Interview Focus

An Irish SME's perspective on medical device certification

> *Achieving certification to I.S. EN ISO 13485:2016 was an important step forward for our company. We had already been manufacturing components for the medical device industry, but the certification has enabled us to expand our customer base both in Ireland and abroad.*
>
> JAMES LAWRENCE, MANAGING DIRECTOR, LAWRENCE ENGINEERING

NSAI

Standards that save lives

An interview with James Lawrence, Managing Director at Lawrence Engineering

When Lawrence Engineering received its certification to I.S. EN ISO 13485:2016 through NSAI for medical device manufacturing, NSAI's CEO Geraldine Larkin put the Sligo-based SME's achievement into context:

"Adherence to international standards is pivotal for businesses to thrive and remain competitive in the global market. The medical technology sector presents immense opportunities, and certification plays a pivotal role in fostering its sustained growth, facilitating the development of life-changing devices and medications."

From startup to Class 8 cleanroom

Toolmaker Michael Lawrence set up Lawrence Engineering in 1984, offering precision engineering to several industries. By 2008, the business was focused entirely on supporting medical device manufacturing.

James Lawrence took over from his father in 2019. Within two years, growing demand for high-quality medical components led the company to invest in a new manufacturing plant with an ISO Class 8 cleanroom in Collooney.

Now employing 35 people, Lawrence Engineering offers medical device manufacturers a turnkey solution, from mould and tool design through to cleanroom manufacturing.

"We had been manufacturing medical components for a couple of years, but without certification to ISO standards, we couldn't reach certain customers. We knew we needed this, and wanted a certifying party that was internationally recognised, which was particularly important for our US customers. That's why we chose NSAI," says James.

Supporting Ireland's medical devices sector

NSAI's Medical Devices division offers a full range of services and support around management system standards and certifications for medical device manufacturers.

This includes offering certification to I.S. EN ISO 13485:2016, an internationally recognised standard, specific to this industry.

ISO 13485 can be a first step towards compliance with European, Canadian and other regulatory requirements for medical device manufacturers.

While it's a voluntary standard, ISO 13485 can be essential when submitting bids to large manufacturers.

Partnering for quality and improvement

James found working with NSAI towards certification to ISO standards encouraged a culture of continuous improvement.

"Our experience of working with NSAI is that they try to make sure you succeed and achieve your certification process, to help us get our quality system up to the correct standards."

"We didn't have experience in a quality system previously, so certain things weren't up to the standard at the start – that's why it's important to have a certification body that is going to make sure your whole system is up to the standard required. There was a lot of work to do before Stage 1 and Stage 2 audits, but it was clear what we needed to do.

"Everything we changed was to meet the standards required, but also to improve our quality system. The ISO system is all about continuous improvement and compliance with requirements for an effective quality management system. So, as well as validating our quality within the industry, it's a great benefit internally, in terms of culture and management. We're always looking at different ways to improve the system and processes, and make things as efficient as possible."

Opening conversations around the world

Much of Lawrence Engineering's international growth in recent years has come from Irish companies which also operate abroad, or from referrals within the global supply chain.

Having an internationally recognised certification means the company never has to miss a business opportunity as its efficient processes mean it can service a foreign customer as quickly as a local provider could.

"Many of our customers and prospects, especially large manufacturers, only work with suppliers that are certified to ISO standards," says James. *"Within two months of certification, new conversations opened up with potential customers, and conversations re-opened with customers we'd worked with previously – all because of certification."*

Words of wisdom

As Lawrence Engineering started its certification process, it worked with external consultants. But things really took off after they hired an internal expert to set up their quality management system. James's advice is to start with the fundamentals in place.

"Make sure you have a quality expert onboard to start with. The first step is to set a clearly defined process, and then build the quality system so that it meets the requirements of the ISO 13485 standard. You'll be on the right track for continuous process improvement, innovation, and quality."

LawrenceEngineering.ie

+ NSAI is a designated Notified Body under both MDR 2017/745 and IVDR 2017/746 and is in a position to provide conformity assessments under MDR and IVDR and grant CE marked certificates to the scope documented on the NANDO database.

+ NSAI Inc in the US is accredited to the Medical Device Single Audit Program (MDSAP), which covers the medical device regulatory requirements for Australia, Brazil, Canada, Japan and the US. It may be provided by NSAI in conjunction with EU auditing activities.

+ To find out more about our work in medical devices, please visit NSAI.ie/medicaldevices

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