

# BEST BUSINESS

## LIFE SCIENCES 2010: PUTTING TECHNOLOGY TO WORK

# Positive outlook for medical devices sector

By Leslie Faughnan

There is simply no part of the business which is not dependent on ICT, according to Gerry McDonnell, chairman of the Irish Medical Devices Association (IMDA). It is crucial both for the effective performance of each corporation, and for innovation and progress in the sector, from product design to automated manufacturing to logistics.

McDonnell, vice-president and general manager of Stryker Orthopaedics, took over the chair of IMDA last month. The organisation represents 160 member companies which between them employ more than 24,000 staff, broadly the same as their pharmaceutical counterparts. Exports at over €6.8 million in 2009 represented a significant 9 per cent growth, while so many other sectors are languishing.

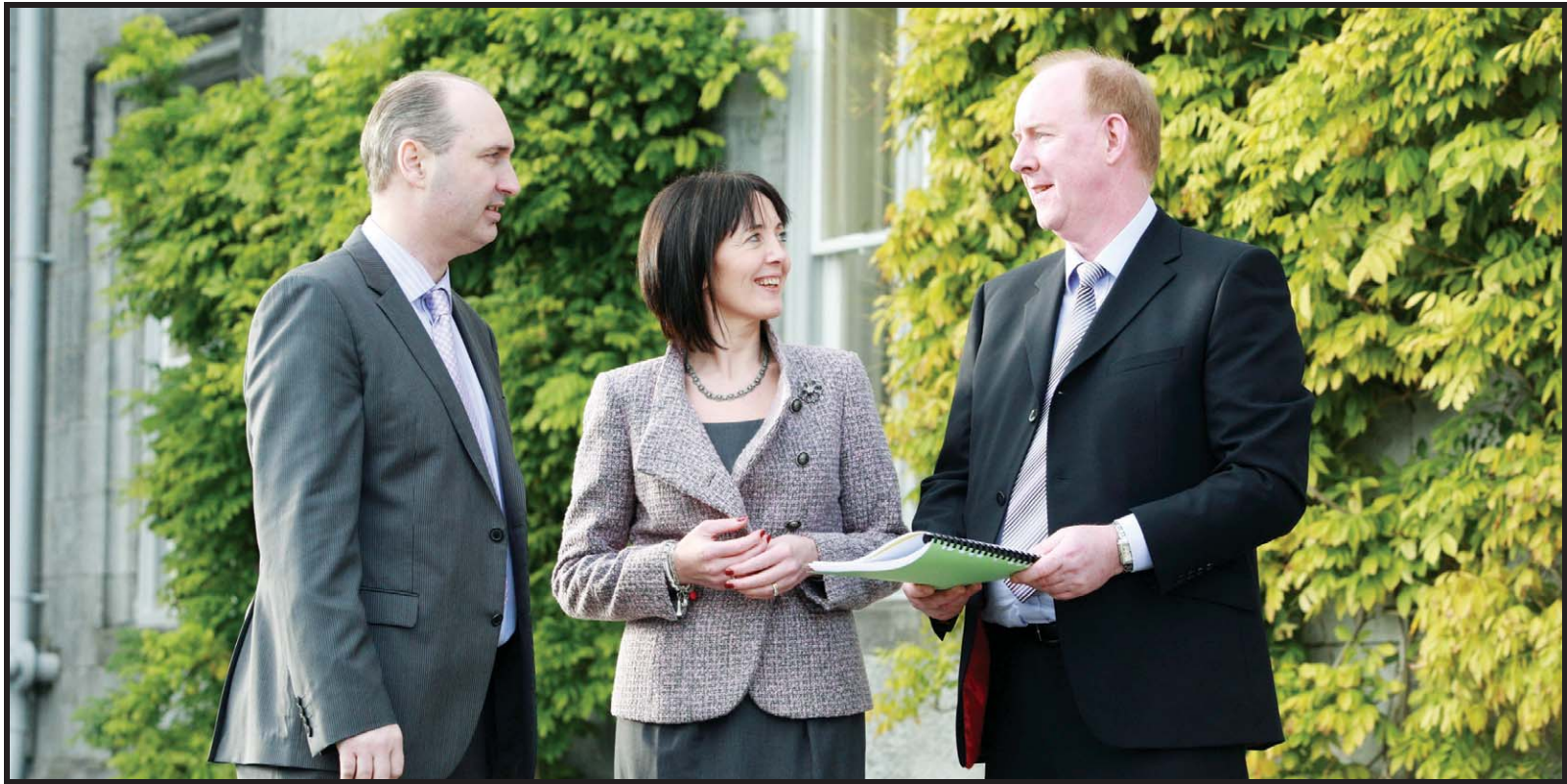
"The general picture for our sector is very positive," McDonnell said. "There have inevitably been some recessionary impacts but, globally, the focus is on innovation and new developments, while people with medical needs worldwide will prioritise whatever they can afford."

In Ireland, McDonnell said there was a strong and concerted movement towards a national 'Innovation Ireland' type of branding for the medical devices sector, led by IDA Ireland and Science Foundation Ireland, with the full support of IMDA and its members and the third-level educational sector.

"We have a significant manufacturing cluster here, with the presence of top global players in medical technology plus a growing indigenous component to keep the balance," he said. "We are well known within the sector worldwide, and the idea is to keep the impetus going by collaboration between all of the parties and sharing of resources to add strength."

A key element is the new set of initiatives at fourth level in graduate schools of medical engineering, with industry-academia collaboration in doctoral programmes in areas such as biomedical engineering and regenerative medicine.

"Continuing to develop a sustainable sector will depend on such initiatives," McDonnell said. "Ireland is on the cusp of becoming a key international hub for the medical devices sector, and partnership programmes like this are going



Gerry McDonnell, Sharon Higgins and Pat Gallagher, of the Irish Medical Devices Association

to help us make this happen."

He said government support was also critical, and welcomed the raising of the tax credit level for research and de-

velopment from 20 to 25 per cent.

"This is genuinely valuable and, while it is not a criticism, we would like to see it in some

way moved from a post-profit calculation to a top line benefit," he said. "In each case, the corporate finances will gain, which is of course a good

thing. But many of the investment decisions are made by R&D decision-makers who would more clearly see top line benefits such as the ability to

offset the credits against other taxation."

Regarding ICT investment and expertise, McDonnell said it was fundamental to the ex-

ension of the medical devices sector here into the next generation of manufacturing, as well as for key functions outside of production.

"In Stryker Orthopaedics, for example, we are moving towards automated manufacturing everywhere and specifically in Limerick, where we are investing \$40 million in a state-of-the-art, fully automated production facility. That will be central to production of our Triathlon partial knee implants, a key product line."

In the sector generally, there are ICT skills required across the complete range of activities, and extending the depth of the foreign and indigenous investment here will increase demand. "ICT is key to areas that are already seeing growth here, such as supply chain and logistics management, quality assurance, customer engagement and, of course, R&D," McDonnell said.

"We need to leverage our ICT skills in all of these areas and in others that are becoming more important, such as demand management, a natural complement to supply chain operations, newer disciplines like serialisation for product traceability, statistical process control and ever more demanding compliance issues."

# Qumas keeps focus on sustainable compliance

By Leslie Faughnan

With a busy office in the US, Cork-headquartered Qumas is one of Ireland's lesser-known indigenous software success stories. Qumas declared profits of more than \$2 million in 2009, its second successive year firmly in the black. Qumas is even a significant enough player in its market to have an annual global user conference, which is next scheduled for January in Florida.

Qumas, which employs 80 people, is now recognised as the doyen of the compliance software world by Gartner and other analysts. It identified a market niche in the mid-90s,

by helping enterprises in regulated industries to ensure their compliance. It started with a focus on pharmaceuticals, extending later to the full life sciences sector, including biotechnology and medical devices. Early in this decade Qumas added financial services solutions to its portfolio.

From the beginning, Qumas has aimed at providing sustainable compliance. "The key, core and essential element is a well-understood, consistent and easily executed methodology," said chief executive Kevin O'Leary. "We have developed key components to capture and understand the relevant regulations, and then work to the organisation's corporate objectives and internal

business processes in complying. It is the combination of the two that consistently ensures compliance."

*Qumas had profits of more than \$2 million in 2009*

Recent client acquisitions by Qumas include Eirgen Pharma and Takeda in Ireland, and Actavis and Basilea in Europe.

US multinational clients include Millennium, Vertex, Lantheus Medical Imaging, MedImmune and Hollister, which recently announced a significant expansion in Ireland.

"There has been some consolidation of software vendors in this broad field in recent years," O'Leary said, "in large measure because clients are seeking integrated enterprise solutions as with other enterprise applications. We have one client, for example, which had six different compliance systems, accumulated over some years and on different sites. It now has just two, with Qumas as the enterprise solution."

Qumas solutions have moved with the times technically; it offers clients the option of a hosted service and software-as-a-service. Currently based in an AAA standard data centre in the US, a European option will be available early in 2011. "The idea that they don't need to commit the resources of their own data centres is appealing to some clients, as is the ease with which partners and third parties can be included and appropriate business rules applied."

Another major development



Kevin O'Leary, chief executive, Qumas: 'Our new solution provides an efficient platform and familiar interface'

is a partnership with Microsoft, which sees Qumas offering a SharePoint enterprise compliance solution for life sciences corporations. "Our new solution, based on SharePoint 2010, provides an efficient platform and familiar

interface from which life sciences personnel can simplify the management of compliance regulations without slowing their daily workflow," said O'Leary.

Business intelligence was an increasingly demanded feature

of compliance management, O'Leary said. "Executives need both the analytical capability and the kind of summary dashboard information for real-time monitoring that has become a feature of most enterprise systems. It enables

them to act and make decisions proactively, and keep on top of what the life sciences industry calls CAPA-corrective and preventive action. That BI functionality is now in all of our solutions, and is key to our competitiveness."

### Commercial Profile: Verify Technologies

## Lean manufacturing solutions made paperless

Lean Manufacturing, Six Sigma and Manufacturing Excellence are the buzz words of modern manufacturing companies in industry sectors including: Medical Devices, Pharmaceutical, Aerospace, and others. Huge investments have been made by companies in these methodologies, over the last decade, in terms of process re-engineering, staff training, inventory systems and so on.

Because companies have evolved process solutions to suit their particular business models over the years, a large paper trail of documentation will follow every work order or production job through the factory. This paper trail might typically include: Inspection sheets, set-up sheets, material usage forms, specification sheets and many more. So while the overall business strategies and methodologies can be considered world class, the day-to-day business operations are often still stuck in the dark ages, swamped in paperwork, spreadsheets and pencils.

The BPA.net platform, available from Verify Technologies, allows companies to easily automate these existing processes in a cost effective and practical manner.

Electronic Batch Record Management (EBR) and Paper-on-Glass are other common terms for electronic control and collection of all of this batch/job data and control information. When this data is collected through electronic forms (eForms) it is instantly available for review and feedback to process im-



John Gleeson, technical director

provement algorithms in the backend BPA.net system.

Verify Technologies adopts a philosophy of "Build the software around the business - not the business around the software." As a result the solutions deployed are configured to the exact needs of the business. This means that the existing processes and knowledge base of employees is leveraged rather than replaced.

In many companies the existing operations processes are ideally suited to the business needs, the problem is just that all of the control and data collection is paper based. This is too slow, too inflexible and too expensive for a modern Lean manufacturing company.

Verify Technologies works in a co-operative fashion with client companies to 'slide in' an optimised EBR system on top of their existing processes and systems. Software links with existing Financial and MRP systems operating within the client company ensure that there is no duplication of

data entry and the entire software suite for managing the business is being updated in real-time.

The BPA.net platform conforms with compliance standards such as 21 CFR part 11 (for electronic records and signatures) and GAMP 5 (good automated manufacturing practice). This is critical to ensure that audit and data integrity issues are in control and fully transparent. Verify Technologies works with clients in a lead role through the complete project life cycle. This includes developing a user specification; defining the optimum module configurations (from the BPA.net platform); configuring the client solution; validation of the system on-site; rollout assistance and training on-site.

For further information contact Verify Technologies Ltd, tel: 061 338392, www.VerifyTechnologies.com



The University of Limerick (UL) is one of the leading Irish educational institutions in terms of close engagement with industry, both locally and nationally.

It has a track record of innovation in course and programme development for the specific needs of certain industries, maintaining academic standards while answering real world skills requirements.

It has become particularly close to manufacturing and especially medical devices, in part because of the growing cluster of such industries within its natural catchment area.

"We see it as a combination of a grand vision on top and feet firmly on the ground," said Professor Eamonn Murphy, research director at the National Centre for Quality Management in UL.

He combines that with his role as university director of advanced manufacturing technology in the National Programme for Advanced Technology.

"We have industry partners that include ten of the top manufacturing employers on the is-



Professor Eamonn Murphy, research director at the National Centre for Quality Management, University of Limerick

land, companies such as Intel, Pfizer, Seagate, DePuy, Bombardier and others."

The objective was to build and continue to develop competency and excellence in manufacturing, Murphy said.

"We are aiming to enhance the performance of our manufacturing and the skills of the people, especially in bringing new and increasingly significant ICT streams such as simulation, predictive analysis and

real-time process control."

Many of these newer technologies had special importance in life sciences because of the tight compliance requirements of the US FDA or Irish Medicines Board, he said.

"Typically, these industries have to work also with massive aggregations of data that are simply incomprehensible in human terms. Vistakon, for example, produces more than a billion contact lenses in Ireland

annually, and its production processes capture 35 discrete pieces of data per lens," he said.

Yet such enormous data stores offered opportunities for statistical analysis and increasingly sophisticated predictive tools, Murphy said. "It's rather like weather forecasting and, in manufacturing, it helps management to foresee where, for example, stoppages might occur."

A current major research project is addressing 'zero defect manufacturing' based on the design and development of autonomous sensing networks for large-scale manufacturing. The promise is that real-time monitoring and analysis can help achieve that zero defect goal. It can take process and product data in from the production floor and, in turn, integrate the results with feedback to the manufacturing machinery and systems to maintain quality.

"This is the type of area in which research and technology meet real world needs and objectives," said Murphy. "None of us has all the answers, which is why it is so valuable to partner with other academic programmes, in our case particularly with NUIG here and Georgia Tech in the US, and with leading manufacturing corporations."

Murphy said that 'Do it in a timescale and make it practical' is something of a mantra for this applied research. "That is where we aim to be good partners contributing to manufacturing industry while, on the academic side, we are continually building our body of knowledge and expertise."

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Matt Moran, director, Pharmachemical Ireland: pharmaceutical exports in 2009 reached €47.2 billion, over half of the national total

# Pharma crucial for Ireland

By Leslie Faughnan

The continued success of Ireland's pharmaceutical sector is a beacon in the current economic gloom and almost a cliché as politicians and national leaders strive to give a positive spin to public utterances.

However, it really is a thriving sector with continued investment, both inward and indigenous, and growing employment potential in terms of higher level jobs and simple numbers.

Pharmaceutical exports in 2009 reached €47.2 billion, over half of the national total, and the sector's contribution in corporation tax was a welcome €1 billion plus. It em-

ployed 24,000 directly and more than the same again in supplies and services.

"It is not always appreciated from outside that the pharmaceutical industry is a major employer of high level skills beyond the obvious ones like chemistry or process engineering," said Matt Moran, director of the industry body Pharmachemical Ireland.

"In that context, ICT is as critical as biochemistry. The management of information is critical across all functions in the sector, and many of the newer processes would be impossible without the smart systems platforms that support them."

Within pharma organisations, ICT skills are highly esteemed as a key component in aligning all elements of the

business in globally competitive markets.

"Some areas are self-explanatory, like the crucial role of ICT in manufacturing systems, a key example being process analytical technology (PAT) which is mandated by the Food and Drug Administration (FDA) to control quality in real time throughout the production process," Moran said.

This is especially important with the new generation of bio-pharmaceuticals, where automated controls and real-time quality assurance management throughout the production process is a key goal.

Others may seem less obvious, but the right regulatory requirements of the FDA or the Irish Medicines Board and the EU demand smart and

complex systems for complete and auditable traceability from ingredients and production all the way through to the patient.

There is also, according to Moran, a significant new area opening up in the mining of huge data sets in genetics and chemistry and others to identify potential new drugs.

Another rapid growth area for technology is in serialisation, the unique identifier mechanism for all drugs which is a complete traceability solution and a significant anti-counterfeiting measure.

"Here in Ireland we have seen the pharmaceutical sector in recent years extend its reach with the creation of shared service administrative centres by many of our multinationals, for EMEA and even for global functions," Moran said.

Moran cited examples such as Pfizer, which has had large shared service operations here for some years, and more recent investments by Allergan, Covidien, Merck and others.

"Novartis is a good example because it has its regulatory centre here, looking after the corporation's compliance across all of its operations and markets throughout Europe."

A skills report by Pharmachemical Ireland published in November recommended deeper and more structured links between the industry and third level education and research institutions.

"The report recommends structured collaboration between industry and academia and this is essential if Ireland is to expand the remit of its pharmaceutical base from

pure manufacturing to manufacturing supported by world-class research and development and key shared services," Moran said. "That is what will secure the long-term future of the sector in Ireland."

The report also recommended the provision of dedicated research and training facilities for the sector. Moran said that business, manufacturing and ICT skills should combine with the other specialist scientific and clinical disciplines.

## Wise investment key to success



Gerry Reynolds, managing director, Takumi, Mary Coughlan, Tánaiste, and Donal Galligan, quality manager, Takumi

By Leslie Faughnan

Despite the name, Takumi Precision Engineering is an Irish company based in Raheen, Limerick. The story of the name and the company's foundation has its origins in founder Gerry Reynolds's six years working for Fujitsu in Japan.

Employed in its Blanchardstown dot matrix printer plant in Dublin after college, he took the opportunity to gain experience and promotion in Japan.

Returning to the Irish factory in 1995 with a Japanese wife, he spent three years leading what had become a contract machine shop.

In 1998, he set up the company with a name suggested by his wife. Takumi means 'craftsman' in Japanese and epitomises the philosophy that, even in today's engineering environment, the ancient craftsman's principles of pride in one's work and striving for excellence are core values.

"We are just over a decade in medical devices, principally as a trusted specialist supplier of high-precision components and products for a range of major multinationals that includes Stryker, DePuy, Lake Region, Medtronic and others," said Reynolds.

Takumi has invested in high-spec equipment and smart technology over the years, typically of about 10 to 15 per cent of turnover. That investment now totals well over €4 million. That was high in relation to the employee headcount of just 50, but was key to the survival and expansion of the business. "Computer-aided design (Cad) has always been central

to what we do, from the earliest stages when we could exchange drawings with our clients and generate machine tool instructions directly from the software," Reynolds said. "That technology and our use of it has greatly developed over the years and we have been using Autodesk Inventor for about seven years now."

This is product design software that is 3D and powerful in creating advanced designs and in modelling or simulating products on screen. Takumi has become increasingly involved in digital prototyping, developing complete products on behalf of its clients.

"We can take a product concept and develop the design through to a physical prototype and manufacturable product as a total solution service," he said. "That was key to our strategic decision last year to push into exporting, working with medical and other partners in Britain and South Africa."

Takumi is working with a Newcastle orthopaedic surgeon to develop a revolutionary hip replacement and alignment system. In South Africa, it is working on a new form of bone replacement implants for limb salvage.

"We are also looking for the first time at developing and branding some products in our own right," Reynolds said. "A huge area is in single-use orthopaedic surgery tools. These are expensive and costly and difficult to sterilise. We believe we can produce Takumi disposable machine saws, drills and other surgical tools at a price level that will be far more economic, just like other disposable items in healthcare."

## Making traceability as easy as possible

By Leslie Faughnan

One of the principal business characteristics of both the pharmaceutical and medical devices industries is that they

are tightly regulated and product traceability is essential from production right through the life cycle.

"We set up in 2004 and targeted that traceability requirement in regulated industries," said Seamus McNamara, chief

executive of Verify Technologies in Limerick.

Verify software products have been developed for the specific needs of the pharmaceutical, medical device and food sectors. "Our core target was and is the production floor 'batch records' which are a mandatory requirement but an administrative headache for all involved because of the sheer volume of paperwork," McNamara said.

Managing batch records was and is still heavily paper-based in most companies in these sectors, McNamara said. "They all have advanced ERP systems and even the logistics and distribution are very smart but on the operations side the batch records still tend to be very manual."

The Verify software approach is to digitise and automate the clients' existing paper-based systems. "Their forms and records document like test results all look familiar to the operators but they are now e-forms and their content can be digitally managed. They are not required to re-engineer their business processes and that has been the key to our success," said McNamara.

In most regulated production facilities, McNamara said,



Seamus McNamara, chief executive, Verify

the administrative processes have grown over time and are usually perfectly adequate, as they have to be for regulatory compliance.

"But they can also be clunky, paper-based and a constant worry for management. Our technology can, as it were, scoop up and automate what they are already doing in their batch record management," he said.

Once the records are digital it is relatively easy to automate processes such as the workflow, approvals and sign-offs as well as reporting and traceability requirements in a single electronic batch record system.

"Because everything is now digital, it becomes easier also to set controls and business rules and in the end have secure, auditable records," said McNamara.



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