

Medical TECHNOLOGY

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Richard Hendron, manager of medical technology division, IDA; Sharon Higgins, director, Irish Medical Devices Association; and Brian O'Neill, manager of life sciences, Enterprise Ireland

MAURA HICKEY

Ireland leads the way

In the complex and growing area of medical technology, Ireland is recognised globally as a foremost centre of excellence, writes **Eibhir Mulqueen**

The success of Ireland's medical technology industry has exceeded the expectations of even the greatest optimists since the industry started here 42 years ago. The sector has trebled in scale in the last 15 years.

Today the country is the envy of other states looking at the success of an industry that combines a thriving multinational base with a rapidly-growing indigenous sector that designs, develops and exports proprietary new medical devices and technology platforms to markets across the world.

The headline figures for the industry speak for themselves: med tech companies in Ireland employ 25,000 people – including 5,000 in the indigenous sector – and produce annual exports of about €6.2 billion out of total FDI exports of €90 billion.

Barry O'Leary, chief executive at IDA Ireland, points to a strong sector within the overall foreign direct investment (FDI) area. This year, the IDA has approved investments in 20 med tech companies, including three new clients.

"The medical device sector has been one of the strong performers in terms of new companies coming in, companies expanding their operations and companies adding on research and development projects," he said.

Across all these areas, major multinational players have made decisions regarding their Irish operations in recent times, from orthopaedic specialist Zimmer setting up in Shannon, to Cook Medical in Limerick expanding operations and Boston Scientific in Galway investing €50 million in an R&D facility.

Frank Ryan, chief executive of Enterprise Ireland, points to the enormous spin-off effect from the multinationals' presence of a whole new indigenous company sector in medical devices.

"There is a burgeoning and dynamic indigenous base of companies which are competing successfully in international markets throughout the world," said Ryan. "Indigenous exports from this sector have been growing at approximately 17 per cent a year for the last three years and indications are

that growth in 2008 is even stronger."

The spread of the industry around the country also dovetails with government regional development policies. More than 90 IDA-supported med tech manufacturing facilities or corporate services centres are located in 45 cities and towns, with the Border-Midlands-West (BMW) region accounting for half of the total industry employment.

Meanwhile, increased moves towards R&D operations are seen as critical to Ireland's future success.

"Building long-term R&D capability is key to driving sustainable international competitiveness," said Ryan. "R&D activity is also central to the current and future growth of the highly dynamic indigenous life sciences base, which is using innovation as a key competitive lever globally."

"Over the last four years, Enterprise Ireland has made strategic R&D investments in more than 70 of these high technology companies, which are located throughout the country."

Along with Science Foundation Ireland-backed funding for research in third-level institutions, O'Leary highlights the growing willingness of IDA Ireland clients to invest in R&D, related to both integration of current manufacturing operations and to commercialisation of longer-term Irish publicly-funded research. This results in further manufacturing and technology development opportunities for Ireland.

"There has been a strong increase in the amount of research and development being done by companies in the last three to four years in particular, right across all sectors and not just in medical devices," said O'Leary. "More than half of med tech companies operate their own R&D functions. This year alone, RD&I [research, development and innovation] investments of more than €75 million from 11 existing clients and one new client have been made."

The global backdrop is one of an industry worth an estimated \$280 billion, and growing by 7 per cent annually. People will spend on their health or that of their loved ones above all else, so the industry is considered fairly re-



Barry O'Leary



Frank Ryan



Helen Ryan



Tom Kelly

cession-proof.

Abbott Laboratories, one of the nine top ten medical device companies with an Irish presence, recently announced that third-quarter sales were up by 18 per cent this year to \$7.5 billion.

Ageing populations in developed countries, including Ireland, are providing a growing consumer base for medical devices, which provide a cheaper and less invasive alternative to major surgery. In turn, their very success is contributing to the longevity of people's lives.

Medical technology is a complex and growing area but the stent – in simplistic terms a cylindrical metal device containing medication – could be taken as a symbol for its development. As with the array of other devices used in human medicine, the drug-eluting stent has revolutionised coronary care over the past decade and, increasingly, the treatment of a range of other illnesses in the human body.

Approximately one million stents are implanted annually in the US, the New England Journal of Medicine states, in what is the world's largest market, amounting to 45 per cent of global demand. Europe comprises 30 per cent, Japan 10 per cent, and the remainder of the world 15 per cent. It is in this last segment that there is potentially massive future demand. Huge emerging economies like China and India could provide fresh markets.

Ireland manufactures almost 80 per cent of the world's drug-eluting stents. Among the other medical devices it produces are pacemakers, catheters, infusers, devices for gastroenterology and urology use, prosthetic lenses, micro heart pumps, diagnostic kits

'We are recognised globally as a centre of excellence in this space'

and, in the orthopaedic area, artificial knees and hips. Sub-supply activities include packaging and sterilisation services to transport and catering.

Richard Hendron, manager of the IDA's medical technology division, said it had taken approximately 40 years to get to our current stage, in which we lead the field in Europe and are of similar overall scale with the med tech clusters on the east coast of the US in Boston, and in Minnesota and on the west coast.

In the late 1980s, med tech started to build on the earlier FDI successes in manufacturing and ICT. Med tech is an industry that relies primarily on mechanical engineering with the increasing addition of pharmaceutical, biotechnological and information technology skills, according to Hendron.

It has put the focus back on engineering and science and the issue of whether the annual figure of more than 20,000 students graduating in these areas will be maintained. But the establishment of Science Foundation Ireland in 2000 has given a strong, public message that science is important, a message that is being pro-

moted extensively by the government, industry and the education sector.

Brian O'Neill, manager of Life Sciences at Enterprise Ireland, cites a recent Swedish report that refers to Ireland as a key case study and comments on its "strongly collaborative medical device environment".

"We are recognised globally as a centre of excellence in this space and many countries are looking at Ireland in terms of replicating the same for the significant socio-economic benefits on offer from participating in this high-tech sector," O'Neill said.

Time and again, industry leaders point to the efforts and expertise of the state agencies in convincing multinationals to pitch their overseas production facilities in Ireland. In one of the most recent examples, Zimmer Holdings' Irish general manager Adrian Furey commented that, without the seamless approach of the IDA and Shannon Development, the orthopaedic device company would not have come to Shannon or anywhere else in Ireland.

The joint government strategy of growing the FDI sector and the indigenous sector in

an industry is a delicate balancing act.

One industry head who has experience of working in the Far East warned this week of how he had seen government policy in an Asian country favour the indigenous sector over the overseas one with predictable results.

"You have got to get the local companies and the multinationals working in harmony as far as possible," he said. It falls to Enterprise Ireland to nurture this indigenous sector and to bring it to the level where it can compete profitably globally. But it moves beyond this role by engaging with the multinational sector at the interface of research and development.

"Enterprise Ireland has a particularly important role, not just in the indigenous sector but also in the international sector, in the commercialisation of publicly-funded research," said Tom Kelly, manager of Enterprise Ireland's environment, industrial and life sciences division.

Between 2005 and 2007, 25 new high-potential start-ups in the life sciences area have been established and developed with the backing of the agency, a third of which have come from the third-level research environment.

"We would expect them to have double-digit growth rates year-on-year with early export presence. The thrust is to grow companies and to grow them to scale," Kelly said.

One of the synergies created between the two sectors is that the cohort of talented management created in one often transposes into operations in the other.

"Some of the companies that have developed have come from people who have gained huge experience in working in the FDI companies," he said. "There is that element to the indigenous sector."

Others are spin-offs from ideas mooted, fostered and brought to fruition in research institutions. "It creates a sense of energy for research. The consequence is that people can identify ideas and take them to the commercial side."

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Ireland's medical technology industry at a glance

- Ireland has the leading cluster of med tech industries in Europe.
- Nine of the top ten global companies have significant manufacturing operations here.
- The industry employs 25,000, including 5,000 employed in the growing indigenous sector.
- It produces annual exports of €6.2 billion.
- The industry is worth €280 billion globally and is growing by 7 per cent annually.
- Ireland has the highest per capita employment of medical technology personnel in Europe.
- The IDA has approved 20 new investments in med tech companies this year.
- This involves a total investment of €294 million and 1,900 new jobs.
- More than 50 per cent of med tech companies have dedicated R&D functions.
- The Border Midlands West (BMW) region accounts for 50 per cent of total sector employment.
- Expenditure on Irish raw materials and services amounts to €830 million and annual payroll to €820 million.
- More than 80 per cent of all foreign direct investment (FDI) clients rate Ireland as a good place to do business.

Supporting Medical Technology Growth in Ireland



Medical Technology

IMDA is central to sector's future

Representing 90 members, the Irish Medical Devices Association is a unified voice for the medical devices and diagnostics sector, writes **Margaret O'Brien**

The Irish Medical Devices Association (IMDA) is the business association within Ibec representing the medical devices and diagnostics sector. Some 140 companies are involved in the sector in Ireland.

They develop, manufacture and market a diverse range of products from disposable wound care products to precision metal implants, including pacemakers, microelectronic devices, orthopaedic implants, diagnostic tests and equipment, contact lenses and stents. "The medical device industry in Ireland employs more than 25,000 people, 11 per cent of Ireland's manufacturing workforce," said IMDA director Sharon Higgins. "The sector exports products valued in excess of €6.2 billion in revenue, making it one of the most important sectors in the Irish economy."

"Many people are staggered by just how much this sector has grown in a quiet way over recent decades. It stands as a shining example of Ireland's success in attracting foreign direct investment, initially in manufacturing and logistics and increasingly in research, development and commercialisation."

"We also have a growing



Sharon Higgins, director; Helen Ryan, chairperson; and Pat Gallagher, vice chairperson, Irish Medical Devices Association

cadre of specialist indigenous design, engineering, manufacturing and packaging companies of international repute. Ireland's opportunity is to continue to expand and integrate the extensive range of strategic competencies on the island that will enable us to adapt to changes in the global economy and continuously strive to not only keep pace with, but to surpass, international competitors."

Today, 17 of the world's top 25 companies, ranked by medical device revenues, are based here. Such is the growth, that Ireland is the highest per capita medical technology employer in the EU and has comparable scale to the largest medical device clusters globally, specifically in Minnesota and Massachusetts.

Currently, IMDA has 90 members, located throughout the island of Ireland.

"Our focus is to provide our members with a proactive organisation," said Higgins.



The IMDA's excellence awards dinner

"We promote and support an environment that encourages the sustainable development and profitable growth of our multinational and indigenous medical device and diagnostic companies."

"This includes assessing and articulating the sector's economic importance and key

competitive issues, developing skills for the constantly changing industry base, enabling best practice sharing, providing benchmarking and information forums and, critically, enabling the development of strategic alliances both nationally and internationally," said Higgins.

'The medical device industry in Ireland employs more than 25,000 people'

The IMDA developed a strategy to support a more complex environment with a strong focus on operational excellence, R&D, shared services, and skills and knowledge.

"Collaboration with key partners in academic institutions, hospitals and other key

industry sectors will be critical," said Higgins.

She said networking and collaboration had benefits within the context of the medical devices industry, as proven elsewhere in the world.

"We held, jointly with IDA Ireland and Enterprise Ireland, a very effective forum for 150 of our industry leaders on November 27. The focus was on understanding global and local industry trends and sharing new and exciting models of business that are emerging."

"The IMDA creates an environment and provides a means for companies and inventors to network and build a community, which we support with the resources to help them grow."

The organisation provides members with information on a range of topics including operational excellence, energy, funding, domestic and international regulatory issues, product licensing, commercialisation of technol-

ogy, intellectual property, and skills and training.

"In essence, the IMDA aims to create a powerful unified voice for the sector," said Higgins. "We also forge relationships and develop strong partnerships with third-level institutions, the clinical community and other sectors within the life sciences group. Importantly, we promote and encourage best practice and the bottom line is that we strive to deliver high value service to our members," said Higgins.

Ireland is very well placed to encourage further growth in this valuable sector.

"We have the high skills and education that characterise the ideal medical device workforce. That said, there is no room for complacency. We need to encourage more students to follow science and engineering paths."

"Medical devices and diagnostics is a strong, well-established industry, continuing to grow despite local and interna-

tional pressures.

"More than 80 per cent of sector companies are innovation active. The success of the sector to date has been underpinned by our ability to market products quickly, which is a key part of our competitiveness. Good regulation is a crucial component of this," said Higgins.

The IMDA regulatory conference held in early November, aptly titled Global Access II, was attended by almost 200 regulatory professionals and industry leaders, and provided a forum for industry to engage with senior international legislators and experts.

"The forum offered detailed global regulatory forecasts to enable industry to proactively prepare for new and emerging regulations, ensuring Ireland can continue to remain competitive and succeed in global markets," said Higgins.

While the sector bucks current economic trends by continuing to perform very well, Higgins said that "in common with all manufacturing industries, the sector faces challenges in the areas of cost, energy, waste, regulation and up-skilling".

The issue of costs is particularly relevant. "We must ensure costs are brought under control, particularly energy and labour costs. We also need to continue to invest in capital infrastructure, with an emphasis on improving our roads, access to Europe from the west of Ireland, and broadband," said Higgins.

"While Ireland has achieved much as a base for medical device and diagnostic firms, we need to further fuel innovation by putting the appropriate processes and expertise in place to allow Ireland to become a world leader in this arena."

"R&D and tax credits are viable and useful tools to help both start-ups and overseas multinational companies and we must continue to nurture companies in this way."

"The IMDA is committed to promoting industry awareness to ensure the sector continues to grow here in Ireland and is promoted globally, thereby enhancing our opportunity for investment and attracting the appropriate skills to the sector."

Emphasis on new sector growth

By Caroline Allen

Of the 200 Irish companies operating in the life sciences sector, between 70 and 80 are directly involved in the medical devices and diagnostics space.

"The med tech sector is of key importance to the Irish economy and Enterprise Ireland is strongly committed to its growth and development," said Brian O'Neill, manager of life sciences at Enterprise Ireland.

"We provide a wide array of financial and non-financial supports to med tech companies across all core business functions, ranging from sales and marketing, to production and operations, to R&D and innovation, and leadership and management development, for example. A key area, however, is the assistance provided to companies through our global network of overseas offices."

The sector has enjoyed a 17 per cent compound annual growth rate for the last three years, according to Tom Kelly, manager of Enterprise Ireland's environment, industrial and life sciences division.

In life sciences, about one-third of start-ups come from an Enterprise Ireland-supported research base. "The support provides a significant contribution to the scientific and technological infrastructure from which all companies here can benefit," said Kelly.

Enterprise Ireland has 32 offices around the world, ensuring a presence in key regions in Europe, the Americas, the Gulf states and Asia. Winning market share in high growth markets such as Brazil, Russia, India, China and Japan is part



John McMahon, former chief executive, Mitralign Inc; Sean McEllin, manager in Boston, Enterprise Ireland; Ken McDonnell, general manager of business development, Interventional Systems Division of Terumo Corporation; Daniel McNulty, former president and chief executive, InfraReDx Inc; Don Hetzel, former vice-president of R & D, Becton, Dickinson and Company; Ann Marie Maxwell, marketing executive in Boston, Enterprise Ireland; Brendan McGrath, former senior executive, Smith & Nephew

of its wide-ranging strategy. "The overseas offices play a critical role in helping companies enter new markets and we are very proactive in identifying opportunities that exist and bringing them to the attention of Irish companies," said O'Neill.

"We have people local to the areas in all our offices which helps cut through the complexity of doing business abroad. We also identify people who can act as mentors and are very active in building networks that can ultimately lead to getting deals done," said Kelly.

National stands are taken at key trade fairs, involving between four and ten companies to promote the capability of Ireland Inc.

"We do a lot of preparatory work with companies so that value-added meetings can occur," said O'Neill.

This year, Enterprise Ireland had a presence at the Medical Design and Manufacturing (MD&M) exhibition in the US, regarded as a key medical show. It also attended Medtec in Stuttgart; PCR in Spain and CMEF [China International Medical Equipment Fair] in China.

"Participating companies put a lot of time, effort and finance into these business ventures," O'Neill said. "We ensure that Irish companies get to meet the right people, in the right companies, at the right time to ensure business is done."

Events are also held in key markets where it is believed Irish companies should be doing business. The medireland.com website has been developed and a medireland global forum, involving 180 key decision makers from leading global companies, is run every two years. The next forum will take place next October.

A market study will be carried out with a visit in April to Japan, the third largest medical device market in the world.

"We are keen to increase the level of business being secured by Irish companies in that market," said O'Neill.

Germany, the largest market in Europe, is being targeted with attendance at MedTech Stuttgart in March. Enterprise

Ireland will also have a presence at the Om Tech orthopaedic show in the US next November.

According to Sean McEllin, Enterprise Ireland's manager in Boston, business worth several million euros was generated as a result of bringing buyers to meet Irish companies in Galway last September.

"In my five years with Enterprise Ireland, all of our global group activities – which were extremely focused – have brought business to Irish companies," he said.

The numbers employed in the med-tech sector in Ireland are growing. "One of the things we are looking at doing is encouraging companies to migrate from traditional engineering and manufacturing into the healthcare space."

"A lot of the bigger device companies globally started out in areas like materials. Creganna, the largest medical device company in Ireland, started out coating metals and then started working with Boston Scientific, which propelled it into the device sector," he said.

"A lot of companies are now specialising in cardiovascular and minimally invasive arenas. The entire healthcare area is now focused on less trauma and time in hospital. Huge investment has gone into developing minimally invasive spinal procedures, for example. This is an opportunity for our companies as they have a very strong foundation in minimally invasive technology that will allow them migrate into other segments of the medical device industry," said McEllin.

Enterprise Ireland is currently running a six-month programme on innovation and partnering, involving ten Irish companies interested in upskilling to move into orthopaedic.

The organisation will follow up after the six month subsidised programme, providing access to clinicians, advisory panels and mentor networks to help companies further develop their strategies.

"As a global team, we take a stepped approach. The group will have the opportunity to visit the Cleveland Clinic, a 35,000-person organisation that has relationships with groups all over the world, and to attend an orthopaedic show in June," said McEllin.

"You cannot put a price on access to clinicians, especially in the US, which uses more than 60 per cent of medical devices globally," he said.

According to McEllin, Ireland has a very strong reputation as a significant device cluster for Europe. "Irish companies have a good reputation and provide more peace of mind. This provides a significant opportunity for the Irish manufacturing sector to get involved in the med tech area. High-end manufacturing can bring real value with the proper regulatory systems in place."

Irish companies are already capitalising on the opportunities, according to McEllin. "Brivant Medical Technologies manufactures a product for one of the largest medical companies in the world and supplies product to a number of large medical device companies. Creganna also works with a number of global players."

The biggest 'to do', he believes, is for companies to get more medical expertise. "We are providing that through our advisers."

Access to growth capital in the current economic climate is another issue. "We are trying to facilitate some of that through our product development fund."

Ireland still leads the way

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A third tranche of companies that have been involved in more traditional pursuits – usually in some form of precision engineering – that have adapted their processes for the medical device industry.

Creganna, a Galway-based, Enterprise Ireland-backed company, is one such example. One of the largest indigenous companies in the med tech industry, it is heading for a €50 million turnover this year, has 500 staff and, in an example of reverse foreign investment, has opened a facility in Massachusetts.

It has been listed as one of Europe's top 500 growth companies but started life as a Galway-based firm working in the electronics industry, specialising in metal coatings that prevented interference between circuits.

It was an area of expertise with applicability in the medical device industry.

"We realised we had to be a global supplier to be successful and survive in the long run," said chief executive Helen Ryan.

"We had the experience in a very negative way, if you like, having been cut out of supply chains in the electronics industry because we did not have global reach. We were presented with an opportunity to solve a problem with a component used in all cardiology devices."

"We managed to come up with a solution that solved those problems and, on the back of that, we won global supply agreements with a number of big players in the industry."

Ryan is also chair of the Irish

Medical Devices Association (IMDA), which last year conducted a strategy review of the industry that concluded that its manufacturing element should remain its centrepiece.

Ryan said manufacturing was the springboard for moving further along the value chain into product development, marketing and distribution rather than eschewing it in favour of such functions.

"We had some concerns that there was a view that manufacturing would be less important in the future. We felt very strongly that that was not the case."

"The vast majority of manufacturing done within this industry tends to be complex products for which there is a very high level of process development to produce them and also, in some instances, a requirement to develop specialised equipment to build the parts."

"There is a knowledge built up that is not easily replicated elsewhere. Our feeling is we have that and we need to work hard to keep that."

This sentiment is echoed by the IDA, which points out, for example, that of 1,000 people employed in production by Abbott Diagnostics, 110 have PhDs.

Ryan said her mantra as IMDA chairperson was that manufacturing should be locked down and its inherent cost challenges addressed.

"We can do things like semi automation," Ryan said.

"We can improve our efficiencies. There are a number of companies that have demonstrated they can be much more efficient in Ireland than in sister operations in other countries."

Medical Technology

Abbott sets standards other firms must meet

The benchmark for industry excellence, Abbott Ireland is helping to drive competitiveness through upskilling, writes **Caroline Allen**

Abbott Ireland's nutritional devices plant in Ballytivnan, Sligo, was last month awarded the overall prize for industry excellence at the Irish Medical Devices Association (IMDA) excellence awards. Supported by Enterprise Ireland and the IDA, the awards were held at Dromoland Castle, Co Clare.

Abbott, one of Ireland's leading healthcare companies, with more than 3,500 employees, manufactures and markets a broad range of healthcare products, including pharmaceutical, diagnostic and nutritional products as well as medical devices.

This award recognises Abbott Ireland's efforts to reinforce its competitiveness through a combination of leading edge automation, productivity and process improvements, underpinned by employee upskilling.

According to John Kilcoyne, site director at Abbott's Sligo facility, the work carried out by the IMDA, in conjunction with Fás and Skillnets, has made a significant contribution to upskilling within the manufacturing sector.

"Employees receive training on modules such as communications, environmental, health and safety, quality and continuous improvement," he said. "A lot of work has also been undertaken in conjunction with the third-level colleges in developing courses that are specific to the needs of this sector, such as the degree in biomedical engineering."

"Foreign companies are also recognising the focus that Ireland is placing on innovation

and R&D," Kilcoyne said. "Ireland's medical devices and diagnostics sector compares very well with that of other jurisdictions, particularly in the areas of manufacturing and support services. Over the past few years, the manufacturing sector has come under increasing cost pressures. In order to respond to these pressures, we have embraced lean manufacturing, upskilling and innovation."

"It is particularly reassuring to see the investment under way in automation throughout our sector. This increased level of automation has required us to invest in the upskilling and retraining of our employees," said Kilcoyne.

"Operational excellence is defined within our organisation as sustained improvement over time. This continuous-improvement culture is embedded in our manufacturing organisations. Without this focus we simply will not survive in today's environment."

In today's competitive environment, all non-essential activities must be eliminated, as these activities represent costs that customers will not pay for.

"Our employees are very innovative and experienced. Through employee involvement and leveraging their innovative skills, we have managed to develop leading-edge automation solutions that have helped us remain competitive," said Kilcoyne.

Companies in the med-tech sector have, he said, fully embraced the concepts of lean manufacturing and business excellence. "They are also focused on innovation and pushing the boundaries of automation. A significant amount of automation is un-

derway within the med tech sector. While this involves a financial investment, I believe it is the way forward if we are to maintain a manufacturing infrastructure in Ireland."

It is critical, Kilcoyne said, that we continue to invest both in people and capital.

"We must invest in automation and processes that keep us to the forefront," he said. "The base of experienced engineers and technical personnel is critical to Ireland's success in manufacturing. Without this pool of experienced talent, it will not be possible for us to compete and win on the international stage."

Abbott's nutritional devices site in Sligo is an integrated manufacturing plant. Much of the sub-supply components are moulded on-site. These components are then assembled into finished products and packaged on-site. The final stage of the manufacturing process is the sterilisation aspect, which is also completed on-site.

"This extensive integration has given us competitive advantage," said Kilcoyne. "Skilled technical staff are also critical to our operations."

"Abbott has a strong manufacturing presence in the country. This has allowed us the opportunity to recruit and develop engineering and technical talent. It is vital that our company and other companies in the med-tech sector have continuous access to a pool of graduates with technical qualifications."

Kilcoyne said Abbott Ireland was committed to continuous improvement across all its operations. "We are particularly proud of our achievements to date, but we are also



John Kilcoyne, site director; Nicola Gilmartin, human resources manager; and Philip O'Donnell, business excellence and development manager at Abbott Ireland's nutritional plant, with their awards at the IMDA Excellence Awards



Abbott's nutritional devices facility in Ballytivnan, Sligo

realistic and we know that, in order to succeed in the future, we must remain competitive, responsive, adaptable and skilled," said Kilcoyne.

"As an economy, we must continue to produce sufficient numbers of graduates in engineering and science. They are critical to our future success. Our university courses must train graduates for the real world. Graduates must leave college understanding and appreciating the competitive pressures Ireland faces in a global economy."

"Graduates must be taught the principles of lean manufac-

turing, business excellence and innovation. These disciplines are required to drive our economy forward."

"All graduates should be encouraged to work in industry so that they can learn from experienced professionals," said Kilcoyne.

To remain attractive for FDI, Ireland must maintain its existing corporate tax structure, he said.

"Increasingly we are gaining a foothold in managing support functions, for example, managing manufacturing located at third-party sites outside of Ireland, support centre

2008, an excellent year for med tech in Ireland – main FDI announcements



management, and cash and treasury management operations.

"These are excellent developments as they make Ireland strategically important as a location for enterprise. We must, however, not lose sight of the

fact that much of this new business evolved through having a manufacturing base embedded in Ireland. We must protect and develop this productive and critical sector of our economy.

"We are fortunate to have

state agencies such as the IDA and Enterprise Ireland. These organisations are well respected internationally and have the contacts to help attract and support new business in Ireland in the years ahead," said Kilcoyne.

Indiana firm to make a joint effort in Ireland

Zimmer is investing €50 million in its new facility in the Shannon Free Zone, writes **Éibhir Mulqueen**

The latest med tech overseas investor to begin operations in Ireland is expected to commence production next spring, manufacturing knee and hip implants for the orthopaedic market.

General manager Adrian Furey said the availability of a vacant building in the Co Clare town had been a big draw for Zimmer. The building was formerly occupied by Nortel and then Flextronics.

"The fact the building was here meant we did not have to build from a greenfield site," Furey said. "The closeness of the plant to a number of major universities and international airports was also a factor."

Meanwhile, the 12.5 per cent corporation tax rate offsets a lot of the extra costs associated with doing business in Ireland, he said.

The tax rate, in fact, was specifically cited as an incentive when the project was announced last February. Senior vice-president of global operations and logistics Richard Stair said it would help reverse "the upward pressure on our effective tax rate over the long term".

Zimmer had a \$3.9 billion turnover last year. The Indiana-headquartered US cor-

poration has operations in 25 countries worldwide and a workforce of about 8,500. Currently there are a little over 30 employed in Shannon, but a workforce of 250 is projected over five years.

"Ireland has built up a tradition of manufacturing medical products and a significant, well-trained labour pool with expertise that can be tapped into," said Furey.

"We look forward to working with Shannon Development and local education institutions to help assure that there is an ongoing supply of well-equipped workers coming into the market for medical technology manufacturing."

He said the joint approach of Shannon Development and the IDA was important when the project was being negotiated.

A native of Galway, he was employed as operations manager by Abbott Vascular in that city until production ceased last May. Before Abbott, he worked for Medtronic for five years but gained his experience in orthopaedic products with DePuy in Cork.

He said that there would be a number of hurdles to overcome before the Shannon-produced implants could be brought to market.



Adrian Furey, general manager, Zimmer: 'We look forward to working with Shannon Development and local education institutions'

As with stents and other medical device products, the market is growing for orthopaedic devices. Furey said the average age of patients requiring hip and knee implants was about 67, but that was decreasing.

This is partly because rising obesity rates are causing joint and arthritis problems for people earlier in life but also because many people are leading more active lives than before, again resulting in joint dysfunction.

Shannon Development

The Shannon Free Zone, adjoining Shannon International Airport, is one of Ireland's largest multi-sectoral business

parks, accommodating a range of advanced manufacturing and internationally-traded service companies with the overseas base being predominantly north American.

Zimmer made its decision to invest in Ireland in late 2006



Michael Foley, manager, Shannon Free Zone

and formally announced this in February 2007. According to Michael Foley, manager of the Shannon Free Zone, the decision followed a detailed assessment of a number of global sites as the company sought to expand its worldwide manufacturing and logistics networks.

"IDA Ireland has driven the development of Ireland's medical technology sector to a stage where it represents a formidable cluster in a global context. Shannon Development, the dedicated regional economic development company for the Shannon region, engages with and supports the IDA in its efforts to maximise FDI investment in the region," said Foley.

"A collaborative marketing programme entailing extensive client and client adviser interaction facilitated the building of a compelling case for Zim-

mer to choose Ireland and Shannon in this particular instance."

Foley said the skills sets and competencies required by Zimmer were visible at Shannon and in the wider Shannon area. Another plus factor was the availability of a building facility surrounded by well-developed expansion sites.

"Geon Engineering – a Shannon-based turnkey facility and project/process development management company specialising in med tech – brought its considerable know-how to the table, as did Mary Donnelly, regional director at Fás, and her team of med tech training specialists," said Foley.

"These factors, combined with the region's established medical device cluster, Shannon's international connectivity, advanced logistics networks, low corporation tax and regional third-level educational linkages were instrumental in helping get the project over the line."

Zimmer's planned investment is in the order of €50 million over a two-year period and the project is expected to create 250 new high-quality jobs supported by Shannon Development over the next five years.

Shannon Development is embarking on a major regeneration programme for its Free Zone business and technology park, in addition to providing a range of building facility options.

Medical Technology

Talent is rewarded by commitment

Attracted by Ireland's talent pool and the high level of support from government agencies, more med tech companies are locating their headquarters and manufacturing operations here.

Éibhir Mulqueen reports

A little-recognised aspect of Ireland's tremendous success in attracting overseas investment is the commitment of many multinationals to this country. These companies are going beyond simply making decisions about subsidiary plants and are establishing their European headquarters here.

Teleflex Medical is one example within the medical technology sector. It has established its EMEA base in Athlone and is currently expanding it. The plant employs 70 people, but next year that figure is expected to grow to 100 as certain functions, such as quality assurance (QA) and regulatory affairs (RA) are increased. An overall target figure of 150 employees is projected. Current turnover for the EMEA region, which employs 4,500 people, is \$500 million.

Barry McBride, president of Teleflex Medical for EMEA and IMDA board member, has worked for the firm since 1990 when he started at its former manufacturing plant in Lurgan, Co. Armagh.

Since then he has moved to several locations with the US multinational, including England, Germany and Malaysia.

Since 2006, he has been overseeing the establishment of the Athlone headquarters. The plant provides multilingual customer service for more than 300 distributors, as well as finance, HR, IT, planning and administration.

"We control 17 direct sales subsidiaries out of Athlone," McBride said. "We are going to drive and grow this business based out of Athlone."

To an outsider, Ireland and Athlone might seem a curious choice for a US company to make this kind of commitment, given the peripheral position of the country. Beyond that, quick access to international airports would seem to be a requisite.

Teleflex's decision to move to the midlands town was finalised early last year, at a time when it was evident that Ireland was no longer distinguishable as a low-cost economy. However, McBride said the decision was not based on monetary cost but on the "total social cost".

"The salaries are directly comparable with mainstream Europe. The people are not cheaper but that was not the reason for moving there. You are not looking for the cheapest. You are looking for the balance of scale in relation to cost."

Part of this equation includes the availability of personnel with language skills and graduates qualified to work in healthcare. Athlone also forms part of a regional

cluster of medical device companies that includes Boston Scientific and Medtronic in Galway.

"Overall we are very pleased with Athlone. We took a leap of faith on the basis that the M6 would be extended out. That has been a big help for us."

Companies such as Elan, also based in Athlone, form a backdrop of general healthcare companies that have allowed for the build-up of skilled management personnel in the area. The IDA's Medical Technologies Division is also based in the Athlone Business & Technology Park and the Athlone Institute of Technology is next door.

"There is a good cluster of companies and supporting services around, all sorts of suppliers and people who can help with regulatory support and also core senior and mid-level management," said McBride. "There is a good pool of talent and experience at senior and mid-level management familiar with the healthcare industry. Some of those skills cross over well. Some of the skills are generic to the healthcare industry."

Irish senior executives are in high demand by med tech players, an example being the recent appointment of John Elwood as vice-president of global manufacturing operations at KCI, after the company being present less than a year in Ireland. KCI has a facility in Athlone.

McBride also cites the 12.5 per cent corporation tax rate, the business-friendly environment and the labour laws as inducements to locate in Ireland rather than elsewhere in the EU.

"Ireland is still a country that promotes investment and has reasonably supportive labour laws. There are [other] environments that make you feel a little bit nervous about making an investment," he said.

Projected growth rates for Teleflex's Athlone and Limerick businesses are in the high single digits, he said.

The Limerick manufacturing plant is an example of how a foreign direct investor in Ireland has been able to adapt. First attracted to Ireland in 1983 because it was a low-cost manufacturing base, Teleflex, as an original equipment manufacturer (OEM), has seen that advantage eroded for the finished products and components it supplies to other leading companies.

Employee numbers in Limerick stand at 160, including 15 in full-time research and development, in a division of the company that has a \$150 million turnover. This compares to just 40 employees a quarter of a century ago.

McBride said that the same product was still being manufactured in Limerick, though with more automation. But the



Barry McBride, president of Teleflex Medical for EMEA: 'We are going to drive and grow this business based out of Athlone'

local company is also specialising in neuro catheters, small-bore catheters developed in conjunction with a team from NUI Galway for the specialised delivery of medication in the body. He points out that this type of proprietary product with a high engineering content cannot be replicated easily and does not rely on a low-cost manufacturing base.

Gerry Kilcommins, vice president of Global Vascular Operations for Medtronic and general manager of its Galway site, also underlines the importance of the corporation tax rate as a draw for overseas companies along with Ireland's

position as a gateway to Europe and the rest of the world. "That should not be underestimated either."

But he also cites the wider government and government agency supports as important factors.

"I think the IDA has done an excellent job over the years in attracting FDI. It is world renowned for the formula it has in selling Ireland as a good place to do business."

"Medical technology is a high-end technology. It was a key strategic move for the IDA. There is a less quantifiable factor that is also important.

"I would put it under the heading of talent and the education system that has produced the employees we hire."

Kilcommins said qualities such as skills and expertise, a can-do attitude, flexibility and the ability to carry through projects come under this 'talent' heading.

"There was a major focus on education back in the 1970s," he said. "There was a major drive back around then to entice our youth into areas like science and engineering and technology with a view to providing the engineers that companies like Medtronic would need in the future. I think that

has been very successful."

There is also a more localised factor. The Medtronic Galway business was originally owned by CR Bard but was acquired first by AVE and then by Medtronic nine years ago. It forms one of a series of medical device companies whose profile in the western capital ranges from small, indigenous start-ups to multinational giants.

"Galway and the west really developed over the past 15 years into a very vibrant medical technology cluster," Kilcommins said.

Locally, he has found the third-level institutions suppor-

ive. The region's expertise in the medical device sector is explicitly recognised by the Galway-Mayo Institute of Technology, which runs an Engineering in Medical Device Manufacturing course.

Within the Medtronic plant itself he has successfully introduced lean manufacturing techniques to reduce waste and improve efficiency.

"Waste equals cost: it is about being ruthless about identifying waste and reducing it. Cost is our biggest challenge, so to continue to be competitive we decided on our own initiative to go on a major lean drive. It is an ongoing journey."

Pat Gallagher, general manager of Baxter Manufacturing in Ireland, is based in Castlebar, where the Irish plant was first established 36 years ago, "the year before Ireland joined the EEC".

Baxter, which also has a plant in nearby Swinford and has more than 1,000 employees in Co Mayo, encompasses the changes that have occurred in the manufacturing industry over that period, having successfully adapted to the demands of its own marketplace as well as a polar change in the Irish cost base over that period.

"We have transitioned through various generations of product now and through various generations of technology," said Baxter. "The company has got its original investment back several hundred times over at this stage."

Over four decades the skills set has changed and is different to what it was even seven years ago. Operations have become capital and knowledge-intensive, he said.

"Today there would be a sig-

'Galway and the west really developed over the past 15 years into a very vibrant medical technology cluster'

nificant development operation both on the product side and very much on the technology side," Baxter said.

"For this sector, it is about identifying clinical problems and then identifying engineering solutions for them. At the end of the day most products are developed by engineers."

Last year it was announced that €75 million would be invested over six years in new technology and higher-value product development.

Baxter continues to be a large exporter, shipping up to 25 containers daily and Gallagher said manufacturing must remain an essential part of the medical device industry if Ireland was to develop it by expanding into other functions.

"You have to retain manufacturing if you want to have bolt-on functions. You are not going to have supply chain operations if you are not going into manufacturing."

"Co-locating R&D with manufacturing develops synergies. You are developing next-generation technologies in real-life situations."

He said that clinicians should also be involved in the product development process. "We have to bring academia and industry and the clinicians together and have a connected strategy."

"Everybody talks about the knowledge economy but you have to bring that down to what that means at company level, and that means moving on from manufacturing and supporting innovation."

He believes this is a key part of the process, whereby multinationals are convinced of the merits of basing their European headquarters in Ireland. Most functions can be moved to other locations, but if the intellectual property behind product launches is being developed in Ireland, it will stay here.

"If you are doing that, you earn the entitlement of setting up your European headquarters here. We know where we are in the cost league. The only thing that is going to counteract that is the innovation on the product side and the technology side."



Teleflex's site in Athlone: the company's decision to move there was based on the 'total social cost'

Galway's med tech sub-cluster continues to grow

By Margaret O'Brien

While the IDA and Enterprise Ireland market Ireland as a medical devices and diagnostics cluster internationally, within Ireland a number of distinct sub-clusters have emerged. The largest sub-cluster is in Galway, where about a quarter of all med tech firms in Ireland are located.

Why Galway? That's a question occupying much of Professor Michael Best's time just now, during his one-year secondment to NUI Galway. One of the world's leading authori-

ties on med tech clustering, Best has published in-depth research into the evolution of the med tech cluster in Boston.

He is currently assisting with a similar in-depth analysis of the medical devices industry in Ireland, in particular examining the inter-relationships among Massachusetts medical device companies and their affiliates in Ireland, of which there are several, mostly in Galway.

Best argues that the roots of the med tech sector in the west can be traced back to computer company Digital, which set up its operations in Galway in 1971, establishing the region as a name in the technology world.

"American computer companies at that time were looking for locations where they could ramp up production quickly," said Best. "In Galway, Digital found willing workers and a good education system."

"The company kept its R&D in Massachusetts, but Massachusetts had never been great in volume manufacturing, so what they got from their base in Ireland was complementary to their set-up in the US. That set the ball in motion, and out of Digital came a lot of well-trained, experienced engineers and managers."

The fact that Galway provided a 'gateway to Europe' was fundamental. "Europe

was the second biggest market behind the US," said Best.

He added that "Americans were happy to turn sales and the task of dealing with languages over to the Irish subsidiary. It solved a lot of problems for HQs back in Massachusetts. In essence, what Ireland was good at was its ability to solve the remote management problem of these companies."

Medical devices started to emerge as a sector in the 1980s and with its growth came a huge need for engineers and business development people and Massachusetts was ready to fill the gap. The region has since grown from nowhere to become the biggest medical

devices hub in the world.

The development of the Galway med tech sub-cluster started with the arrival of Boston Scientific in 1994.

While Galway and indeed Ireland's strength lay in manufacturing to world-class standards, its world-class manufacturing capabilities were imitated by emerging economies that had the added advantage of lower labour costs.

This put Ireland under pressure. In response, Boston Scientific initiated product development in Galway and a new era began.

The growth of a larger, skilled labour pool and greater engineering skills has become

a magnet for other countries. While medical device companies in Galway are predominantly US-owned, European companies have also been attracted.

Education is very important to the continued growth of the industry. To that end, GMIT and NUI Galway have developed courses focused on the sector.

"Young people in the region look at the companies on their doorstep and that often influences their career decision. Someone who wants to work in Galway might decide to take a course in medical engineering so they can get a good job locally, and so it all evolves organically," said Best.

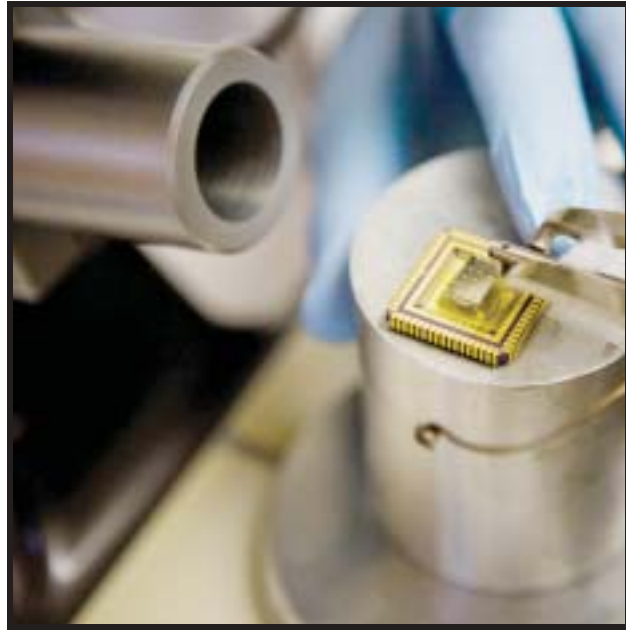


Professor Michael Best, NUI Galway

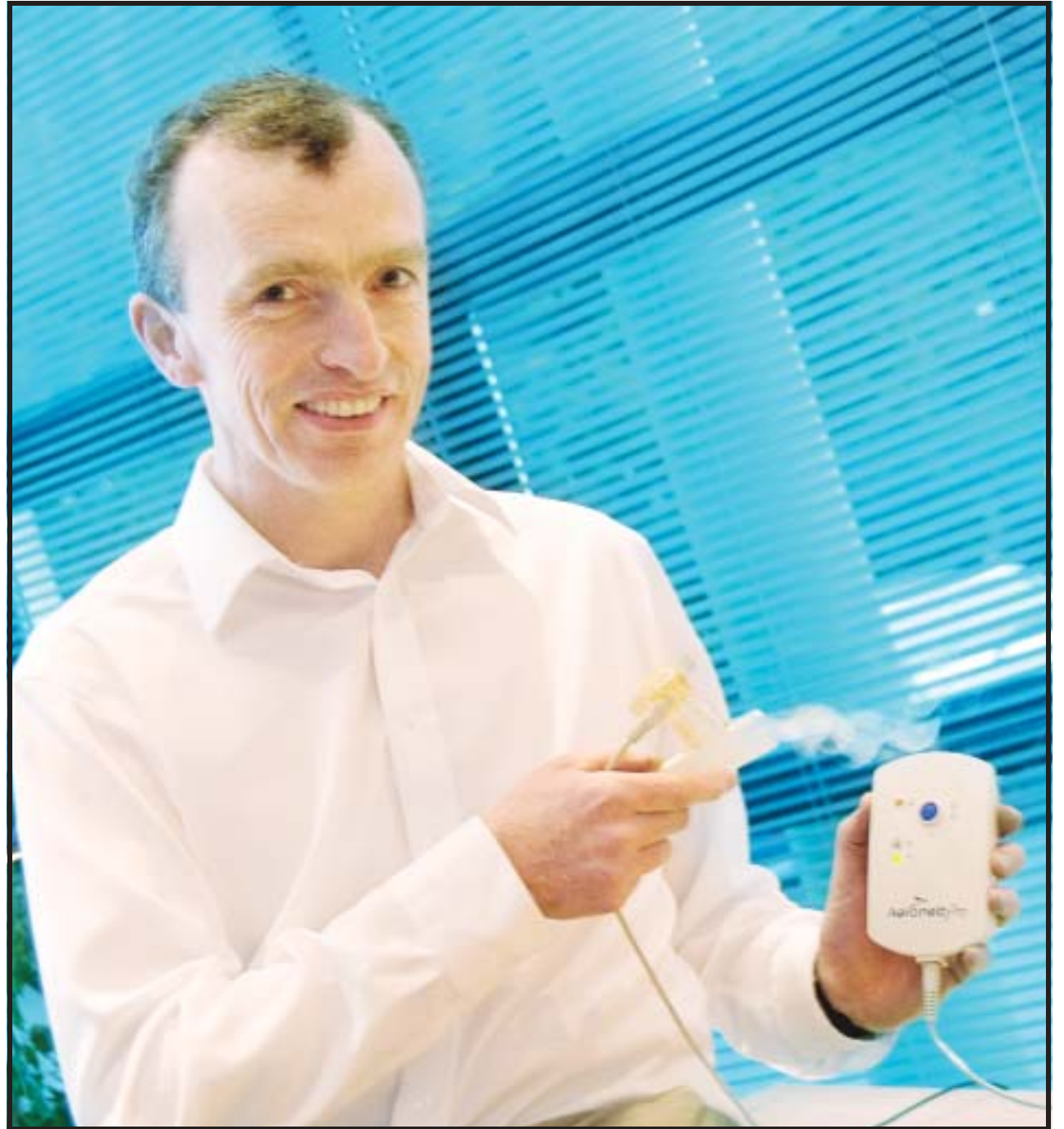
Medical Technology



John O'Dea, chief executive, Crospon



Crospon product design



John Power, chief executive, Aerogen: 'The US is still the prime target to steer your product towards'

Irish companies nurture global opportunities

Ireland's med-tech firms are focused on creating innovative products and expanding their export markets, writes **Dermot Corrigan**

Building an export strategy and establishing global distribution networks are among the priorities for indigenous Irish medical device companies, according to John Power, chief executive of Aerogen, which won the innovation award at last month's IMDA Excellence Awards.

"From Ireland, if you are going to be a medical device player, you have to think exports straight away," he said. "Aerogen exports to more than 50 countries worldwide. The US is still the prime target to steer your product towards."

Indigenous Irish medical device companies had to aim for unique, specialised products, Power said.

"If you are selling a 'me-too' product, I would say you would want to be gearing to get out of that market," he said. "Eventually that only goes one way, and that is cost base. Our products are unique, we have more than 30 patents in our portfolio. We do not develop any product that does not hit a unique market sector."

Aerogen

Aerogen specialises in drug delivery technology for the respiratory sector. Its core tech-

nology, the OnQ micro-pump aerosol generator, is used in nebulisers for drug delivery to patients in the intensive care and homecare settings.

The company was established by Power in 1997 before being acquired by US giant Nektar in 2005, but bought back via a management buy-out led by Power in January 2008.

"Things have been going very well as an independent company again," said Power. "We have grown sales by about 50 per cent, year-on-year."

Aerogen employs 36 people at its headquarters in Galway and offices in Britain and the US. Products are developed in-house in Galway, and manufactured by partners in Galway, mainland Europe and the Far East.

"We have a very strong R&D focus," Power said. "Some 40 per cent of our operational expenditure goes into research and development. Everyone in Aerogen, apart from the accountant and the receptionist, is involved in product development."

The company does not sell directly to healthcare providers. "We sell through major blue-chip OEMs," said Power. "Our customers would be the likes of GE Healthcare, Cardinal Health and Covidien. These are some of the biggest medical companies in the

world. We integrate our technology into them, it is a bit like the Intel inside-type scenario."

Aerogen has further new products in the pipeline, according to Power.

"We have other products for non-invasive ventilation and drug delivery during oxygen therapy that we are working on," he said.

"Over the past two years we have also been working with the leading laparoscopy laboratory in Strasbourg on delivery of drugs during laparoscopy procedures. It will be 18 months to two years before a product will be on the market, but we see that as being a major potential market for us in the future."

Crospon

Crospon, another Galway-based indigenous medical devices company, has also benefited from time spent under the wing of a large multinational company. Its chief executive, John O'Dea, an IMDA board member, had previously set up respiratory therapy equipment manufacturer Caradyne, which was sold to US giant Resprionics in 2004 for €5.9 million.

O'Dea went into Resprionics with Caradyne, but when the company closed its manufacturing facility in Ireland in

'From Ireland, if you are going to be a medical device player, you have to think exports straight away'

2006, he decided it was time to set out on his own again.

"I had a good research and development team there and had some ideas I was looking to explore in different areas of medical technology, so I decided to take the plunge again," said O'Dea. "I started up again with about six of the team from Resprionics."

Crospon is currently developing its Endoflip product, which is a unique diagnostic tool for assessing the competence of the gastroesophageal

junction in patients with gastroesophageal reflux disease (Gerd). However, O'Dea said that, initially, he was unsure exactly what path Crospon would take.

"In a sense I had the company and the team almost before I had the right product," he said. "I had no great dream of getting into gastroenterology, but I did not want to see the team scattered to the winds."

"Initially we had some licensed technology we were looking at in the area of non-invasive glucose monitoring. But we realised there were some technical challenges that might not be overcome, and we did not want to put all of our eggs in one basket."

Crospon has access to the technology behind Endoflip on a licensed basis, O'Dea said. "Our new business development director was actually looking at doing a start up himself on this," he said. "When we sat down with him we decided that a licence deal might be the best way to work it. We have spent the last 18 months working through the design process."

"The product is very close to regulatory approval both in the US and Europe. We are targeting the first quarter of next year to launch the product."

O'Dea stressed that, due to regulatory constraints, Cros-

pon was not yet actively marketing the Endoflip, however he was confident that it would be a commercial success.

"There is a decent market opportunity as Gerd is a very prevalent disease and one that is quite difficult to diagnose properly," he said. "It is also very difficult to assess whether patients would benefit from surgery and that is an area in particular where our diagnostic works. The technology is very novel, so we will have to build the market for it. That will involve going into a degree of clinical trials and papers and so on."

Crospon has grown thus far with support from Enterprise Ireland and the Western Development Commission, along with investment from O'Dea and other private individuals. "There is no VC funding in the company at present, but in the new year we will be looking to raise about €3.25 million in a new round of funding," O'Dea said.

O'Dea said that one area for improvement in the Irish medical devices arena was the local clinical trials infrastructure.

"The IMDA and the IMB and the health research board have been working together in advancing this particular issue," he said. "There is a new clinical trials centre in Dublin and a new opening in Galway soon."

He also said there was further opportunities for Ireland in the clinical trials space.

Creganna

Not all of Ireland's most innovative indigenous med-tech companies are recent start-ups. Creganna took time to evolve into the sector, according to its vice-president of commercial operations, Alan Crean.

"We started off serving the electronics manufacturing cluster that was here at the time," said Crean. "Through providing one particular technology solution to a medical device sector, we entered that market. We saw that as the way forward, and invested in research and development. Ten years ago, we decided to exclusively focus on the medical device market."

Creganna is among the larger of the indigenous Irish medical devices companies, employing more than 520 people in operations in Ireland and the US. It specialises in solutions for catheter and speciality needle applications.

"We do not put a device on the end market in our own name, we are a sub-supplier to the OEMs," said Crean. "We provide a whole range of products, technologies and services to medical devices and

lifestyle companies, which they incorporate in their devices.

"It might be design components, sub-assemblies or the device manufacture. We offer everything from concept development, through concept design services to prototyping to transfer to production to volume manufacturing."

The company is currently expanding its US operations, according to Crean.

"We had an official opening of our new manufacturing plant in Marlborough, Massachusetts earlier this year," he said. "We have 50 people employed there now. Last month we opened an office in the Silicon Valley hub of Mountain View, California. We are constantly trying to increase our footprint in North America, ensuring we have a presence on the ground there, in that time zone."

Creganna is always on the lookout for new technologies to bring into the company, Crean said.

"We just purchased the IP of a Swedish company called Micromuscle," he said. "It has developed a very innovative biocompatible electro-active polymer material that can be used to make a device move in a particular direction, or to emit a drug or a substance. We will have a launch at Anaheim in California at the MD&M West show at the end of January."

EnBIO launches new ground-breaking technology for the medical market

By Post Reporter

EnBIO, which has its headquarters at Fota Point Business Park in Cork, launched its ground-breaking surface modification and coating technology earlier this month. The new technology will be sold to world markets in medical implant areas such as orthopaedic, cardiovascular and dental applications.

The firm's technology modifies the surface on medical implants such as artificial hips, stents and dental implants in a way that enables delivery of therapeutic drugs directly to the implant location, thereby potentially removing the need for patients to take the drug orally.

The application of antibiotic coatings on orthopaedic implants will reduce infections, the most common reason for hip replacement failures. Another application of EnBIO's technology is the application of drugs to coronary stents for the reduction of thrombosis or



Vincent Grady, chief financial officer, EnBIO; Dan Philpott, chief executive, EnBIO; and John O'Donoghue, chief technology officer, EnBIO

clotting following cardiovascular surgery.

"EnBIO's product offering is truly unique, and the company's innovative discovery is set to be embraced by medical devices industries worldwide,"

said Micheál Martin, Minister for Foreign Affairs.

"Its collaboration with University College Dublin, Cork Institute of Technology, the University of Ulster and the University of Liverpool is to

be commended, and I am really pleased to see that the product is now going to market."

EnBIO is already collaborating with a large US company to validate the technology for

non-medical applications.

"This significantly expands the commercial opportunities for our technology," said chief executive Dan Philpott. "We are working to put further funding in place to exploit this opportunity under the government's Business Expansion Scheme."

EnBIO's team of ten employees includes several graduates who are highly qualified and experienced in the biomedical industry. Commenting on his work with EnBIO, Dr Denis Dowling, director, surface engineering group, University College Dublin, said: "EnBIO's implant coating technology offers the possibility of the first significant improvement in orthopaedic implants in over 20 years."

EnBIO was incorporated in July 2006 to exploit a concept invented by John O'Donoghue, EnBIO's chief technology officer. In the interim, a significant intellectual property portfolio has been put in place and €3 million has been raised from private investors, the promoters and Enterprise Ireland.

SensL secures lucrative US and Korean deals

By Post Reporter

SensL, an international, low light sensing solutions provider headquartered in Blackrock, Cork, announced contract wins in the past fortnight with Samsung Medical Centre at Sungkyunkwan University in Seoul, South Korea, and with the Department of Radiology Molecular Imaging Program at Stanford University in California.

The contracts, worth in excess of \$300,000, are to supply SensL's novel technology, which produces enhanced brain imaging for PET/MRI scanners. Expected to be completed in two phases this year (Samsung Medical Centre) and next (Stanford University), SensL will produce its solid-state, low light detector technology for incorporation into the groups' PET/MRI systems.

PET/MRI is an emerging technology which seeks to provide better cancer and Alzheimer's disease detection and



Carl Jackson, founder and head of sales, and Joe Gantly, chairman, SensL

treatment. Detector arrays will be produced by SensL to allow a full PET ring to be built which, when incorporated into the system, will be large enough to surround a human head. This will allow simultaneous PET/MRI images to be taken. SensL's technology was chosen over traditional technology for its ability to operate in the large magnetic fields required by MRI.

Established in 2004 and now under the chairmanship of Joe

Gantly, the former head of Apple Europe, SensL has pioneered several new technological advances in the photonics arena, interfacing with some of the world's largest corporations and research institutions.

SensL is a spin-off from the Tyndall Institute in Cork, and has an experienced management team. Its 19 employees, along with a host of contractors, work extensively to develop low light sensing solutions.

Medical Technology

Commercialisation is crucial

Innovation in Irish firms is playing a vital role in helping to advance research and development, writes **Dermot Corrigan**

The research and development (R&D) work undertaken by indigenous Irish medical devices companies must be focused on commercial outcomes, according to Alan Crean, vice-president of commercial operations with Creganna.

"From an Ireland Inc perspective, research and development is extremely important," Crean said. "Innovation and differentiation in products is absolutely critical to success in the industry."

However, research and development needs to be rooted in commercial sensibility. There should not be R&D for the sake of R&D – we need to get out there and commercialise the R&D outputs internationally."

The innovation and product development function in the medical devices sector encompasses the majority of a company's staff, according to Andrew Jones, chief executive at Clearstream Technologies.

"In the medical device industry the net around product development and research and development tends to be fairly broad," said Jones. "It is not just the engineers doing the design work, there has to be a team approach."

"There is the initial technician work in designing processes, right through to the regulatory people who have to get the C mark, to the clinical people who have to do the clinical protocols in order to get the product evaluations done before the product is finally approved for sale on the market. The team also goes beyond that to include finance people doing return on investment calculations, the manufacturing and materials people, and so on."

Crean said that Creganna placed great importance on its own internal innovation. "In terms of technology and research for a company of our size, we punch above our weight," he said.

"We have got ten PhDs on staff, which is unusual for a company of this size. We have 60 engineers in our contract design services division and we have our R&D division alongside that."

Donal Devery, chief execu-

tive officer at Vysera Biomedical, said that bringing in external R&D expertise also helped indigenous Irish med-tech companies to compete on the global level.

"Our clinical advisory board consists of seven world-renowned clinical experts," he said. "These particular clinicians are leaders and, as such, driving change and innovation within their own sphere of influence. Vysera's interaction with this group has created an innovative dynamic that leads to a convergence of ideas and realisation of unique products."

Jones said that Clearstream worked with key customers and partners to keep abreast of what the market required.

"In the past two to three years, we have focused very much on building up a cohort of key opinion generators," he said.

"These would be customers or potential customers that we have identified who are eminent in their field. Some of these are Irish, some come from other countries."

"Our basic concept there is to go to the customer, understand their practice and listen to their difficulties, and work with them through identifying potential products, coming up with concept prototypes, bringing those back to them," said Jones. "There is constant evolution and feedback to the point where we have a product."

Structural supports

Strong links between indigenous medical technology companies and third-level institutions and research centres played a key role in product development and innovation, according to Devery.

"Vysera has collaborated successfully with the research expertise at NUI Galway," he said. "The first programme focused on prototyping and testing of soft tissue materials was successfully completed earlier this year. The company has recently embarked on a software modelling project that will add value to future product design cycles."

Jones said that Clearstream had particularly strong con-



Contract design and development of minimally invasive devices at Creganna, Galway

nections to researchers in Trinity College Dublin.

"The head of the Trinity Centre for Bioengineering [TCBE] is actually from Ennis-corthy, so he has been interested in our progress from the very start," he said. "Various students from that group have worked here over various periods, and one of those was a full-time employee for a number of years, and is now a senior researcher in the group there."

Crean said that Creganna also worked closely on projects with a number of different third-level institutions around the country.

"We have done some polymer science research with Queens University Belfast, under the InterTrade Ireland Programme," he said. "We have worked on programmes with campus companies within UCG and GMIT and we have worked with the Royal College of Surgeons through Enterprise Ireland."

Much of the research being undertaken by the indigenous Irish sector has grown from

operations by the US-led multinational medical devices companies in Ireland, according to Devery.

"In Ireland the medical device sector has evolved from manufacturing activities to a stage where most of the, primarily US, multinationals have established research and development capability to support both local and global markets," he said.

"This local R&D activity within multinationals has fostered the growth of external support requirements such as third-level educational programs and research facilities similar to what one would experience in, for example, the general Massachusetts area. From an indigenous perspective, this infrastructure has enabled entrepreneurs to exit their multinational base and establish their own business to exploit new product opportunities."

Enterprise Ireland also helps Irish companies to access supports and networks both in Ireland and outside the country when required, Devery

said. "Enterprise Ireland has been very supportive in the development of Vysera Biomedical by providing early-stage seed funding, access to facilities and a network of business mentors," he said. "As the company reaches the commercial phase of activities, Enterprise Ireland is providing very important support from its overseas offices and through its US-based Medical Device Advisory Board. They have helped develop key clinical and commercial relationships in the US."

Internal processes

Jones said that innovation in product design and development stemmed from innovative internal processes at Clearstream.

"We have a product development stage gate process," said Jones. "We go through concept prototypes and then through various design stage gates, to the point where we actually have a product that we can put

on the market. This is a model we have used for some years now. At one point, Enterprise Ireland gave us some assistance in developing our product developing model through a training programme they ran."

"Key for us is our series of product platforms," he said. "By mixing and matching components, we can very quickly adapt the catheter platform to suit other clinical applications."

"Then that allows us to bring out another distinct product with a different clinical application, and bring it through the product development process very quickly."

"The product development platforms are also linked to a largely standard manufacturing process, so that no matter what product platform it is, they can all be run down the same manufacturing lines, which allows for a very quick changeover and a very flexible manufacturing process."

"The innovation has been in designing these various platforms, and then being able to

rapidly adapt those to different clinical applications," said Jones. "We have 26 different products on the market, although we are a relatively small company. We could not cope with that range of products, if we had not developed all of these standardised platforms."

Future plans

A challenge for indigenous medical device companies here has been that clinical trials have historically been carried out abroad, but this is hopefully changing, according to Devery.

"Vysera's initial product addresses chronic gastroesophageal reflux patients with a device that controls reflux to normal levels," said Devery. "Since there are large gastrointestinal centres in the US – for example the Mayo Clinic – and in Europe – Sahlgrenska in Gothenburg – Vysera has established ongoing clinical test programs at these facilities. "Additionally the clinicians



Andy Jones, Clearstream Technologies



Niall Behan, Vysera



Donal Devery, Vysera

at these facilities advise the company on product definition. The development of one of our new products will be carried out in collaboration with Irish-based clinicians and tested initially at Irish clinics."

Jones said that while the current network of supports and guidance on offer to indigenous Irish companies here was impressive, there was still plenty of room for improvement.

"We have availed significantly of RTI [research, technology and innovation] grants through Enterprise Ireland, and a continuation of that would be critical to us," he said. "Anything that would bring further links with third-level education should be encouraged."

"Everyone wants third level and industry to get together, but sometimes it is harder work than it needs to be, as the timelines, approach and mentality can be different. While tax credits do not directly benefit us at this point in time, they are a welcome incentive to R&D."

Infrastructure supports worldwide access

The regulatory environment is changing to keep pace with rapid development taking place in the med-tech sector, writes **Dermot Corrigan**

This month sees the introduction of a new version of the EU directive that impacts significantly on all involved in the Irish medical devices sector.

"The 2007/47/EC directive which amends existing medical device law will be transposed into Irish law by December 21, 2008 and implemented on March 21, 2010," said Ann O'Connor, medical devices director, Irish Medicines Board (IMB).

"The revisions to the Medical Devices Directive will enhance the legal framework governing medical devices and will lead to more abundant safety data collation, greater pre-market review and enable more effective monitoring of technological evolutions."

The National Standards Authority of Ireland (NSAI) is the body nominated by the IMB to assess and regulate medical devices produced in Ireland to ensure their compliance with the directive. Dr John O'Dwyer, medical director of certification services at the NSAI, said that the new directive was necessary to deal with the fast pace of innovation and development in the sector.

"The 2007 version is not a complete makeover, it is a modification of the existing directive, which was written in 1993," said O'Dwyer. "It was



John O'Dwyer, European manager, medical devices department at the NSAI

modified to update requirements due to innovation in technology and R&D, drug/device combinations, nanotechnology, innovative high-risk devices and also lessons learned over the last ten years."

"The new version of the directive is more transparent and accountable," said O'Dwyer. "It puts a very strong emphasis on clinical data and clinical trials required for high risk devices, and on post-market surveillance of high risk devices, such as coronary and orthopaedic implantables. It puts the onus on manufacturers and notifying bodies to get feedback through periodic update reports and to monitor trends in relation to perfor-



Ian Purdy, vice-president, regulatory affairs for Europe, Middle East and Africa at Boston Scientific, speaking at IMDA's biennial regulatory conference in November

mance history."

Ian Purdy, vice president, regulatory affairs for Europe, Middle East & Africa at Boston Scientific, welcomed the new directive, albeit with some reservations. "The industry very much welcomes the revisions that have been brought in with the publication of the directive and the conclusion of the basic strength of the system," Purdy said. "It is disap-

pointing that we did not see an outright ban on the re-use of single use devices, but the directive does provide a route by which this controversial subject will be addressed in the future."

O'Connor said that another significant change in the medical devices regulatory infrastructure was the publication of further new legislation last July.

"This aims to strengthen the performance of notified bodies which grant the CE mark and also to put in place a common approach in Europe to market surveillance of medical devices that are placed on the EU market," she said. "This will be applicable from January 1, 2010 and should ultimately protect European citizens from products that do not meet regulatory requirements."

Purdy welcomed the publication of guidance documents on drug-eluting stents by the EU Commission this year.

"These documents were developed in a very open and constructive approach involving the EU commission, European member states, notified bodies, manufacturers and physicians," he said.

Both the Irish Medicines Board and the National Stan-



Ann O'Connor, medical devices director, IMB

dards Authority of Ireland offer support to indigenous Irish companies regarding their regulatory requirements.

"The IMB provide support to the medical technology industry by providing advice at an early stage of product development," said O'Connor. "This advice often centres on the appropriate classification of a product, which is key to the appropriate decision regarding route to market. The IMB also deals with applications for clinical investigations that often relate to new technologies."

"We have a lot of SMEs and indigenous Irish companies who get in touch with us," said O'Dwyer. "We have pre-submission conference calls and

meetings with them, where they discuss their technology with us, and everyone is made aware of the clinical implications of the relevant directive. We do not provide scientific advice, but we share with them what lies ahead, the types of technical and clinical data they will be required to deliver to us to ensure compliance."

Early access to regulatory advice gives companies a competitive advantage in their market sector, according to O'Dwyer. "All medical devices companies are competing with other similar type technologies, and time to market is critical," he said. "Whoever gets into the market early can establish themselves. This requires regulatory guidance to be provided well in advance by the notifying body," he said.

O'Connor said that regulation played an important role in ensuring the health and safety of the patient and the viability of the Irish medical devices sector going forward.

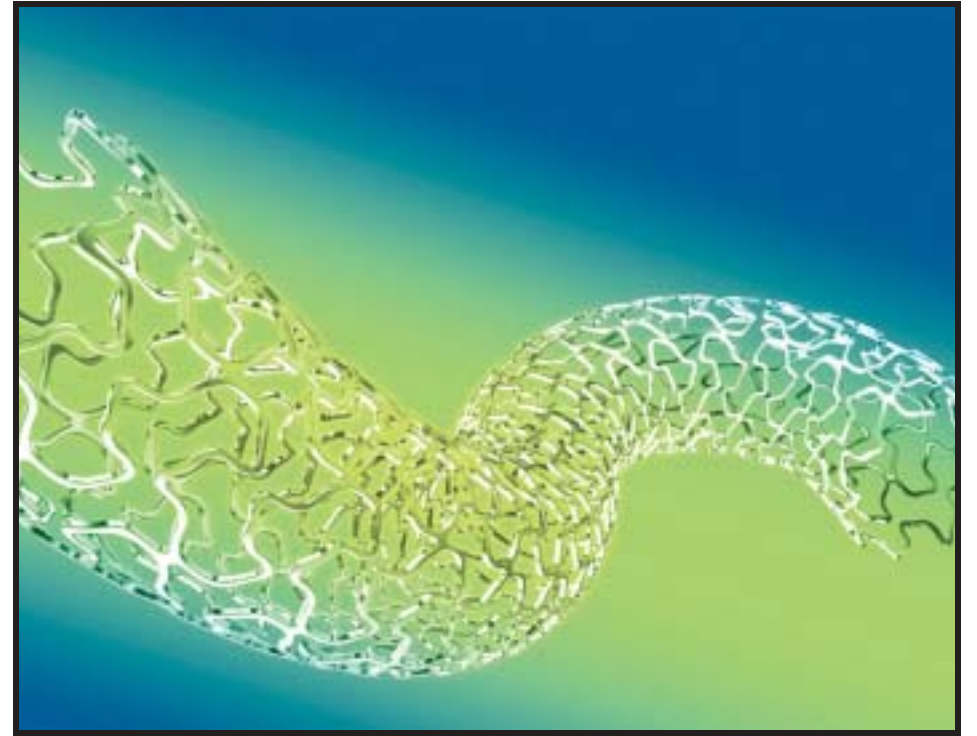
"The most important issue for the Irish Medicines Board is patient and user safety," she said. "Links to stakeholders are critical to effective regulation. For example, reporting of issues with the performance of devices on the market by users is important as it can highlight product issues that can be corrected and as a result lead to improved patient safety."

Medical Technology

Overseas companies locate facilities here to benefit from Ireland's cluster of med tech firms and advanced R&D activities, writes **Caroline Allen**



Paraic Curtis, managing director, Boston Scientific Galway: 'The outcome here is that work content, not work quantity, is being incentivised'. Right: Boston Scientific's drug eluting stent



One of Ireland's key attractions for overseas med tech companies as a location in terms of research and development capacity is the critical mass of multinational companies and indigenous companies, according to Una Murphy, industrial outreach manager for the Applied Optics Group at NUI Galway.

"The combination of multinationals and indigenous companies forms a very healthy, innovative industrial sector," said Murphy.

"The people and the competence in medical devices are here," said Finbar Dolan, associate director of Georgia Tech Ireland, an applied research facility that focuses on bridging the gap between the worlds of innovation and implementation.

"The companies have clustered here and biomedical technology research institutes have developed as a response," said Dolan.

"FDI companies locate in Ireland as a result of the cluster effect and they locate R&D facilities in Ireland for the same reason: the effect of the cluster of advanced research and development programmes in the National Centre for BioEngineering, The BioMedical Diagnostics Institute, The Trinity Centre for BioEngineering and Remedi [The Regenerative Medicine Institute].

"Ultimately, when companies make an investment decision in a highly regulated industry where the quality of the design and manufacture of the product is key, they need to go to where the knowledge and experience is greatest. That is what Ireland offers," Dolan said.

"Stacked up, we are perhaps leading the world, not only in manufacturing excellence, which you need to take on new products, but also in process product and now original product research and development," he said.

Ireland is definitely boxing above its weight in its share of the overseas med tech industry, according to Paraic Curtis, managing director of Boston Scientific Galway, which has played a leading role in the development and commercialisation of the most significant product launches in the company's history. Curtis is also a board member of IMDA.

The Galway site continues to lead ground-breaking research into future generations of products in the drug eluting stent business.

"Two of the primary reasons the multinationals are here are the capability in manufacturing, a major plus in the product development cycle, and the availability of some of the top talent in the world in the med tech industry," Curtis said.

"The collaborative environment fostered by industry and the universities is also important, whether it relates to the design of appropriate degrees and other offerings or the use of the universities' infrastructure in performing or facilitating research. The strong presence of manufacturing and sub-supply is also a major asset in that pilot manufacturing and clinical build activity can be managed at source.

"Of course, none of this matters if you can't execute – that means delivering quality products and processes to the business where and when it is needed. We are fortunate to have a work ethic in this country of wanting to be the best at what we do," he said.

Enterprise Ireland and the IDA, together with SFI, have provided outstanding support to the industry, he said. "The shift by the IDA, in particular away from headcount-based incentives toward research-based incentives, is particularly far-sighted. The outcome here is that work content, not work quantity, is being incentivised, the philosophy being that if you can secure the R&D, the manufacturing will follow."

Curtis said the introduction of the tax credit was a very positive development for the indigenous sector. Further enhancements were made in the most recent budget, which will begin to make this a usable incentive for Irish R&D startups.

"We know we are no longer a cheap economy. We need to add an edge to making R&D in Ireland more financially attractive. The other area we need to watch is that we are constantly feeding the supply of talent through our schools and universities in the sciences."

According to Murphy, the education sector has played a major role by continuously reviewing and updating the portfolio of graduate programmes, particularly in life sciences, technology (including information technology) and the business degree programmes at third level.

"Med tech companies, both indigenous and multinationals, are keen to engage in collaborative research with univer-

sities via industry-sponsored PhD programmes," she said.

Over the past ten to 15 years, the industrial sector has reached out to third level to develop R&D linkages. "Initial forays in materials testing and process development led to activity in design development and, in more recent years, strategic research into new technologies," Dolan said.

Over the same period, he said the third-level sector responded by developing undergraduate and postgraduate programmes in related R&D activities in Trinity College Dublin, NUI Galway, University of Limerick, and the Athlone and Sligo Institutes of Technology.

The establishment and success of Science Foundation Ireland is, according to Murphy, a significant differentiator in attracting FDI to Ireland, and in retaining and expanding Irish operations along the R&D value chain.

"SFI's industry programme has been very innovative, and provides a healthy model for industry, through the IDA's R&D programme to collaborate with university-based research groups."

An example cited by IDA was an investment decision by one of the world's top three orthopaedic companies that do not have operations in Ireland (three of the top six do). Smith & Nephew, together with the NUIG-based Remedi, has established a €6 million collaborative research programme.



Una Murphy

This research will concentrate on developing groundbreaking new treatments for bone and joint diseases, such as osteoarthritis, and links orthopaedics to the regenerative capabilities at Remedi, whose initial remit was in cardiovascular applications.

Professor Frank Barry, scientific director of Remedi, said: "This is a very significant milestone for us in our research programmes. We are delighted to be working with Smith & Nephew in the development of novel, cell-based therapies for osteoarthritis. In addition to this support from Smith & Nephew, we acknowledge the critical support that Science Foundation Ireland has provided in the initial establishment of Remedi and the funding now provided by IDA, which will allow us to expand our efforts in developing a new generation of arthritis therapies."

Murphy said: "The proven ability of the Irish development agencies, such as IDA, Enterprise Ireland, SFI, IRCSET [Irish Research Council for Science, Engineering and Technology] and HRB [Health Research Board] to work in partnership with the university research sector and industry organisations such as IMDA and IRCSET is, I believe, unrivalled in any economy in the world.

"This is what sets Ireland apart and is a very valuable competitive advantage. Through the seamless interaction between the stakeholders, we can generate and share intelligence about the med tech sector, collaborate on a joint strategy to further develop the sector, attract the best graduates and post-graduates, and position Ireland, not only as the centre for European med tech clusters, but as the global centre," Murphy said.

While Ireland's medical devices and diagnostics sector compares reasonably well in innovation, R&D and commercialisation, compared with countries equivalent in size and population, being good enough is not acceptable in this strategically important sector, according to Murphy.

She believes that a quantum shift is required to elevate the sector. "We need to develop capacity to design, develop, patent, manufacture, commercialise, licence and export new cutting-edge products and processes."

Murphy said the establishment of a national centre for medical devices and diagnos-

tics, research, development and technology transfer, directed by industry representatives, would be of strategic importance. It would attract international companies to engage with the sector in Ireland and with agencies such as SFI.

Currently, Georgia Technology Ireland works with leading universities, companies and clinicians to design, develop and prototype technologies. It is concentrating at present on developing new products and services with companies using radio frequency identification (RFID) and internet protocol TV (IPTV) technologies.

Its RFID test bed is developing asset tracking solutions for medical device and pharmaceutical companies as well as patient monitoring solutions. Companies in the manufacturing sector are looking to develop automated supply chain management (SCM) solutions and the maturity of RF technology has led medical device manufacturers to start developing new products, for example, wireless sensor-enabled interventional devices.

Its IPTV programme is working with companies to develop secure telemedicine services for healthcare service providers, clinicians and patients, for example, in remote medicine and community care. "In healthcare, the potential is enormous, particularly where clinicians are under immense time pressures in seeing, treating and caring for their patients," said Dolan.

Another organisation work-

ing with companies on R&D projects is the Applied Optics Group (AOG). According to Chris Dainty, director of AOG, the group conducts basic research in applicable areas in optics, covering a range of areas, including vision science, imaging and communications. In the past two years, it has established significant links with 29 companies, 18 of which are in Ireland.

"We focus on innovative, high-risk projects that really move the commercial opportunities forward. We are working with an eye-care company on a next-generation intra-ocular lens – used in cataract surgery – that could provide the elderly with the best eyesight of their whole life, correcting the imperfections of their natural eye," Dainty said.

"We are working with an ophthalmic instrumentation company to develop the next generation of wide-field fundus cameras for examining the health of the retina; and with a Japanese multinational on a new form of high resolution microscopy. Several other industry-motivated projects are also in the pipeline."

AOG projects with industry may involve the participation of advanced researchers or PhD students. "The PhD student route, facilitated by IRCSET, is a particularly attractive way for companies to work with us on a low-cost basis. The advantage for the company is as much about the relationship developed with us, as the detailed project itself."

Healthy future for Irish firms

Supplying the global demand for orthopaedics

DePuy's supply chain centre in Cork coordinates the manufacturing and supply chain operations for the J&J orthopaedics business globally

One of Ireland's biggest attractions for global medical device companies is a workforce that understands the quality requirements for manufacturing products to sufficiently high standards for implanting in the human body.

"We need to consistently be delivering quality standards," said Sylvia Fouhy, vice-president of supply chain for DePuy, Johnson & Johnson's [J&J] orthopaedics division.

"We've got over 600 people at DePuy's Cork facility, where we have sought to develop manufacturing excellence by adopting lean techniques," Fouhy said. "We've had to do that because of cost pressures."

As medical device companies seek to move up the value chain in terms of innovations in advanced manufacturing techniques, she said companies were looking for access to higher calibre graduates.

Linkage programmes with Irish universities and government agencies play a vital role. "Access to R&D grants and expertise within universities as well as government support is critical," she said.

As the medical devices sector has grown in Ireland, there has been growth in the number

of smaller indigenous suppliers to the multinationals in the areas of tooling, polishing and coating of medical devices.

"We now have a sound second-tier supplier base that can be used to support the manufacturing operations of multinationals," Fouhy said.

Several factors influenced J&J's decision to locate its global supply chain centre in Ireland.

The company originally set up a manufacturing plant in Cork in 1997, and its excellent track record over the years established its credentials as an acknowledged base with a high degree of competence.

"It made a lot of sense to build on the existing infrastructure in Ireland. The company had a high degree of confidence that we could deliver results and attract the high calibre of people needed to run a successful, global supply chain organisation," Fouhy said.

"Our geographic location between the US and Europe and the rest of the world was also very favourable in terms of pulling the business together.

"Government incentives in the areas of R&D and innovation were also key factors, to-



Sylvia Fouhy, vice-president of supply chain for DePuy

gether with a favourable tax regime on non-manufacturing profits."

Compared with other locations, Ireland rates well in the areas of cost, tax and innovation, according to Fouhy. "We compare quite well although, without doubt, we have seen increased costs being an issue. However, J & J has tackled that head on with the introduction of lean manufacturing and automation," she said.

"We have developed rela-

tionships with a number of universities in Ireland [notably the University of Limerick and University College Cork] to help us with this, and these relationships have been key to our success.

"From a tax perspective, while we're not the lowest tax regime in the world, we do compare favourably, particularly when you take into account other factors such as the protection of intellectual property and a sound legal system."



DePuy's site in Cork

Other plus factors include the quality of the workforce in Ireland and the similarity of culture and language.

"From an R&D and innovation perspective, I think we've come a long way over the last number of years. However, on a recent visit to China, I was hugely impressed by the level of government support for high-tech companies in their incubation stages and also by the level of investment in R&D generally. This is an area where we need continued focus in Ireland," said Fouhy.

DePuy's global supply chain centre in Cork coordinates the manufacturing and supply chain operations for the J&J orthopaedics business worth more than \$5 billion annually.

"A key aspect of our business is the worldwide strategic sourcing of materials for both the manufacturing plant and for the instrument sets that are used in surgeries for implanting our hip or knee products.

"Another aspect is the demand and supply management of products to market. We coordinate the worldwide demand for our products and ensure the cost-efficient supply of these products to market."

The centre manages J&J's orthopaedic inventory on a global basis. "We own and manage inventory in hospitals worldwide. The centre in Cork is also responsible for DePuy's worldwide distribution strategy and for configuring the network to ensure delivery of products to market as quickly and efficiently as possible," Fouhy said.

"As the supply chain activities for DePuy's multi-billion dollar business, located in more than 40 countries, are coordinated in one place, this gives us visibility to drive efficiencies and improvements in the way we run the organisation, particularly in reducing costs."

The implementation of lean

manufacturing processes is paying dividends, according to Fouhy. And in the area of new product development, bringing a product from its R&D stage through to the manufacturing stage, the company is embracing new technologies.

"We bring technical and business expertise to a whole host of areas, from supply chain management and finance to quality, engineering, manufacturing and R&D," Fouhy said.

"Our job is to add value to the J&J/DePuy organisation and we do that through our expertise and our ability to give the organisation what it needs to be successful globally, namely getting high quality products to market as efficiently and effectively as possible."

In 2008, DePuy established an innovation centre in Cork with the support of the IDA. The innovation centre focuses on two areas, namely product development and transformation process development.

"This is a centre of excellence for product development, metallurgical science, process development, automation and process control," Fouhy said.

This year, the company has also launched a multi-million euro investment in both buildings and capital to create modern offices in Cork for its global supply chain operations, as well as to continue investing in automation.

According to Fouhy, continued support by the Irish government is key. "We need continued R&D investments

and expansion of our linkage programmes with universities."

She said the increased cost issue also needed to be addressed in innovative ways to bring down costs. For example, the cost of energy is an issue that could be addressed by research into alternative energy sources including wind generation.

"We need continued government support. We also need continued partnership with the IMDA and better collaboration between medical device companies across the sector."

Fouhy predicts more convergence between sectors. Products such as the anti-infective, drug-coated hip implant (where the pharma company produces the drug coating) requires close collaboration between medical device and pharmaceutical companies.

"From a J&J perspective, our presence in Ireland forms a unique opportunity in that we can partner with sister J&J companies, for example Janssen Pharmaceutical and Centocor Biologicals in Cork and Cordis, our stent manufacturing division in Cashel," she said.

At the other end of the spectrum is growth in demand for medical devices from the key emerging markets of the BRIC region: Brazil, Russia, India and China.

"Products for these markets need to be sold at significantly lower prices, so cost pressures will continue to apply," Fouhy said.

Medical Technology

Irish firms attack the global market

Ireland is fertile ground for a growing number of indigenous diagnostics companies, writes **Dermot Corrigan**

Medical devices entrepreneur Cormac Kilty, former chief executive and founder of Biotrin, which was sold in July to Italian firm Diasorin for €25 million, said he had high aspirations for his new independent venture Argutus Medical.

"Argutus Medical has the potential to be as big as Biotrin," Kilty said. "We are doing R&D at the moment, but in the last 12 months we have done about €1.6 million in sales. We are spending over €600,000 a year in R&D. We will probably look for a larger round of funding next year, but at the moment we are well funded by my own capital injection and Enterprise Ireland."

Argutus Medical is focused on the acute kidney injury market, Kilty said.

"We have developed the world's first acute kidney injury test, which is an immunochemical test that can be done in urine," he said. "There is very big potential for that in a number of areas. Our present business focus is primarily on selling liver and kidney tests to the pharmaceutical industry."

"Our growth potential is in selling those tests, and developing new ones, in the human clinic. That means people being monitored in hospital. We are particularly looking to monitor patients with acute kidney injury post-coronary bypass."

Kilty said that Argutus, which has 13 staff, had developed technology that could locate markers in different sites within the kidney.

"Different diseases and different drug compounds damage different parts of the kidney," he said. "We can pick up kidney damage weeks in advance of what is being used today."

"The pharmaceutical companies are using these markers to monitor volunteers in phase one, two and three trials. That is great validation for us, as they know it works and are willing to pay real money for it."

Argutus conducted research

in association with educational institutes and research centres both inside and outside of Ireland, Kilty said. He said that it would continue working with partners to grow its business.

"In three years' time, we expect to be the world's leading kidney diagnostic company, with sales of more than €6 million," he said. "But, more importantly, we should have completed our development of this unique kidney detection technology and have done a number of licensing deals to multinationals with the distribution networks to get our tests to patients worldwide."

Developing world markets

Another company with designs on future expansion is Cork-based Audit Diagnostics. Its managing director, Michael O'Donovan, addressed last month's Irish Medical Devices Association CEO Forum, with a presentation entitled How Irish Companies are Delivering Diagnostics Globally.

"It is all about building up relationships in these countries, making sure that the head people go there, and that you go there for the long haul, not for a quick buck," said O'Donovan. "There is a long timeframe for the establishment of relationships and markets. You have to go there again and again. It is worth it though, as the payoff is immense."

O'Donovan, also an IMDA board member, said Audit Diagnostics had distribution partners on four continents. "We are targeting developing markets, including China, India, Africa and South America," O'Donovan said. "China is our fastest growing market, and we have six people working on the ground there."

O'Donovan said that Enterprise Ireland's work was key to helping smaller Irish companies to connect with customers in these countries.

"Enterprise Ireland trade missions have been probably the greatest source of business we have had," he said. "To be able to finalise contracts with



Michael O'Donovan, managing director, Audit Diagnostics: 'There is a long timeframe for the establishment of relationships and markets'

the prime minister or president of your country there on the spot really helps to attract customers."

Audit Diagnostics' recent research work has been around new patient point of care testing, O'Donovan said.

"We want to get away from the idea of having to go to a hospital for every single thing," he said. "We have recently launched our own patient testing system, which is the first of its kind in the world. You can now do all the diagnostic testing in a remote clinic anywhere using a briefcase-sized mobile lab, and have the results in two to four minutes."

O'Donovan said there was also a significant market for the product closer to home. "In the developed world,

GPs can screen the blood there and then, instead of having to wait a week to get results back from a hospital lab," he said.

All the company's product development and manufacturing is done in-house, according to O'Donovan.

"We started with a two-person operation in 1993 making four products for the Irish market," he said. "We now employ 54 people and have approximately 400 products."

The company still retains a strong R&D and product development focus. O'Donovan said that Audit Diagnostics had also recently developed an innovative hospital hygiene product called Sterl Stat.

"It kills all hospital-acquired infections, such as the MRSA vomiting bug," he said. "All

'In the last year, we have gained markets all over the world'

products up to now have been alcohol-based, but they only kill for about two minutes. Once the alcohol evaporates, the effectiveness is gone.

"Our product will kill everything within one minute. There have been extensive evaluations done in the US and Britain to show that this technology works far better than any chemical or alcohol treatment. In the last year, we have gained markets all over the world."

Engineering genetics

Discovery, rather than diagnostics, is the real starting point of the medical devices sector, according to Mark Davies, director of Limerick company Stokes Bio.

"We are not a diagnostics company, because diagnostics comes after discovery," he said.

"First of all, you have to discover what changes in DNA put people at risk, or signify a disease. That is what we do."

Stokes Bio's work is in microfluidics-based systems for genetic analysis, particularly for the measurement of gene expression and gene target detection. The systems will be used in basic life science research and in the molecular diagnosis of cancers, pathogen detection and pharma-genomics.

The company was established by Davies and fellow director Tara Dalton, commercialising technology that they had been developing at the University of Limerick's Stokes Research Institute. A catalyst for the original research work was the publica-



Dr Cormac Kilty, Argutus Medical

tion of the human genome, said Davies.

"Tara and I are engineers, not molecular biologists," he said. "We started to look at interesting things that we could do with applying engineering to the things that were going to come out of the human genome. In 2005, we were approached by Kernel Venture Capital, which said it would be interested in making a €1 million VC investment to launch a company out of what we were doing."

The university gave its blessing for Davies and Dalton to take their work into the business world.

"We set up the company with the full support of the University of Limerick, which took a 10 per cent equity stake in the company," he said.

The company employs 15 staff, ten of whom have PhDs, and has spent approximately €3 million thus far. Davies said that Stokes Bio's innovation was in combining its founders' engineering background with a medical discovery focus.

"A lot of bench-top science has been done," he said. "What is lacking is engineering systems that produce vast amounts of data at very low cost, and that is what we do. That means you can afford to go and do discovery work, and subsequently health providers can afford to do diagnostics work."

Davies said that Stokes Bio was nearing the point when sales would commence.

"We are a little bit early to do marketing work, but we are in discussions with customers now for sales," he said. "We have already worked with collaborators to put early prototypes into laboratories. We would expect some interesting things to go to sale in the near future. We expect our first complete product launch to take place at the end of 2010."

Building strong bonds in the scientific sector

Linkages between research institutions and the med tech industry are strengthening, writes **Eibhir Mulqueen**

Ireland is at an exciting point in its development of scientific research commitments and its transferring of them to a commercial capability. According to Stephen Simpson, director of life sciences at Science Foundation Ireland (SFI), the establishment of SFI since 2000 has marked a new era in research and development, and the engagement of industry with research institutions.

Over the past eight years, Simpson said, Ireland had become a strong backer of developing world-class research and its subsequent engagement with industry to power the knowledge economy.

"Ireland has always had the strength, in that we have a large number of industrial players here. In a sense it has been ready to go. I think it is as important for the medical technology sector as much as any other sector," he said.

Simpson cited the example of the Biomedical Diagnostics Institute, established at Dublin City University three years ago, as one which is doing groundbreaking research in the development of next-generation diagnostic devices.

"It is all about bio-sensors and point-of-care for patients and taking away the need for expensive diagnostics in a hos-

pital and bringing it home. "That is a good example in the medical technology area, where we have physicists, biologists and chemists working on a new initiative with industry and generating some interesting technology."

SFI has responsibility for investing €1.4 billion allocated for scientific research under the National Development Plan 2007-2013.

"SFI had a budget of €179 million for 2008. That funding is going to existing commitments at SFI, to researchers who have ongoing research, and some of it will go to new researchers this year."

There are about 300 scientists being funded by SFI in "the higher-education institutions across Ireland".

SFI has two core programmes that encourage academic-industry collaboration: the Strategic Research Clusters (SRC) one – which helps develop partnerships between scientists and engineers in academia and industry – and the Centres for Science, Engineering & Technology (CSET) programme, which focuses on developing research centres in third-level institutions such as DCU's Biomedical Diagnostics Institute.

"Across our portfolio we have about 80 companies en-



Stephen Simpson, life sciences director, Science Foundation Ireland

gaged with SFI-funded researchers through the CSET and SRC programmes," he said.

"These are collaborative efforts, and most are strongly engaged with industry and other groups around the country. Their opportunity is stronger as a group than they might be as individuals."

At present, there are nine CSET centres, with approxi-

mately 40 industrial partners. "CSETs are an expanding part of our programme," Simpson said.

He added, however, that there was a range of other programmes across a spectrum, extending from the funding of new researchers to recruiting professors to Ireland to some of the CSET projects.

Paul Roben, director of bio-

technology commercialisation at Enterprise Ireland, said he agreed that the linkages between research institutions and industry were improving. He cited an internal survey which noted that 60 per cent of researchers said they had strong links with industry.

"The annual spend on research is about €1.2 billion across the country," said Roben. "We came from a fairly low base five or six years ago,



Paul Roben, Enterprise Ireland

in terms of research funding.

"Three years ago, Enterprise Ireland earmarked €30 million to support the Technology Transfer System. That pays for people in third-level institutions involved in the production of intellectual property and the transfer of that intellectual property to industry. Now, we have a system where we have researchers doing research and a way to transfer that out to industry," said Roben.

At company level, there are also many instances of firms being funded through the Enterprise Partnership Programmes to develop research programmes in conjunction with third-level institutions. There is also evidence of increased cross-party funding of research into such areas as biotechnology, industrial technologies and applied food science.

The healthcare sector remains one of the most exciting areas where research is being

carried out.

According to Enda Connolly, chief executive of the Health Research Board, the statutory agency that supports and funds health research, €200 million is being invested to develop infrastructure, build capacity and nurture innovation in health research to improve patient care.

"We have invested €54 million to develop clinical research facilities in the grounds of hospitals in Galway, Cork and Dublin, where this can be made a reality," said Connolly. "These facilities are the interface between the research discovery and delivery of care."

These facilities provide the opportunity for research to be developed in line with patient care and people are given the opportunity to participate in world-class clinical trials.

"An additional €56 million is invested to develop health professionals' skills and ability to conduct research and translate this into better care for patients."

Dublin-based consultant Jim Egan said he believed that the new consultants' contract should be amended to allow for research and development.

Egan, a consultant respiratory physician at the Mater Hospital, said advancing R&D in medical devices was an important step forward as Ireland Inc sought to develop its industry.

"For the 25,000 people employed in the industry it is important – and this is a global competitive environment," he said. Egan added that ethics committees needed to be professionalised and medical de-

vice trials distinguished from pharmaceutical studies.

"Most of the industry-type work that happens in hospitals are studies with drugs. Medical devices are completely different," Egan said.

But he said that, as with new drugs, when it came to medical device product development, companies needed access to patients to conduct trials.

"This is a win-win situation here because exposing patients to the latest technology advances has clear benefits for the patient."

"Furthermore we know that patients who participate in studies in general do better than they do by going to their local hospital and getting the standard treatment."

This view was echoed by Derek Young at the Royal College of Surgeons in Ireland (RCSI). As head of the college's Surgical Innovation Centre, he said one of the biggest problems in the medical device industry was that those who developed medical devices did so in isolation from the surgeons and clinicians who used them.

"The potential to have a forum whereby surgeons, innovators and device manufacturers work in harmony would be of enormous benefit."

He said the SME sector and large multinationals required greater support for clinical evaluation, training development and product design review.

"Development of such a link would position RCSI and the medical device sector at the forefront of surgical technology and surgical practice for the future," Young said.

Medical Technology



Helen Ryan, Creganna; Alex Ingle, IBM; and John O'Dea, Crospon at the Meeting of Minds conference on convergence, hosted by Ibec and Enterprise Ireland



BiancaMed's Baby Monitor, which monitors the quality of a baby's sleep



Dr. Conor Hanley, co-founder and chief executive of NovaUCD-based BiancaMed

A new era for healthcare

The convergence of several independent technology streams is creating new opportunities for medical companies, writes **Caroline Allen**

The day when a patient can log on to their interactive television and have a consultation with their GP from their own living room, aided by sensors in the home, is not far off, according to Stephen Cross, executive director of Georgia Tech Ireland, which works with organisations such as Medtronic, Boston Scientific and Crospon.

"In ICT we have had a lot of success in improving manufacturing processes, improving efficiency, decreasing errors and enhancing quality of service overall," said Cross. "This is now being done in healthcare. It does not replace the experience or knowledge of the healthcare professional but it should improve diagnosis and treatment."

In November, Intel Corporation announced the Intel Health Guide, a care management tool designed for healthcare professionals who treat patients with chronic conditions. It represents Intel's entry into a new category of personal health systems that go beyond the simple remote patient monitoring systems currently available.

The regulated device that carries the CE mark under the EU Medical Device Directive, is a comprehensive personal health system that combines an in-home patient device as well as an online interface, allowing clinicians to monitor patients in their homes and manage care remotely.

Initial chronic diseases being focused on are diabetes,

congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD).
Conor Hanley, chief executive of BiancaMed, a spin-out company from UCD's School of Electrical, Electronic and Mechanical Engineering – located at NovaUCD, the Innovation and Technology Transfer Centre at UCD – said the trend of people living longer and spending more on healthcare had resulted in a need to transfer from reactive central healthcare to a focus on proactive personal well-being.

"The intersection between IT and medical devices and clinicians' input is a very exciting area," said Hanley, whose company develops products and services to measure sleep and breathing in the home. Its technology can measure breathing and sleeping without contact with a person, so they do not have to wear any sensors or devices on their body.

"Our technology platform combines our small, sensitive non-contact biomonition sensor – which can be placed on the bedside table of an individual and detect their heartbeat and respiration while they sleep without ever having to touch them – with our own unique software algorithms, which convert the raw heartbeat and respiration signals from the sensor into meaningful data on the quality of the person's sleep."

"This combination allows for an accurate measurement of sleep quality to be collected effectively and efficiently in the person's own home and

with zero intrusion on the quality of sleep," said Hanley.

The time is right for this convergence of ICT and healthcare because communication is so much more pervasive and convenient, Hanley said.

Technology convergence is an exciting development, best described as a mélange of several technologies from a variety of different technology areas, according to Pat Duane, senior director of R&D at Medtronic, a global leader in medical technology that has been in Ireland since 1999, when it acquired the CR Bard operation set up here in 1982.

More than 2,000 people are employed by Medtronic in this country, with most working at the company's modern Galway facility.

An example of convergence, Duane said, includes combining implantable devices and pharma with this confluence already evident through products like drug-coated stents and other drug-coated devices.

"Combining implantables and biologics sees the use of devices such as catheters and stents to deliver biologics including cells and genes to help regenerate damaged or dead tissue."

Duane said that the convergence of medical technologies and IT had created a whole new technology space called bioinformatics. This entails the development of highly sophisticated data collection and analysis systems, which communicate with implantable devices to collect data on specific patients, facilitating remote



Medtronic's research & development lab in Galway. Below: the company's drug eluting stent



patient monitoring and management.

"Global demographics indicate that people are living longer. For example, a baby girl born in Japan today has a 50 per cent chance of living to 100 years of age. This increase in life expectancy creates new and exciting challenges for companies like Medtronic that are driven by their mission to apply biomedical engineering for the treatment of chronic diseases," said Duane.

"Many of our current devices are 'dumb'. By placing nano-sized sensors on the devices we can improve our understanding of the disease and therefore its treatment."

"Once we have the knowledge, we need to get better at local site-specific delivery and the latest technology in robotics and navigation will help us to do this," Duane said.

The convergence of these independent technology areas is creating significant business

opportunities. "As we move towards ever more sophisticated therapies and convergent areas, it is imperative we develop the skill sets necessary to cross the borders between science, engineering, information technologies and medicine," he said.

Academia has a huge part to play, in the provision of research collaborators as well as knowledge generators and educators, according to Duane. "Innovation through collaboration will be the key to our success."

The global market potential will depend on the technology area. However, Duane said the numbers would be significant.

"As an example, the commercialised drug-coated stent convergence created a circa \$5 billion market for a single device. This is just the tip of the iceberg, a real example of the market that could materialise for the convergence of known technologies."

Ireland, Duane said, is extremely well positioned to take advantage of these technology trends. "The great news is that we have already recognised this."

Industry, academia, clinicians, state-funded bodies and industry lobby groups such as the IMDA and the American Chamber of Commerce are among the consortia likely to participate in this convergence activity, Duane said.

One of the biggest challenges, he believes, will be creating an environment of trust between independent companies that will foster collaboration and its offspring – convergence.

The impact on regulatory groups will be significant as the early engagement of these groups will be critical for the early and successful commercialisation of therapies and products, Duane said.

"The strong recent history of convergence with drug and device combination products has given rise to regulatory challenges with many combination products having to go through a drug approval route as well as a device route," said John O'Dea, chief executive of Crospon, which develops leading edge minimally invasive medical devices for monitoring, diagnosis and therapy in endocrinology and gastroenterology.

"The regulatory arena in Europe and the US has improved but will continue to present challenges that will need to be addressed," he said.

Capitalising on some of the knowledge developed in the gaming software industry by major players such as Havoc could have interesting implications for medical imaging, according to O'Dea.

"Interventions such as putting catheters down arteries or employing stents, integrating sensors and graphics in the way gaming consoles do could have very interesting potential applications, for example in guiding catheters down the body," said O'Dea.

"If we could knit those together, it could offer great opportunities and is a good example of convergence in IT and medical technology," he said. "We have great gaming software capabilities in this country and harnessing that in medical imaging could offer some intriguing possibilities."

In September 2007, Galway-based Crospon and HP attracted global attention when they entered into a licensing agreement for a drug delivery platform that enables painless controlled release of one or more drugs in a single patch applied to the skin.

Under the agreement, HP licensed its intellectual property to Crospon in return for roy-

alty payments. Crospon is in the early R&D phases of developing the patch, which was invented by HP Labs, the company's central research facility, and plans to make it available to pharmaceutical companies to use in various therapeutic areas.

Ireland has a unique opportunity to take advantage of its position as a base for all the leading IT manufacturers, along with more than half of the 25 top medical device companies in the world, O'Dea said.

He believes the proximity between the IT and medical device sectors could be harnessed here with Ireland playing a key role in the emerging technological space. "From an Irish standpoint, if multinationals were looking to move into the converged medical devices space, they may look more favourably on Ireland because of the close proximity between medical devices and the IT sector here," he said.

One factor that could help oil the wheels of the convergence process, according to O'Dea, would be the establishment of an Enterprise Ireland competence centre.

"Within the island of Ireland we have all the necessary skills as well as very strong IT, medical device and pharmaceutical sectors, so it is more a matter of how everything is pieced together. We have all the core competencies for the different pieces of the jigsaw," said O'Dea.

However, if convergence took off, it may become common for people to take a primary degree in one discipline and a Master's degree in another.

"Science Foundation Ireland C-SETS could potentially serve as breeding grounds for the development of multidisciplinary products," he said.

Medical firm reaps reward for shared services centre

By Margaret O'Brien

Leading medical device firms competed for recognition in the development of products and services at the recent Irish Medical Devices Association (IMDA) annual awards in Dromoland Castle, Co. Clare.

There were five award categories and the gold award for the Shared Service Category went to Cook Medical, for its

success in establishing its European Shared Services Centre (SSC) in Limerick.

Cook Medical integrates minimally invasive medical device design, biopharma, gene and cell therapy and biotech to enhance patient care. Cook Medical products are used in more than 135 countries throughout the world, and the company employs about 7,000 people globally, with the Limerick plant accounting for 480 jobs.

The SSC accounts for 160 of

the 480 jobs at the Limerick facility and has paved the way for similar models of shared service centres to be established elsewhere in the world.

It has allowed management at Cook Ireland to establish the Irish facility as a key location in the global infrastructure of Cook Medical, the largest private medical device firm in the world, and further reinforces Limerick as a flexible and innovative location.

Conor Cronin, marketing communications manager, ex-

plained the background to the SSC. "The 160 members of staff in our SSC are employed across a range of services, which include marketing communication, HR, customer services, tenders, pricing, IT and certain financial functions."

The SSC in Limerick is a pioneer in the medical devices sector. According to Cronin: "The work carried out in our SSC feeds back into Cook Medical globally. It is the first such base for Cook, which is now looking to set up similar

bases in Asia and North America, based on the success of the Limerick model.

"The fact we are English-speaking, and are culturally close to the United States, together with our highly educated workforce, were key factors for Cook when choosing Limerick as the site for its first SSC. We also offer the benefit of attracting highly educated people from outside Ireland, albeit for short periods, which is also a plus as they bring fresh skills."

Fifteen languages are spoken fluently among staff at the SSC. "Language skills and excellent education are important factors because staff interact with customers, who are physicians working in hospitals worldwide.

"A strong culture of training and progression in the company also ensures staff are well equipped to communicate with customers. The SSC allows us provide a consistently high level of service and also allows us leverage to achieve

efficiencies across the company, all of which benefits the customer and ultimately the patient," said Cronin.

SSC staff members are delighted to have won the IMDA award for excellence in the shared service category this year, one of the four award categories. "The awards are a good indicator of best practice in the med tech sector in Ireland and, as such, we were proud to win the shared services category," said Cronin.

Bill Doherty, managing di-

rector of Cook Medical, said the firm had employees from 24 different countries, "who have transformed our business and have helped develop a truly multilingual and multicultural working environment."

"The SSC model has allowed us to ensure the same high level of support and quality of service to customers throughout Europe and means that we can deliver the most innovative medical technology and devices to patients, wherever they are located."

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Irish workers have top quality skills

The demand for more complex skills has prompted the evolution of training programmes, writes **Éibhir Mulqueen**

A critical aspect of the medical technology sector's success is the people who work in it. At all levels, specific skills are required to turn around products that rely, above all, on their efficiency and safety before being accepted in the marketplace.

The skills sets required go from manufacturing level to product research and design, through to management and leadership. Baxter Healthcare in Co Mayo has long experience of sourcing skills needs, having originally set up in 1972 as a manufacturing plant.

Pat Gallagher, general manager of the Castlebar-based plant, said he hired at all levels but that the firm also ran a graduate development programme. The price of success is that he has lost people at higher levels after they got promoted within the Zurich-headquartered corporation to one of the other 16 manufacturing plants in Europe. "The Irish are boxing above their weight in terms of the key positions they occupy," he said.

He puts this phenomenon down to not just a skills set built up through the education system, in-house training and a wider industry that produces a savvy workforce, but also a "can do" attitude that many key personnel display.

"They do whatever it takes to make it a success and bring it within the timelines," he said. "I think the Irish are very eager to develop themselves and their abilities, maybe more so than other nationalities."

Baxter employs more than 1,000 people in Castlebar, the vast majority of whom live within a 15-mile radius but who are attracted to the area from Galway, Sligo and further afield. "There is absolutely no problem finding the right skills set and people wanting to live in Mayo. We found over the last ten years that people who came back to Ireland and were from this area came to this company."

A variety of technology skills is needed at the plant, with employees being drawn from engineering, electronics and

computing backgrounds. However, a cluster of medical technology companies in the region and a strong pharma presence helps in the creation of a workforce accustomed to the stringent demands of the healthcare industry.

"The particular regulatory environment and, to a lesser extent, the quality environment is a little bit unique to the medical industry," Gallagher said.

However, as the industry overall has developed, the demand for more complex skills has prompted the development of dedicated training programmes.

In November 2007, following an intensive engagement by a cross divisional team from IDA and Enterprise Ireland, Baxter announced a major transformation, including a €75 million-plus investment in new technologies, processes and significant up-skilling.

"Working with long-established clients such as Baxter, IDA particularly focuses on assisting them to completely transform their operations and so position them for growing their Irish operations further in the future," said Richard Hendron, manager of IDA's medical technology division.

Leadership development across the industry is another key thrust. "To lead a modern, growing, internationalising company, what becomes quite critical is the leader," said Tom Kelly, manager for the environment, industrial and life sciences division of Enterprise Ireland.

"We want to identify the leaders in particular companies and we get them to work with the best leaders in the world through participation in international programmes."

He added that leaders tended to emerge naturally through the start-up process so training programmes were aimed at expanding their capabilities. "It is exposure to the best thinking and to their peers and enabling them to work within that kind of milieu."

He said that formal training measures had also been introduced to upskill personnel at other levels within the industry.

"Building the leadership capability, confidence and



Participants on the Leadership 4 Growth programme at Stanford University, which caters for chief executives in the technology and life sciences sectors



Sharon Higgins, director of the Irish Medical Devices Association; Liam Hynes, plant manager; and Lorraine Nicholson, QA analyst, Covidien Athlone

know-how to successfully grow companies of significant international scale is critical for the medical devices sector," said Liam O'Donoghue, Enterprise Ireland's head of leadership development.

Two successful programmes have been designed in recent years in collaboration with Enterprise Ireland, companies in the sector and education partners.

"The first of these, Leadership 4 Growth, is delivered in conjunction with Stanford University and is aimed at the chief executives in the software and life sciences sectors. In March 2009 the programme will go into its third year," O'Donoghue said.

The programme focuses on ambitious chief executives and their senior teams seeking to develop their start-ups to global competitor stage. Developed in partnership with the Irish Software Association, it is delivered by Stanford Graduate School of Business over three five-day modules in the US. O'Donoghue said another focus area was the sales capability of export-focused com-

panies, for which an international selling programme has been designed by Dublin Institute of Technology (DIT).

"This results in sharper value propositions to clients, well-grounded sales processes and systems to support different customers in different markets and a strong ability to manage channel partners."

The international selling programme will be run at least three times next year with up to 90 companies involved.

IMDA Skillnet

Pauline O'Flanagan is network manager for the Irish Medical Device Association's (IMDA) Manufacturing Excellence Skillnet, a training programme she describes as novel.

She points out that foreign direct investors expect access to a pool of labour with specific skills and specialist knowledge of the med tech industry.

But many of the inputs into the industry are no longer cost-competitive and the

Building the leadership capability, confidence and know-how to successfully grow companies of significant international scale is critical for the medical devices sector



Pat Gallagher, general manager, Baxter Healthcare



Liam O'Donoghue

IMDA programme is aimed at increasing competitiveness by upskilling and certifying operators.

O'Flanagan said the elimination of waste and finding more efficient ways to do business were a priority for the medical devices and diagnostics industry.

"The Skillnets programme is focused on educating and transferring knowledge across

the sector to support the manufacturing function through operational excellence," she said.

The vast majority of people employed in the industry remain in the manufacturing sector, making the advancing of operator skills a key element in the IMDA's education and knowledge strategy.

Personnel in manufacturing are targeted with training tailored to the needs of the sector.

"Training is facilitated through shared learning, which helps to reduce costs and encourage companies to communicate amongst themselves in order to benefit from the knowledge that is present across the sector," said O'Flanagan.

With this new initiative, for the first time those working in the sector can take part in sector-specific training programmes, in a blended learning format, and they are assessed afterwards. Successful candidates are eligible to apply for level 5 Fetac certification.

The modules are delivered by trainers across multiple sites

simultaneously in two-hour sessions. This minimises the impact on day-to-day operations, said O'Flanagan.

"This system provides life-long training opportunities for trainees while also enabling companies to implement continuous improvement programmes across their organisations, reducing cost and improving efficiency dramatically."

By the programme's end, participating companies will have documented evidence of training and proof of competence, an essential requisite in the highly-regulated medical technology sector.

The programme currently consists of ten modules: core skills; health and safety; GMP/quality; environmental/communications; lean/six Sigma; overview; 5S; flow; error proofing; control of variances; TPM/ effectiveness; and sustaining progress.

IMDA hosts a job opportunities page on its website. Earlier this year, it launched the Imagine website to promote careers in the sector. See www.imda.ie/imagine.

Securing venture capital funding for life sciences

By **Éibhir Mulqueen**

Venture capital funding of start-ups in the life sciences area has taken off, with two specialist private companies now in the marketplace.

One, Seroba BioVentures, set up a €20 million fund in 2002, which it has now fully committed to eight companies. A partner in the company, Seamus O'Hara, said it was at an advanced stage with a new fund. "I think it will be a larger fund," he said.

Life sciences is a vibrant area but O'Hara said it needed specialists to provide essential backing at the early stages of company formation.

"Seroba was the first Irish venture capital fund dedicated to life sciences. We are a specialist in that area and we set up with that purpose."

O'Hara has a background in life sciences, having worked in Enterprise Ireland's bio division. "We are still investing in companies that continue to be working within my area of expertise. When you are dealing with technology companies that are still at the R&D stage, it is important that you understand that aspect of the business as well.

"It is a combination of technical, financial and even commercial skills that you have to bring to the equation."

He said he and his partners liked to see promoters who brought relevant product de-



Seamus O'Hara

velopment know-how, particularly if, in the past, they had combined that with business development or commercial experience.

"However, it is equally im-

portant that they have a high level of motivation and strong commitment to succeed."

His partners, Peter Sandys and Alan O'Connell, have backgrounds in finance and industry.

"We also have extensive networks internationally with experts in the areas in which we invest. Seroba has been active in the med tech sector to date and has invested in Irish start-ups such as Novate Medical, Biosensia and Crescent Diagnostics. This will continue to be a sector of high interest," O'Hara said.

Another of the companies, Seroba, has invested in AGI Therapeutics, which now has a listing on London's AIM. Another company they backed has been acquired by a US

buyer in a trade sale and O'Hara expects to be exiting from some of the others over the next few years.

"Typically, the venture capital funds are ten-year funds. Normally you are looking to commit over the first four to five years and then to realise all of the investment by the end of the ten-year period," he said.

The fund is usually backed through a combination of pension funds, corporate and government backing and sometimes equity from high net worth individuals.

Venture capital funds normally bring 100 per cent equity to the table, so there is no debt involved, unlike private equity, which might leverage up to 80 per cent of its fund as debt.

"Normally banks do not come into the mix in companies in which we are investing. They are pre-revenue. They are not operating off bank debt. They do not have the security that banks require. The money needed to develop those companies comes from venture capital, not banks.

This makes venture capital an important ingredient for start-ups, particularly in the med tech space, where product development is expensive but where "it also has to advance at an optimum pace since the first products to market capture most of the value."

"A good VC capital syndicate will make sure the company has the financial capacity to deliver on this goal. Specialist VCs will also bring knowl-

edge and know-how, increasing the chances that the right decisions are made at critical stages along the way," O'Hara added. Enterprise Ireland often co-invests in the projects they back.

"We would not see ourselves as competition. Often they would have invested at a seed funding stage, alongside the promoters of the project."

Enterprise Ireland invested €50 million in venture capital funds last year and is committed to investing €175 million up to 2012 under the Seed and Venture Capital Scheme.

It recently organised its first ever international investor forum. The event's focus was to promote linkages between Irish companies and large international investment houses

with the funds to bring technologies and products to market or through later stage clinical development.

Business propositions were presented by 20 leading Irish companies – 15 in life sciences and five in clean tech – to 66 senior representatives from 52 international investment houses from the US, Europe and Japan.

Brian O'Neill, manager of life sciences at Enterprise Ireland, said more than 120 partnering meetings were held between Irish companies and venture capitalists on the day.

"We actively support groups of Irish med tech companies in accessing international business in key global markets through group trade fairs," he said.