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Quality assurance

Safety and quality are non-negotiable in the medical devices industry. Regulatory requirements are becoming increasingly stringent throughout every step of a product's life cycle, including service and delivery. More and more, organizations are being put under a microscope, expected to demonstrate their quality management processes and ensure best practices in everything they do. At genae, we tap into our wide range of quality and regulatory experience and expertise to guide you through every stage of your clinical project.

Since genae focuses solely on medical device and IVD companies, we understand the industry inside out – unique needs, intricacies and complex manufacturing scenarios. With offices worldwide, our exceptional team of talented and trusted QA consultants has helped many medical device and IVD manufacturers achieve ISO 13485 certification.

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Case study

genae provided regulatory support services for a med tech start-up that developed a wearable device to collect non-invasive physiological and vital signs for subjects that require constant monitoring. Like many start-ups, it was strong on technical know-how and product design expertise. The team also did its homework, accruing insights on customer requirements and unmet needs. What they lacked was the understanding of product regulatory requirements pertaining to medical devices. To help achieve market access, genae was asked to establish and implement a **Quality Management System** (QMS) in accordance with **ISO 13485**, plus prepare a Technical File so the product could obtain a **CE Mark**.

What were the challenges?

Three key challenges had a significant impact on the ultimate objective -- to get the product to market as fast as possible. Firstly, an ambitious deadline to complete the project by the end of 2019, even before finalizing the design and development. Secondly, regulatory strategy. They wanted a CE Mark certification in compliance with the current Medical Device Directive, not with the new Medical Device Regulation. Finally, and by far the biggest challenge, was helping them to understand the importance of a constructive and efficient quality system… and doing so in record time.

What did we do?

Specifically tailored to the company's size, needs and processes, genae established an entire quality system baseline, including the writing of the manual, procedures and associated forms. What's more, we provided ongoing techno-regulatory support throughout the implementation of all quality procedures [(Risk Management File, Design History File (DHF), Device Master Record (DMR), Technical File, Medical Device File (MDF)] and vetting of suppliers and subcontractors. During the Notified Body's audit and post-audit activities, we advised the team on how to respond to audit findings and guided them on a corrective action plan.

How did we help?

The audit concluded with a recommendation to the Notified Body to certify the company's QMS to ISO 13485. Throughout the project, the manufacturer repeatedly emphasized their trust in genae, stating 'that we do not simply execute the project, but are very much part of the project team'.