

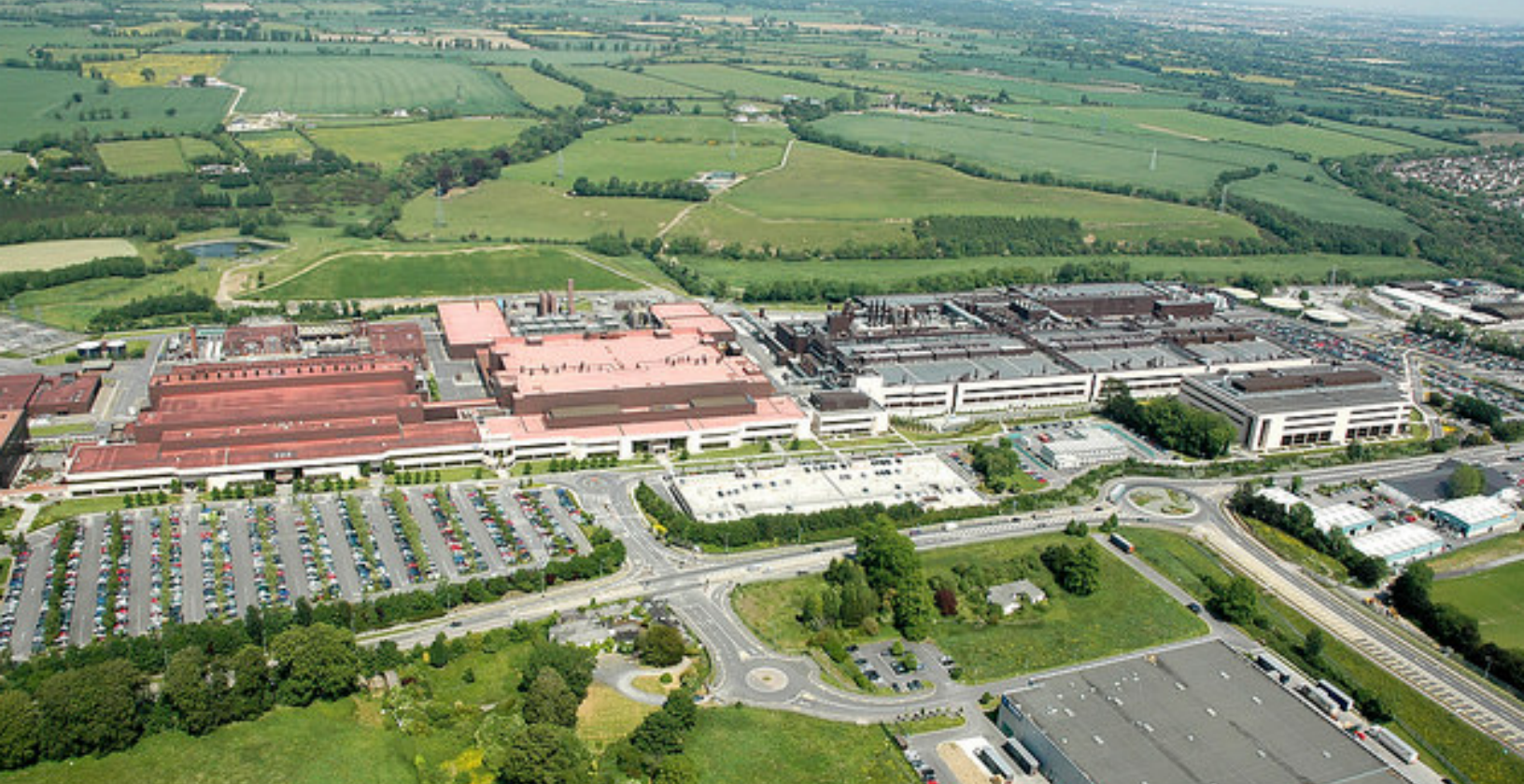


US Medtech Industry Looking at Ireland as a Resource

by Rachel Shelly, Head of Medical Technologies, IDA Ireland

While the American medtech industry is thriving, it still must deal with challenges that include higher production costs, finding skilled staff and the ongoing issues innate to a highly regulated sector. Then there are global concerns such as competition, funding and the high cost of research. With Europe and the United States being the key markets, many U.S. medtech firms have located some of their operations in Ireland in order to take advantage of an established, flourishing life sciences sector, strong governmental support and easy access to the lucrative European market. Among the more than 300 companies with Irish facilities are Boston Scientific, Abbott, Vistakon, Medtronic, Teleflex, Stryker, Cook Medical, Zimmer Biomet, DePuy Synthes, Hollister, and BD. The medtech field in Ireland employs more than 32,000 people, which is the highest per capita in Europe. One quarter of the world's diabetics -- 30 million people -- rely on an injectable device manufactured in Ireland, while half of all ventilators used by acute hospitals worldwide are also made there. Meanwhile, three quarters of global orthopedic knee products were produced in Ireland.

There are several important reasons why American medtech companies have been choosing Ireland as their European base of operations.



Intel Ireland

Manufacturing expertise

Ireland has become a center of excellence for biomanufacturing devices and drugs with a "right first time" approach. The country's supportive attitude toward medtech was appealing to Stryker, which opened a new global technology development center and a centralized additive technology manufacturing hub in Cork in 2016, where the company is doing groundbreaking work in 3D medi-printing. Additive manufacturing has the potential to radically alter the sector through the delivery of advanced complex products and Ireland is at the center of this revolution with capabilities spanning research to commercialization.

Another example of this burgeoning area of 3D printing in Ireland is the opening last year of the I-Form Advanced Manufacturing Centre in Dublin, which is focusing on developing and implementing advanced manufacturing technologies, in particular, 3D printing. The new center resulted from a national collaboration among five research institutions and 25 companies and has strong links with a number of leading manufacturing centers worldwide. Benefiting companies is another important new source of world-class manufacturing knowledge: CONFIRM, the Science Foundation Ireland Research Centre for Smart Manufacturing in Limerick. It has 42 industry partners that include Johnson & Johnson, Medtronic, Stryker and Boston Scientific with the goal of using smart technologies to create the factories of the future.

Demonstrating its commitment to high-quality

product manufacturing, Ireland has received more Shingo gold awards for operational excellence than any other country outside the United States. These were achieved by Abbott Vascular, Abbott Diagnostics, Johnson and Johnson (DePuy Synthes) and Boston Scientific. Innovation at these Irish sites has provided valuable knowledge transfers for American companies' global supply chains.

Access to R&D facilities and trained workers

A good example of Ireland's accommodation of medtech is seen in the National Institute for Bioprocessing Research and the Centre for Research in Medical Devices (CÚRAM) which develops innovative implantable "smart" medical devices. These implants are designed and manufactured to respond to the body's environment and to deliver therapeutic agents, such as drugs, exactly where needed. CÚRAM offers companies the ability to have clinical collaborations with industry partners and hospital groups and to enable rapid translation to the clinic. There are many US multinationals currently working in CÚRAM including Boston Scientific, Stryker and Arch Therapeutics.

Workers at these facilities are joining a rich pool of educated individuals in Ireland, whose university system is ranked in the world's top ten. Besides being the only English-speaking member of the EU after the impact of Brexit, Ireland has an international talent pool due to the country's appeal to tech workers and its business-friendly immigration policies.



Data analysis skills

Ireland is already considered the data center of Europe because so many data giants like Google, Facebook, LinkedIn, Twitter, Microsoft, Apple and others are located there. Such a critical mass of expertise and trained workers will be needed as data increasingly becomes a key part of medtech, whether for analysis of how devices are working implanted in a body or capturing data flowing from the devices themselves given the rise of wearable medical devices like "smart" glucose monitors. Analyzing data is essential for medtech firms and Novartis is a good example of how Ireland can accommodate that objective. At the Novartis Analytics center in Dublin, the company's 600 workers are crunching data from clinical trials around the world, then pushing it out to sales forces and digital marketing channels in their native languages.

Now and in the future, data will be sent to and from the medical devices themselves. For example, a new hip -- 3D metal-printed, perhaps -- can monitor the patient's activity level and deliver reminders of proper behavior such as increasing activity to ensure healthy adoption of a new hip. The rise of smart devices will require high levels of data capture and analytics, which means finding facilities and workers with such skills.

Collaborative environment

Competition is certainly a big part of industry but Ireland also promotes collaboration as a better way to create solutions and increase sales. This involves collaboration between companies, academia and research organizations. An example of this is an innovative insulin "pen" developed in Ireland by Intel that use a low-power IoT chip and other technology to quickly, easily and accurately deliver injections with data saved and communicated with healthcare professionals.

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Financial advantages

In addition to an attractive corporate tax rate of 12.5%, Ireland provides an R&D tax credit of 25%, which coupled with direct grant supports available from IDA Ireland, enables medtech and biotech companies undertaking qualifying R&D to significantly reduce costs. Such a powerful incentive is appealing, in particular, to medical device OEMs since the industry spends more than most others on R&D: an average of 7% of revenue, according to Kalorama Information.

Ireland's advantages of operating a medtech facility were compelling to Edwards Lifesciences, the leader in heart valves and hemodynamic monitoring that is based in Irvine, California. The company just announced it is investing €80 million for its first plant in Ireland that will supply parts for the technology to deliver its heart valves by catheter in minimally invasive surgical procedures.

Meanwhile, another new Irish operation was just announced by major U.S. diagnostics company Quidel, which will construct a 75-person business center in Galway. To be staffed by a range of professionals including those in finance, support, sales, marketing, IT and legal, the new center will better equip Quidel to serve customers in its international market.



Airbnb Offices in Dublin

Regulatory Advantages

According to analysis by Emergo Group, regulatory issues -- whether existing regulations or anticipated changes to them -- continue to be the biggest business challenge for medical device companies of all sizes. While American medtech companies doing business in their home country obviously need to get FDA approval, those with an Irish operation aimed at the European market have advantages.

Besides quicker approvals, Europe's CE Mark -- the FDA equivalent -- also involves a less costly process and some researchers have noted how European regulators are more responsive to clinical needs than their American counterparts. American companies can therefore gain CE Mark and begin marketing their device and generating revenue in Europe while going through the FDA approval process.

Of significance to medtech companies are recent EU regulations in the area of medical devices and in-vitro diagnostics that put in place even stricter controls in a range of areas. These regulations will require additional investment and operating model changes among manufacturers so Ireland's strong regulatory culture, internally and externally, and close alliances

with European regulatory bodies, government and industry can help ease the transition toward successful compliance.

While the FDA approval process has sped up significantly in the last year, regulations in Europe become more complex, so medtech firms hoping to doing business internationally can benefit from Ireland's track record of engaged regulatory agencies that work closely with manufacturers to ensure compliance and trouble-free launching of new processes.

Companies in the medtech industry have the major advantage of inexhaustible demand -- people always need innovative healthcare solutions. But savvy companies must also focus on making smart business decisions to utilize these opportunities. In the United States, companies weigh the challenges of improving their R&D while expanding production efficiently, finding qualified staff, navigating regulations and better reaching key markets. Given the fact that Ireland exports €12.6 billion in medtech products annually, it's clear that American companies are leveraging the nation's many advantages to address the challenges and realize greater success.



To Learn more about the advantages Ireland offers to US MedTech companies, please contact:
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