Case Study

Technical File (TF) Updates Medical Device Company

Problem Identification

One of the major requirements for achieving CE mark approval for a device, which allows a manufacturer to market that device in the European Community (EU), is the assembly and maintenance of a Technical File (TF) for each product. A Technical file contains the most important information about a device; how it works, how it is manufactured, and how it meets the applicable regulatory requirements. As technology in the life sciences industry become more and more complex, these files can often make or break a device's certification, especially if the file contains inconsistencies or has missing parts.

Nature and Scope of Challenge

In the face of this increased regulatory scrutiny, one of the leading players in the orthopedic device market enlisted EG Life Sciences to analyze and develop a practical, integrated strategy to address weaknesses and gaps in their legacy product technical files. Our client required a cross-functional team of 30 technical specialists to review, assess, identify gaps in, and update technical files of marketed product families. Timeframe for completion of these updates was six (6) months (26 weeks).

Problem Resolution

A two-phased approach was employed, utilizing a project team made up of Regulatory Affairs Specialists, Product Development Engineers, and Quality Engineers.

In Phase 1 of the project, the team quickly assessed the number and scope of products that had received CE mark approval, and correlated those technical files to individual products. The assessment identified that there were multiple files covering the same products, which made it extremely difficult to keep each file updated and accurate. The team recommended, and implemented, a strategy to "bundle" and consolidate the myriad of files into several files covering just product families. This strategy allowed the client more easily manage their product portfolio and to raise their compliance level for these important documents.

The second phase of the project was the most resource intensive, and included intense training sessions on the client's systems, processes, procedures and products, and then the consultant team members reviewing the contents of each of the existing technical files, updating and filling in the gaps in the specific required documentation, and finally re-packaging and coalescing the files into approximately seven product family Technical Files.

Weekly reviews of progress against agreed upon metrics was conducted between EG Life Sciences team members and the client's stakeholders. Periodic adjustments were made to ensure completion of the project by the required completion milestone. In addition, the Team devised and developed a plan for sustaining the updated files moving forward so as to maintain compliance.

Value Proposition

This engagement demonstrated EG Life Sciences ability to quickly scale a large project, successfully execute a custom search for consultant resources expertly suited to meet the client's specific needs, and deploy those individuals seamlessly when and where the client required them.

The flawless execution of the EG Life Sciences team, in collaboration with the client's internal resources, resulted in timely Technical File updates that were compliant with European regulatory requirements, thus allowing the client to continue to market their products.

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