

**IMDA finds cure to develop skills**

The medical devices industry is one of the less heralded in Ireland's export sector where training of the workforce is seen as a significant factor in facing the increasing demands of productivity, innovation and new product development as well as evolving higher standards required by the regulatory bodies. Skillnets has played a crucial role in helping companies meet these challenges through lifelong learning in the workplace and the development of the industry's own national accredited standards for assessing and demonstrating operator competence

To help ensure standards and build a skilled and adaptable workforce, the Irish Medical Devices Association (IMDA) Skillnet has created a competence system for its industry, with agreed standards, enabling trainees to attain a National Skills Certificate. The training developed with the backing of Skillnets, was undertaken by several hundred individuals enabling them to gain formal recognition of their skills and knowledge. An impressive 11 member companies from the IMDA Skillnet gained approval as Registered Centres for Certification, with that number expected to double at the end of 2003.

Although electronics and pharmaceuticals are often cited in media discussions regarding Ireland's economic progress in recent years, one of the most important export sectors of recent times is the medical devices industry. Under this broad heading, there is now direct employment approaching 22,000 (about 9pc of the total manufacturing workforce) and annual foreign trade worth over €3bn. It shares some characteristics with pharmaceutical and chemicals, notably the fact that Ireland has become a significant location on the world map and 13 of the top 25 medical devices and diagnostics manufacturers currently operate manufacturing plants here. It is more geographically dispersed, however, with companies located in 18 counties. There is also a high average skill level – over 40pc of workers have third level qualifications – and world-class manufacturing environments that must comply with stringent standards, notably those of European and US Federal regulatory bodies.

The Irish Medical Devices Association (IMDA) is the IBEC sectoral representative body, with 60 members spanning a diverse range of products and manufacturing processes from plastic disposables like syringes to high-tech diagnostic equipment. Employment ranges from about 2,000 in Boston Scientific to half a dozen in some start-ups. There is also a growing cohort of indigenous Irish



Sharon Higgins and Rosemary Duncan, Network Co-ordinators, IMDA

companies in the sector, strongly supported by Enterprise Ireland, building on component and sub-supply opportunities and professional experience gained by Irish employees in the multinationals. The sector members share an ambition to make this country a recognised centre of excellence in the medical devices field. Since they do not compete with each other in this market, co-operation between the companies in the industry and with third-level colleges and development agencies is excellent.

#### Productivity demands

The IMDA Skillnet grew from the recognition across the sector that the ongoing education and training of the workforce was a significant factor in facing the increasing demands for productivity, innovation and new product development as well as evolving higher standards required by the regulatory bodies. The route to meeting these challenges is in large measure through lifelong learning in the workplace, IMDA decided. Today the industry has developed its own national accredited standards for assessing and demonstrating operator competence through the Skillnets programme and with the specialist assistance of FÁS.

There is now in place a National Skills Certification system for operations personnel in the medical devices industry. The essential areas cover Safety, Environmental Awareness, Quality and current Good Manufacturing Practice and Communications for Production. Among the job-specific skills for which standards have been developed are Warehousing, Packaging and Labelling, Automated Assembly Operations, Automated Milling and Turning, Bonding and Product Filling. This whole process of upskilling and accreditation of the workforce is important for the companies as they compete in world markets and for the industry in Ireland as it looks for further inward investment, notably from the USA and major European countries.

The IMDA Skillnets project is managed on a day-to-day basis by ARC Management, based in Cork. "The programme provides a measurable and effective training system with National Accreditation," says ARC director Clare Ryan. "But of course it is complementary to whatever internal training the larger companies might already have in place. What it sets are the standards and assessments – how any plant implements such training or what materials it uses is entirely a matter of choice or convenience. It is driven by the operations people themselves, which has proven valuable in gaining acceptance and in fact enthusiasm among the individual participants. There is no sense of a 'final exam' which most people would understandably dislike but more of a demonstrated competence with a knowledge base underpinning it."

#### Quality assurance

Probably the major driver of the IMDA Skillnet is the increasing level and extent of demands for quality assurance and product standards by the regulatory bodies in anything to do with human health. Meeting those strict standards – and demonstrating at all levels from the plant floor up that you can and do – are major responsibilities of manufacturing management in the sector today. The IMDA Skillnets programme is providing tangible benefits from that point of view because it is standards-based and auditable. But it is also raising the value of the sector workforce generally by promoting and inculcating knowledge and best practice – and raising standards of competence – at the level of the individual plant operator. The employees in turn gain from the formal recognition of their skills and knowledge.

Several hundred individuals have received training under the IMDA Skillnet system so far but rapid acceleration in the numbers involved is currently taking place as the second programme reaps the rewards of the infrastructure development and training of the first crop of

internal assessors and verifiers. A total of 11 companies received the status of Registered Centre for certification of the training system in the first round, a total which is expected to double by the end of this year. "The important things are that the national standards and system are in place," Clare Ryan points out. "In each company it is more a question of a process that has been started and will be ongoing and evolving. The precise implementation will vary according to circumstances, size and other factors."

In fact, the network element has proven particularly

valuable to participants in sharing ideas and pooling experience of different systems and approaches. As for the future, while the National Skills Certification element within the industry is to some extent self-perpetuating, the IMDA as the industry body will continue to endorse and sponsor the system to maintain continuity and act as the reference point for participating companies. It is also recognised as the only feasible agency to expand or develop the training system in the future as industry developments may well require or opportunities suggest.



Antoinette McTighe and Mary Carty, ANSAMED

*'Through the Skillnets we now have national benchmark levels'*

### ANSAméd

ANSAméd is an Irish-owned and managed company that specialises in the design and production of sterile medical devices as well as plastic precision extrusion based components and sub-assemblies for leading edge medical device manufacturers. ANSAmed now manufactures diagnostic, delivery and retrieval systems in cardiology, radiology, neurology and urology. It offers customers a comprehensive integrated service ranging from product design and development through to manufacture, packaging, sterilisation and ultimately to EU and FDA registration. Based in Boyle, Co. Roscommon the plant began operations in 1992 as the European arm of the US-owned Adam Spence but was bought out by its local management team in 2001. It currently employs 65 people and works a three-cycle 24x5 roster.

Shortly after the MBO the management team became involved in the early planning of the IMDA Skillnet and were convinced that this was the way to go in determining and verifying competencies within the industry and especially in their company. ANSAmed manufacturing director Antoinette McTigue has taken responsibility for the project within the company, which began with discussion with the entire operating team. The project and objectives were explained and from the first day greeted with enthusiasm and immediate volunteers for the pilot programme.

"We have always conducted in-house training, but at times it could be hard to be sure that people had grasped the significance or implications of things completely," says Antoinette McTigue. "So one of the great benefits of the Skillnet programme is that you are always working with industry-wide benchmarks – you have all the indicators and know what level of competence can be expected from the training inputs."

*'Having your skills recognised – and assessed objectively and fairly – is very satisfying'*

### Common purpose

In fact ANSAmed began with the design and development of its assessment documents. It turned out to involve a lot more work than initially thought but also made the valuable contribution of highlighting gaps in the company's existing training programme and even elements in standard operating procedures that needed to be tightened up or more clearly specified.

"It was also interesting to see how other companies in the sector of very different sizes and specialities approached these tasks. Because we all shared a common purpose, we genuinely learned from each other. Some areas were especially important to establish common industry levels, notably in regard to environmental and safety standards which are so important in our industry. Through the Skillnet we now have national benchmark levels."

The actual training programme within ANSAmed has been a clear success, with feedback from all of the candidates that they valued progressing through the assessments and receiving recognition and certification for their skills. They also appreciated the overall view they gained of the external and internal factors affecting the progress of the business and their own place and fit within the organisation.

A second group of operatives is now working through the Skillnet training modules while Antoinette McTigue says that the attitude and responsiveness to training among all of the staff has become more positive: "We are able to introduce much more flexibility on the floor, with operatives moving between departments and operations. There is an underpinning of common knowledge, of basic requirements that can then be complemented by whatever specific task training is required. Essentially, the whole thing is a process that is now started and will be continuously supported and developed over time."



Mary Carty and Edel Scanlon, ANSAmed

### Edel Scanlon, Production Department Trainee, ANSAmed

Born and reared within a few miles of the plant, Edel Scanlon is a Boyle mother with schoolgoing children who joined ANSAmed just over three years ago as a back-to-work trainee in the production department. She was one of the participants in the pilot Skillnet programme and immediately found that she grew in confidence on the job as her knowledge increased. "Having your skills recognised – and assessed objectively and fairly – is very satisfying," she says, "and the fact that the whole assessment process and so on is certified by FÁS is important. It is also rewarding to begin to understand the whole process in the plant rather than just being conscious of your own little bit. As for the actual training, it was not difficult and it was

helpful that we were given plenty of time to learn and to let things sink in and to look over the support material."

The total importance of quality control in the medical devices industry is an area that Edel Scanlon is now very conscious of working on the production line: "Of course you always knew it was important but the real thing is understanding the international context, the regulatory bodies and all of the strict requirements we have to meet. Then you can appreciate the specific things in our plant and with our products.

"I think I am much more confident now in taking responsibility for quality-related things, making decisions on the production line without having to look for guidance from someone in authority. I feel I understand our quality control systems and procedures and I know what we are looking out for – and why!"