' and offer clinical decision support tools for oncologists. ONCOassist is the third European company to receive the European Union quality control regulation (Kennedy, 2013).

Ireland's medical device export sector is valued at \$10.6 billion (Thornes, 2014). In order to fuel this growing trend a ready supply of skilled engineers is necessary. In addition to the demand for medical device engineers for multinationals based in Ireland, there is a demand for emerging medical device engineering start-ups. Med-tech start-ups are innovating in such areas as stroke management, cancer treatment, orthopaedics and surgery all over Ireland (Doyle, 2013).

## 2.6 National Legislation

There are three types of medical devices outlined in the Medical Devices Legislation. They are general medical devices, active implantable medical devices and In-Vitro diagnostic medical devices. All Irish and EU based manufacturers who place a medical device onto the Irish market must notify and be clinically investigated by the Irish Medicines Board (IMB) under the Medical Devices Regulations. Devices carrying the CE mark can be freely marketed anywhere in the EU. Similar registration requirements are necessary for active implantable medical devices under the European Communities Regulations 1994 and manufacturers of In-Vitro diagnostic medical devices have regulation obligations under the In-Vitro Regulations (Lex Mundi, 2011).

In the U.S. it takes five years for medical device products to come to market. In the EU it only takes two years. This makes Europe and in particular Ireland a very attractive place for foreign direct investment, especially for U.S. companies to launch their products (BCG, 2012). It also provides European patients and healthcare providers' access to the latest advancements in medical technology up to three years ahead of the U.S. and five years ahead of Japan. Suggested changes by the European Parliament to introduce an additional year could affect Ireland's competitiveness.

## 2.7 Future Prospects

Multinational Corporations establish their subsidiaries in clusters to access specialised capabilities, which in turn enhances the cluster's position as its specialised technological capabilities becomes more valued. As the technological capabilities becomes more specialised however, it becomes vulnerable to technological lock-in. To avoid a technological lock-in,

technological clusters must continuously upgrade their knowledge-intensive capabilities (Ryan & Giblin, 2013).

The main focus within the medical device sector of Ireland is on manufacturing. There is little software development being performed even though the ICT industry employs 70,000 individuals. ICT, in the global market in comparison forms a major part of the medical device sector. There is a very high dependence on the continued use of stents in the treatment of cardiovascular disease. The discovery of an effective drug treatment for vascular plaque for example could negatively affect the future growth of the Irish medical device sector. A stronger focus on integrating the ICT sector with the medical device sector could help sustain the future growth of both sectors in Ireland (McCaffery, 2015). There is a further opening in the Irish market for electronic based medical devices, which would include substantial software development. As Ireland is internationally recognised for its software exports, it has a very strong foundation upon which to grow the Irish medical device industry (McCaffery, 2015).

## **2.8 National Policy Objectives**

There is a vision to further develop Ireland's position as a global hub for medical devices. This can be achieved through the development of enterprise and research strengths, and through diversification and innovation (Forfás, 2013).

According to the Priority Area E, medical devices action plan, this vision can be accomplished through the implementation of five objectives. The first objective declares that research that meets the immediate and strategic needs of the medical device sector should be funded. The second objective is to deliver a functioning innovation ecosystem for medical device development in Ireland. Objective 3 is to ensure a leading regulatory environment for medical device development. Objective 4 is to ensure availability of appropriate skills necessary for the development of the sector while the final objective is to ensure appropriate connections exist between universities, hospitals and industry in order to drive efficient technology transfer (Forfás, 2013).

Government and industry funding of €245 million has recently been announced for the establishment of five new-world-class Science Foundation Ireland (SFI) Research Centres in Ireland. Some €155 million of this funding will come from the Department of Jobs through SFI while €90 million will be invested through industry partners. The investment will directly support 700 researcher positions while addressing research in critical and emerging areas of the

economy including applied geosciences, software and medical devices. The five SFI Research Centres include, ADAPT, CONNECT Centre, CÚRAM Centre, iCRAG Centre and LERO (Science Foundation Ireland, 2013).

Previous Government funding includes capital funding of €7.5 million for a new Clinical Research Facility at University Hospital Galway, directly employing 20 individuals, enhancing research and development capacity in the medical device and pharmaceutical sectors (Taoiseach, 2010).

The Irish Medical Devices Association has the strategic objective to strengthen the medtech ecosystem and to safeguard the sustainable development of the industry in Ireland. This will be achieved by promoting integrated and collaborative relationships, by supporting policy development and by developing business models throughout the global supply chain. The IMDA has the further objective of strengthening the entrepreneurial environment by addressing barriers faced by medical device entrepreneurs, ensuring the ongoing availability of experienced mechanical engineers and to develop the collaboration between industry and third level education (IMDA, 2012).

# Regional and Local Overview of the Medical Device Sector

## Regional and Local Overview

### Introduction

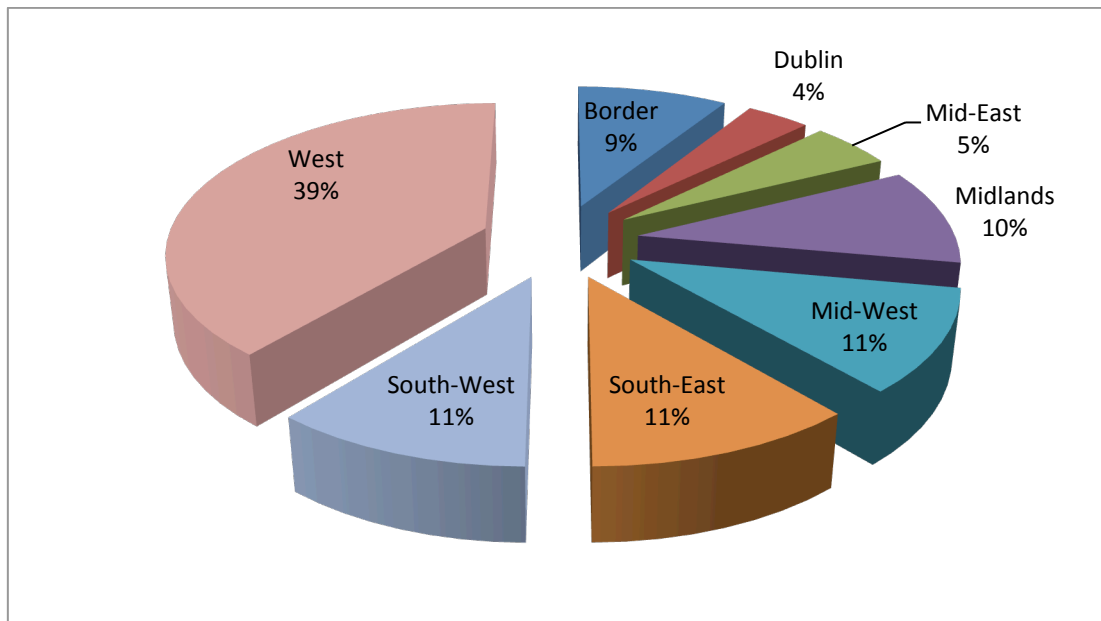
Since the original success story of the manufacturing facility set up by Digital Equipment Corporation in the Galway region in 1971 followed by its Software Distribution Centre, Galway is considered to be a key hub for multinationals. In line with the growing success of the manufacturing and software sector of Galway, medical technology activity was initiated with an investment from CR Bard in 1982 and thus triggered the growth of the medical device sector of Galway. Medical device companies that have an R&D and manufacturing base in Galway have proven to be extremely successful with the advantage of having a lot of expertise in one place, outlining the advantage of a small geographical area. As the world's leading firms like Boston Scientific and DuPont are American, they are attracted to Galway as they are provided with a skilled English speaking workforce (Anecto, 2015). The main centre of the Irish medical device sector is around Galway, with almost 40% of employment in the sector being in the West region, and 31% in Galway City and County. (Enterprise Ireland, 2010)

## 3 Regional and Local Overview

### 3.1 Regional and Local Market Size

Galway employs one third of the country's 25,000 medical device sector's employees. Galway has the second highest concentration of medical device companies outside of Minnesota (Kennedy, 2009). Figure 12 illustrates the regional distribution of medical devices companies, with the West dominating the employment share within the medical device sector of Ireland (Forfás, 2008).

**Figure 12:**  
Regional Distribution of Medical Devices



(Adapted from Forfás, 2008).

### 3.2 Medical Device Companies in Galway

There is a large cluster of medical device companies in Galway (Enterprise Ireland, 2013). The two largest employers within the Galway region are Medtronic and Boston Scientific, employing over 4000 individuals, both based in Galway City.

**Table 2:**  
Medical Device Companies in Galway

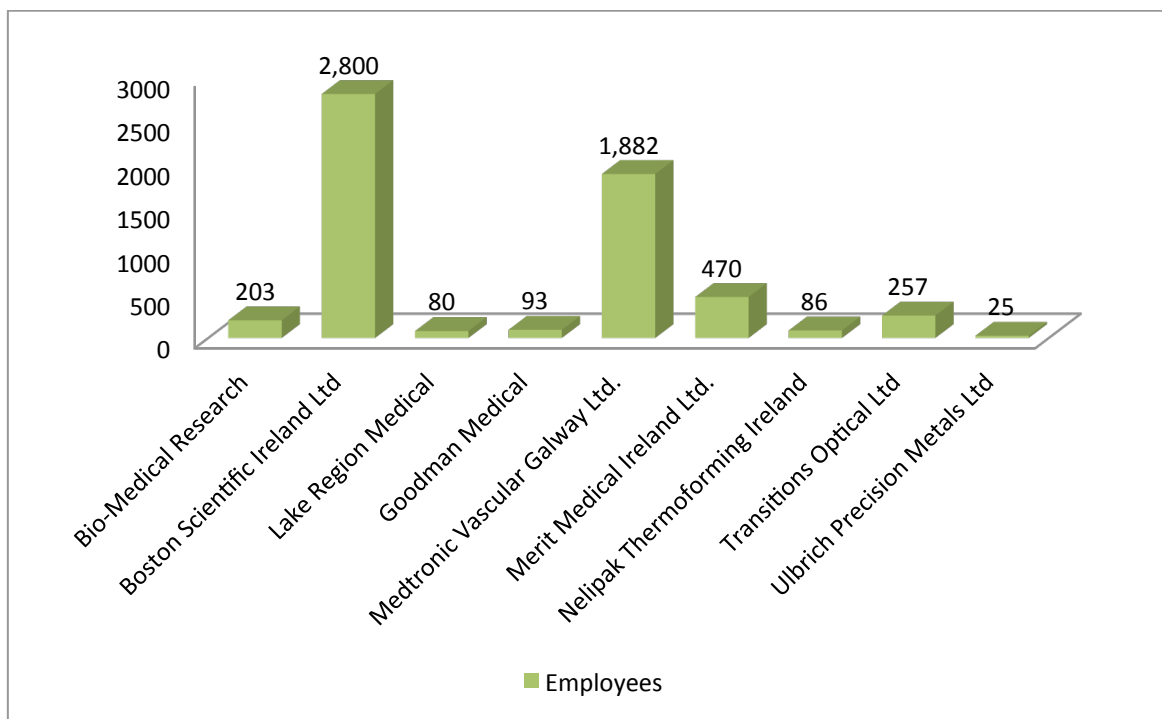
Company	Location
<b>Galway City</b>	
Biomedical Ltd.	Parkmore Business Park, Galway City
Beckman Coulter Ireland Inc.	Mervue Business Park, Galway City
BioMonitor Ltd	NUI Galway, Galway City
Boston Scientific Ireland Ltd.	Ballybrit Business Park, Galway City
Nelipack Healthcare Packaging	Mervue Business Park, Galway City
Goodman Medical	Mervue Business Park, Galway City
Medtronic Vascular Galway Ltd.	Parkmore Business Park, Galway City
Merit Medical Ireland Ltd.	Parkmore Business Park, Galway City

Nelipak Thermoforming Ireland Ltd.	Mervue Industrial Estate, Galway City
<b>Galway County</b>	
Star Guide - Europe	Westlink Park, Oranmore, Co. Galway
Transitions Optical Ltd.	IDA Industrial Park, Tuam, Co. Galway
Ulbrich Precision Metals Ltd.	Westlink Park, Oranmore, Co. Galway
Lake Region Medical	Westlink Business Park, Oranmore, Co. Galway
USCI Japan Limited	IDA Business Park, Ballinasloe, Co. Galway

(Adapted from Enterprise Ireland, 2013).

There are high employment rates within Galway's medical device sector. The largest employer, Boston Scientific Ireland Ltd employs 2,800 individuals, while Medtronic Vascular Galway Ltd. employs 1,882 individuals (see Figure 13).

**Figure 13:**  
Employment Rates within Galway's Medical Device Sector



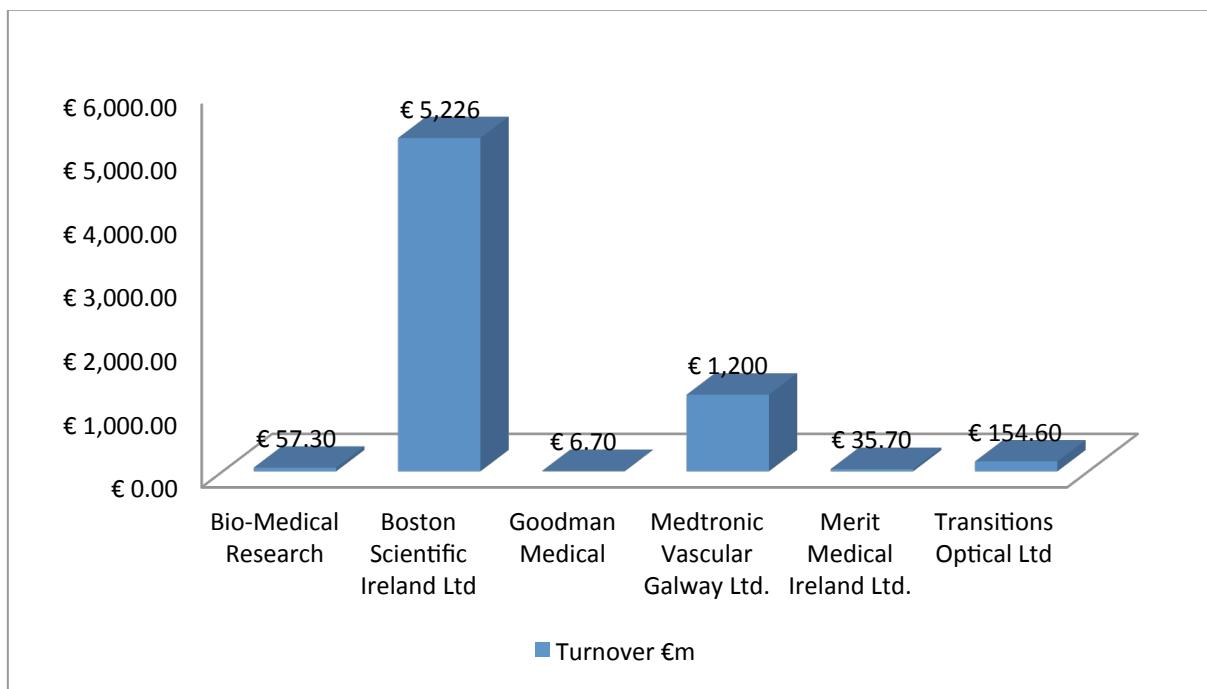
(Adapted from Irish Times Data, 2015).



The success of these medical device companies is illustrated in Figure 14, with Boston Scientific Galway's annual turnover reaching €5.2 billion and Medtronic Vascular Galway Ltd reaching €1.2 billion annually.

The establishment of Boston Scientific and Medtronic in Galway in the 1990s contributed to the growth of the medical device cluster in Ireland, specifically in Galway. The transfer of technology is paramount to the success of this industry as well as the process of government funding, university research, and licensed business participation (Leary, 2013). The clustering effect of this vibrant medical devices cluster in Galway occurs through university-industry linkages, a continuous development of a skilled labour pool, international reputation through the success of Boston Scientific and Medtronic, the growth of supplier firms and knowledge transfers establishing new start-ups (Business & Leadership, 2010). The medical device companies within this cluster are supported by such organisations as Enterprise Ireland, IDA Ireland, Udaras na Gaeltachta, Local Enterprise Office Galway, GMIT and NUI Galway, providing business development support, finance, access to markets and new customers, leadership development, access to a skilled workforce, knowledge and research facilities (Maree, 2014).

**Figure 14:**  
Annual Turnover of Selected Medical Device Companies, Galway



(Adapted from Irish Times, 2015).

Further foreign investments include Tyco Healthcare, Beckman Coulter and Merit Medical. As these investments upgrade from initial manufacturing sites to product development facilities, there is the positive spillover effect of the transfer of knowledge, skills and capabilities (CISC, 2010). There is however vulnerability attached to a dependence on FDI in the form of divestments, including the closure of Abbott in 2007 and the divestment of Beckman Coulter. The success of these multinationals acts as a catalyst for indigenous start-ups like Brivant Medical Engineering who were later acquired by Lake Region Medical and Labcoat who were acquired by Boston Scientific in 2009 (Percival, 2009). These foreign investments have been upgraded in recent times, from initial manufacturing sites to product development facilities, resulting in a transfer of knowledge, skills and capabilities to the locality (Giblin and Ryan, 2010)

The medical technology industry continued to invest in Ireland in 2013. IMDA members announced significant investments during the year, creating high quality jobs and bringing new skills and expertise to Ireland. Some examples of these investments from the last three years, taken from IMDA annual reports, are listed below:

- Advant Medical is set to invest €2.4m in a major development programme at its Galway City plant, with the company planning to create 34 jobs over the next three years.
- Aerogen is to licence out its nebuliser technology to Dutch electronics giant Philips. The deal will add a further 20 R&D posts at its headquarters in Galway City, bringing the total workforce to 80.
- Medtronic opened a new Customer Innovation Centre in Galway, providing state of the art facilities for physicians and Medtronic engineers to develop new therapies. The new CIC cost €7.7 million and was supported by IDA Ireland
- Cambus Teo is to create 35 new jobs following the 50% acquisition of the company by global medical device company Helix Medical. As part of that arrangement, Helix Medical agreed to provide expansion funding to the Galway County company for further development.
- Delcath Systems, Inc. opened its European Headquarters in Galway City. Delcath is the developer of the Hepatic CHEMOSAT® Delivery System, a device used in a new therapeutic approach for patients with cancers in the liver.
- Merit Medical Systems announced the creation of 200 new jobs over five years at the official opening of its new €20 million Galway facility. The investment is supported by IDA Ireland.

- Alere is establishing its International Business Service Centre in Galway City and creating 100 jobs over four years.
- Goodman Medical Ireland is expanding its Galway City site, creating up to 115 new jobs and investing €1.1 million.
- Metal Improvement Company is to establish a new facility in GalwayCity , initially create 20 technical manufacturing jobs, with a further 20-30 jobs planned by 2015.

Another recent announcement related to the medical device sector in County Galway came from IDA Ireland. In January 2015 it was announced that Zimmer, a worldwide leader in musculoskeletal health care, will invest €51 million and create up to 250 new manufacturing jobs over the next 5 years, at its facility in Oranmore, Co Galway, supported by IDA Ireland.

### **3.3 Galway's Medical Device Cluster and the Lucerna Project**

The Lucerna database, developed at the Centre for Innovation and Structural Change (CISC) at National University Galway and funded under the EU's Marie Curie Transfer of Knowledge programme is a partnership between NUI Galway and the University of Massachusetts. The database contains data on high-tech companies illustrating technological capabilities, deep craft skills, emerging industry dynamics and churn rates. This open access data allows policy makers and academics to research high-tech industrial sectors. The Lucerna database includes rapidly growing companies, multinational subsidiaries that are the carriers, developers and consolidators of regionally distinctive technological capabilities (Lucerna Project Report, 2010).

Due to the influential presence of Boston Scientific and Medtronic in Galway, many companies in Galway are involved in cardiology-related devices, particularly drug-eluting stents and their components, such as guide wires, balloon catheters, hypo-tubes and filters. This has resulted in Galway becoming recognised for its specialisation in coronary devices. Data within the lucerna database indicates that minimally invasive cardiovascular interventional products that are manufactured by Galway firms have 500 or more employees. The database also indicates that the establishment of CR Bard in Galway was followed by many other Galway plant openings in the 1980s and 1990s (Lucerna Project Report, 2010).

In terms of the origin of the products within the Galway cluster, Diagnostics Equipments & Testing Devices, Basic Medical Products, Surgical & Medical Monitoring Equipments, Surgical & Medical Specialised Equipment as well as Basic Surgical & Medical Instruments are produced heavily by foreign owned companies in Galway (Lucerna Project Report, 2010).

NUIG contributes to meeting the labour skill requirements of Galway's medical device sector. The Department of Mechanical and Biomedical Engineering has given rise to an average of 22 graduates per year since 2003. As the medical device cluster in Galway is driven by foreign owned multinationals these graduates are crucial to the development of endogenously-based capabilities (Lucerna Project Report, 2010).

### **3.4 BioInnovate Programme**

The establishment of the BioInnovate Ireland Fellowship Programme was inspired by the success of the Biodesign programme at Stanford University. The 10 month fellowship is supported by Enterprise Ireland, the Irish Medical Devices Association, NUI Galway, University of Limerick, Dublin City University and University College Cork, plus several medical device companies including Medtronic, Creganna-Tactx Medical, Lake Region Medical, Boston Scientific and SteriPack. A multidisciplinary team with various backgrounds like medicine, engineering and business are recruited to research a particular disease and then to observe clinical practice in Irish hospitals and to identify potential innovations to address clinical needs (O'Connell, 2012).

A team recruited in Galway, focusing on cardiovascular disease identified the need for a vascular support device for grafting and technology to improve vascular embolism or closing off blood vessels. Both of these projects gained funding from Enterprise Ireland (O'Connell, 2012). The BioInnovate Programme builds on the resources and potential innovations present in Ireland and helps engineer solutions to medical problems within the medical-device industry (O'Connell, 2012).

### **3.5 Serial Entrepreneurship**

A serial entrepreneur is one who opens repeat businesses. The success of the business is measured by the duration over which the business is in operation (Lafontaine & Shaw, 2014). There are a number of serial entrepreneurs within the Galway region who have prior multinational corporation experience. There are strong links amongst affiliates of foreign-owned and indigenous start-up medical device companies as well as with key serial entrepreneurs in the Galway region (Das & Ryan, 2010).

John O'Shaughnessey, Charles Taylor and Paul Gilson were originally senior executives of CR Bard. The acquisition of CR Bard triggered a series of start-ups by these entrepreneurs. The first series of start-ups, Salviac, Carotid Interventional Systems (CIS) and MedNova proved to be successful with CIS and Mednova being acquired by Abbott. John O'Dea, John O'Shaughnessey and Conor McNamara set up Crospon Technologies and set up the research and development facility for Puritan Bennett before starting Caradyne, which was acquired by Respironics (Das & Ryan, 2010).

### **3.6 REMEDI**

The Regenerative Medicine Institute (REMEDI) was established at NUI Galway with funding from Science Foundation Ireland in 2004. It is a research centre focused on using stem cell and regenerative medicine technologies to treat human disease. Through the research into stem cell biology REMEDI's mission is to translate and commercialise the results by developing regenerative therapeutics (REMEDI, 2015).

REMEDI has recently received €47 million in funding grants for pioneering research initiatives delivered by the Department of Jobs, Enterprise and Innovation, through the Science Foundation Ireland Investigators Programme. The Programme will provide funding over a three to five year period, for 36 research projects involving over 200 researchers. The funding will directly support over 200 highly skilled researchers in Ireland through to 2019, and is linked to 62 private sector companies (REMEDI, 2015).

### **3.7 CÚRAM, Galway**

NUI Galway has recently been announced as the lead in a new national medical device research centre called CÚRAM. The research centre will design and manufacture implantable medical devices to deliver therapeutic agents. CÚRAM is going to connect researchers from NUI Galway, UCD, DCU, UL, UCC and the Royal College of Surgeons in Ireland. The centre will include approximately 40 industry partners, supporting product development and the establishment of new start-up firms. This new research centre in Galway will help grow Galway's profile as a hub for some of the world's largest multinationals as well as developing research from biomaterials, stem cells and drug delivery (McGuire, 2015).

### 3.8 Galway-Mayo Institute of Technology (GMIT)

As well as NUI Galway's contribution to the medical device sector, GMIT's Galway Medical Technology Centre (GMedTech) has a recognised capacity for designing and developing advanced pre-clinically relevant in vitro simulators replicating various parts of the human anatomy. These simulators accelerate the development of the next generation of medical devices and training platforms for clinicians as well as aiding in surgical planning (GMIT, 2015).

In collaboration with GMedTech, cardiologists at University Hospital Galway will soon be using 3D printed heart replicas to help with surgery for heart defects in adults and babies (Varley, 2014).

GMedTech has obtained over €3.5 million worth of funding for an applied biomedical research project and has developed three cardiovascular type simulators for assessing heart attacks, stroke and aortic aneurysms. GmedTech was recently shortlisted as a finalist for the annual Med Tech CEO & Awards Forum 2013, hosted by Enterprise Ireland, IDA Ireland and the Irish Medical Devices Association. The nomination was in recognition of the Neuravi's neurothrombectomy device for ischaemic stroke that was tested within a challenging anatomy of the cerebral vasculature developed within the GMedTech Centre. The successful demonstration of Neuravi's device helped Neuravi secure €5.2 million of venture-capital funding, which created 25 new jobs and resulted in a significant economic benefit to the Galway region (Morris, 2014).

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