GFORCE SUCCESS STORY

SUBJECT MATTER EXPERT, GLOBAL REGULATORY AFFAIRS, REREGISTRATION

GForce Life Sciences worked with the Global Regulatory Affairs Director for an Orthopedic Medical Device manufacturer who wanted to focus on global registration efforts. The company had not yet consolidated the product portfolios a year after merging with another large medical device implant company and was lagging behind schedule. Internal resources within the various business units were handling other critical projects and, as a result, international re-registrations were significantly delayed.

There was the potential for a lapse of global registrations.

We provided a Subject Matter Expert in Global Regulatory Affairs to help lead this effort and mentor a junior team of employees in this project to prepare the standard technical documentation (STED) for hundreds of product codes.

Under our consultant's leadership at the global headquarters, a STED team was organized and trained on a detailed protocol that our consultant authored to consistently prepare the STEDs to be compliant with global requirements and acceptable to the various client business units responsible for filing the re-registration documents with the competent authorities.

Additionally, our consultant mentored the team members (5 engineers, scientists and pharmacists) in the specific regulatory affairs requirements of the client's products. Country-specific requirements had to be addressed along with challenges in obtaining current data. Communication with the various business units and in-country representatives was established to strategically resolve delays, omissions, and other issues.

Within a short 5-month timeframe, we were ahead of the schedule to complete 165 STED portfolios (documentation describing more than 15,000 items requiring compilation of drawings, specifications and other technical reports) and we began the knowledge transfer to the employees who would carry the torch through completion.

During this period, regular reporting was established allowing the Director visibility to critical issues and the team's progress. Clearing this backlog of delays has saved our client millions of dollars in potential and unrealized costs related to product recalls.

The Global Regulatory Affairs Director responsible for the project expressed appreciation for our consultant's leadership and technical competency in training and directing a team of inexperienced individuals to becoming sufficiently skilled to complete the project.