GFORCE SUCCESS STORY

FDA WARNING LETTER RESPONSE, CAPA SUBJECT MATTER EXPERT, MEDICAL DEVICE REMEDIATION

GForce Life Sciences worked with the Vice President of Quality of a global medical device manufacturer. They had received a 483 observation and, subsequently, a Warning Letter.

When we met with him, he was very concerned about the challenges he was facing regarding his vision of an efficient and compliant management of their CAPA process.

Due to the FDA 483 and Warning letter observations, a total of 8 new CAPAs had been opened to address the plan of action. This added to their current CAPA portfolio of approximately 30 CAPA records that had to be managed with a process in place that was lacking the elements of an efficient, well-structured and fully compliant process. The lack of a standardized corporate process, a computer-based management system and lack of the skillset required to properly document CAPAs and root cause analysis contributed to the poor management of the CAPA process.

The Vice President need help and **GForce Life Sciences** provided him with a CAPA Subject Matter Expert with deep medical device knowledge and experience.

As part of the proposed remediation action plan, a corporate process and a computer based CAPA management system were soon implemented, but the expertise to execute the process and document the current CAPA records in full compliance including phase planning, adequate root cause analysis, good documentation practices was lacking. **GForce Life Sciences** provided them with the improvement of records, the training on the required skillsets for good documentation practices and root cause analysis, and a world class management approach to their CAPA portfolio based on industry best practices.

Over a period of six months the execution of the new harmonized CAPA process was fully structured and implemented with a clearly defined and assembled cross-functional, executive level CAPA committee. This committee committed to having bi-weekly meetings on the management of the CAPA portfolio and the review of sources of quality data for CAPA escalation, the review of the current CAPA portfolio for documentation gaps and root cause analysis. Key CAPA stakeholders and CAPA owners were trained on a full CAPA training program consisting of 5 modules delivered over the course of one week, covering CAPA best practices, good documentation practices, root cause analysis and use of the available tools for CAPA record documentation.

During a period of one year after the client engaged our services, two third party Quality Management System (QMS) audits took place from a leading external firm and QMS registrars, auditing the CAPA process and the FDA remediation CAPAs in detail, with outstanding results and praise of the process in place and quality of the CAPA documentation**. GForce's Subject Matter Expert was presented a corporate wide award for excellence in CAPA for his contributions to the team.**