



Taking better care of medical manufacturers

~ The benefits of metrology in medical applications ~

Ireland is one of the largest exporters of medical products in Europe, with annual exports of 12.6 billion euros. Medical device manufacturers in Ireland are constantly looking for new ways to enhance competitiveness, improve productivity and generate new growth in the area — could metrology make a real difference? Here Jason McGlynn, commercial manager for Ireland at industrial metrology specialist, [The Sempre Group](#) explores three factors to consider when searching for a metrology supplier and equipment for medical applications.

The goal of medical device manufacturing is to produce exactly what the patient needs. As such, manufacturers should consider how they will validate the process to ensure this is the case.

However, metrology is often an afterthought in the product's lifecycle and is simply used to validate products and detect defects at the end of production. With regulatory requirements becoming increasingly stringent, there is added emphasis on proving safety and quality throughout every step of the product's lifecycle. For metrology specifically,

ISO 13485 lays out how to maintain an effective quality management system specific to the medical device industry, covering every stage of product lifecycle from design to disposal.

Accuracy

Precision is key when manufacturing any medical device to ensure the best outcome for the patient. Take an insulin pen as an example — if any dimensions are slightly incorrect it could lead to false deployment, overdosing or underdosing — putting the user at risk.

Manufacturers can invest in nano and micro precision measurement equipment to validate a variety of parameters, from dimensions to surface characterisation. This equipment can effectively validate the accuracy of devices, so long as it is calibrated correctly. So, when looking for a metrology supplier, medical manufacturers should check that a supplier's equipment and services meet relevant standards.

ISO 17025 accreditation and certification from the United Kingdom Accreditation Service (UKAS) demonstrates competence and performance capabilities of organisations that provide certification, testing, inspection and calibration services. The Sempre Group is also one of the very few companies that is able to offer UKAS calibration for Optical or Vision CMMs, such as Micro-Vu systems, ensuring their reliability.

Traceability

When applying to regulatory bodies for approval, medical device manufacturers need evidence to prove that the device safely and effectively meets its intended use. Proving compliance requires manufacturers to document every stage of the process – so improving traceability should be a priority.

Investing in automated, real-time data collection software, such as the [Prolink SPC Data Collection Software](#), will help manufacturers spot any changes that occur during production and identify where they happen and why. It extracts result data from any device or machine and enables full analysis and reporting, providing total visibility and control across the entire process and reduces the risk of human error that comes with paper documentation. When choosing a software, medical manufacturers should also ensure it is 21 CFR Part 11 compliant, as it assures that any electronic documents generated are authentic.

The full package

The earlier that manufacturers involve metrology specialists in a project, the more successful it will be. Finding a supplier early in the process means that the metrology company can provide everything manufacturers need to improve quality at every stage of the product's lifecycle, ensuring ISO 13485 compliance.

Smaller businesses can also benefit from involving metrology specialists early on so that they can build a solution that grows at the same rate as the project. The supplier can build bespoke systems to meet the needs of the application and upscale the solution as the

medical manufacturer scales up production, ensuring that the solution will always meet production requirements.

UK and Irish medical device manufacturers know that metrology is needed to ensure a device operates to design intent and safety requirements. By considering metrology as a higher priority and investing in a fully integrated approach to quality, medical manufacturers can gain the competitive edge required in such a large industry.

Do you want The Sempre Group to be your one stop shop for metrology? To find out more about the equipment, software and services that The Sempre Group offers to support you throughout the entire product lifecycle, visit www.thesempregroup.com or call +44 (0)1452 632 712.

Ends: 684 words

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About Sempre Group: The Sempre Group, previously Metrology Direct, provides comprehensive measurement, inspection and design solutions across the UK and Ireland. With four divisions aimed at creating a tailored experience for each partner and customer, The Sempre Group is a strategic partner in quality, automation, innovation and efficiency for manufacturers in Great Britain.

Ref: SEM025/10/20