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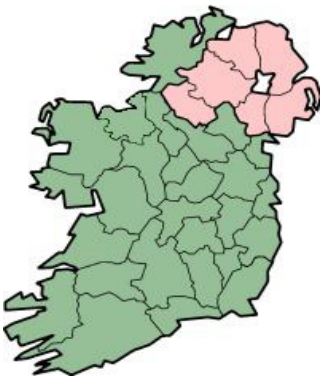
Medical Devices Sector in Ireland



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Country Facts:

Basic Information

Official Name: Republic of Ireland

Date of Establishment: 29 December 1937

EU Accession: 1 January 1973

Time Zone: GMT

Capital City: Dublin (1.084 m 2009)

Neighbouring Countries: Northern Ireland

Area: 68,890 km^2

Population: 4,670,976 (July 2011)

Territorial Division (26 regions): Carlow, Cavan, Clare, Cork, Donegal, Dublin, Galway, Kerry, Kildare, Kilkenny, Laois, Leitrim, Limerick, Longford, Louth, Mayo, Meath, Monaghan, Offaly, Roscommon, Sligo, Tipperary, Waterford, Westmeath, Wexford, Wicklow

Ethnic Groups: Irish: 87.4%, Other White: 7.5%, Asian: 1.3%, Black: 1.1%, Mixed: 1.1%, Unspecified: 1.6%

Economic Data

Currency: Euro since 1 January 2002

Inflation: -1.6% (2010)

GDP ($bn): 204.144 (2010)

GDP (Purchasing Power Parity): 173.614 (2010)

Real GDP Growth 2011: 2.3%

Real GDP Growth 2010: -0.3%

Structure of GDP: Agriculture 2%, Industry 29%, Services 70%

Key Industries: Pharmaceuticals, Chemicals, Computer Hardware and Software, Food products, Beverages and Brewing, and Medical Devices

Political Data

State Organisation: Republic

Political System:

Parliamentary Democracy

President: Mary McAleese

Prime Minister: Enda Kenny

Membership of International Organisations: EU, UN, UNESCO, OECD, IMF, UNIDO, WHO, WTO, INTERPOL, EMU, CE, IAEA, ICC

Medical Devices Sector in Ireland:

Globally, the medical technology industry is estimated at €173 – 196 billion and some forecasters predict growth of 10% over the next 5-6 years. Such growth on the international level can be attributed to increasing longevity as well as the growing incomes of the developed and developing economies.

In Ireland, the medical device sector is thriving. Ireland is now the second largest exporter of medical technology in Europe, second only to Germany. The sector has grown rapidly over the last decade, particularly from inward investment.

Companies are engaged in relatively high growth and high value manufacturing activities, with many also involved in significant R&D projects.

The Medical Devices Sector in Ireland is primarily involved in developing, manufacturing and marketing a diverse range of products and services including:

- disposable plastic and wound care products;
- precision metal implants such as pacemakers;
- microelectronic devices;
- orthopaedic implants;
- diagnostics;
- contact lenses;
- and stents.

Main Activities In Ireland:

The main activities in which the Medical Devices sector is involved in are:

- Research and Development
- High Value Manufacturing
- Globally Traded Services
- IP Management and Supply Chains

Contribution to the Irish Economy:

- There are currently over 160 medical technology companies in Ireland, exporting €6.8b worth of product annually

- The Medical Devices sector employs 24,000 people directly - the highest number of people working in the industry in any country in Europe, per head of population.

- Exports of medical devices and diagnostics products now represent 8% of Ireland's total merchandise exports; and growth prospects for the industry globally remain good.

- Medical device exports increased by 11.19%, to €4.38 billion in 2010.

- The Irish government has identified the medical technology sector as one of the key drivers of industrial growth for the future and provides a wide range of supports to encourage and foster this growth.

Industry Characteristics:

- The sector invests relatively heavily in training. Irish-owned medical devices companies spend more on training than nearly every other manufacturing or internationally traded services industry.
- The US is a major source of investment for the medical device sector in Ireland.
- Most employment in the sector is in the Irish operations of US medical devices companies.
- It is primarily an export sector.
- The main markets for most medical devices are with healthcare providers.

Industry Trends:

- The medical technology industry in Ireland is changing from being prominently manufacturing to being more complex and driven by R&D. It now involves intensive collaboration between a broad range of partners, including research institutions, clinicians, manufacturing companies and government agencies.

- Current research indicates that the demand for people with engineering, scientific, technician, sales and purchasing skills will continue to rise as well as the demand for those qualified to Masters and PhD level.

- The industry is likely to see a move towards greater numbers of engineers, scientists, analysts and technicians. Relatively modest numbers of new operators, assemblers and quality control staff will be required.

- Rising costs and increased competition from low cost manufacturing economies has resulted in the need for many multinational companies in the medical technology sector to restructure.

Regional Distribution of Medical Devices Companies:

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

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

Emloyment in the Medical Devices Sector:

• Currently, employment in the medical devices sector is dominated by manufacturing operations. R&D operations are another significant employer of medical devices personne

Key Players:

- Abbott Ireland
- Bayer
- Becton Dickinson
- Boston Scientific
- Johnson & Johnson
- Medtronic
- Smith and Nephew
- Kinectic Concepts Inc (KCI)
- Novate Medical
- Stryker
- Teleflex Medical

Investment Incentives:

Ireland's intellectual property laws provide companies with generous incentives to innovate:

• A highly competitive corporate tax rate of 12.5 % has yielded extremely positive results. Recent surveys show that 30% of American

investors in Ireland site the corporate tax rate as the most significant factor in choosing Ireland as the location for overseas operations.

• Also, Ireland recently introduced a new R&D Tax Credit, designed to encourage companies to undertake new and/or additional R&D activity in Ireland. It covers wages, elated overheads, plant/machinery, and buildings.

• The Stamp Duty on intellectual property rights has been abolished.

Key Challenges for the industry:

• There is a relatively low overall level of engagement by clinicians in research. This stands as a challenge for the future of medical devices research in Ireland as significant medical devices innovations frequently emerge informally from the application of engineering principles to clinician insights.

• The Medical Devices Sector owes much of its growth to overseas investment. However this record of growth is now being challenged by rising costs, unfavourable exchange rates, and the improving manufacturing capabilities of competing low cost economics.

Achieving Regulatory Approval:

Medical device manufacturers are subjects to many regulatory systems, international and national standards. The National Standards Authority of Ireland is the Notified Body in Ireland that provides for the following certifications:

• CE Markings – Necessary for EU and EEA markets

• ISO 13485 – The internationally recognized Standard for a comprehensive management of medical devices.

• CMDCAS – Canadian Medical Devices Conformity Assessment, vital for selling into the Canadian market.

• JPAL – Japanese Pharmaceutical Affairs Law by the Ministry of Health Labour and Welfare.

Higher Education Research:

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

• Science Foundation Ireland;

• The Higher Education Authority, through the Programme for Research in third-level Institutions;

• The Health Research Board;

• Enterprise Ireland;

• The Irish Research Council for Science, Engineering and Technology;

• EU research programmes;

• And other government sources.

Nationally, funding by Irish businesses accounted for 3% of higher education research funding in 20048. In the main, the research that is directly relevant to the medical devices sector is being undertaken by academics and graduate students in engineering, with a particular focus on biomechanical engineering, but also some activity in bio-materials and bio-electronic engineering. However, they are engaging in cross disciplinary work with other disciplines, including biological sciences and medicine, on significant numbers of research projects.

Useful Links:

NSAI – National Standards Authority of Ireland (http://www.nsai.ie)

IDA (Irish Development Agency) (http://www.idaireland.com/)

Biomedical/Clinical Engineering Association of Ireland (http://www.beai.ie/)

Irish Medical Devices Association (http://www.imda.ie)

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