GFORCE SUCCESS STORY

MEDICAL DEVICE REMEDIATION, 483 RESPONSE, CAPA TEAM

GForce Life Sciences worked with the Quality Director for a surgical division of a global medical device manufacturer. They had just received an FDA 483 Observation for CAPA process nonconformity (among other items). Additionally, the documentation for the investigation into root cause was inadequate.

The Director had many challenges that worried him. He was very concerned that the CAPA Owners and team members lacked the investigation skillset and training, the investigation tools were not clearly defined or explained effectively in procedure/work instruction, and CAPA procedure did not clearly define the criteria for effective management of each phase of the CAPA process. They needed to execute this remediation successfully in order to respond to the 483 or the state of the site could worsen greatly. Moreover, our client expected that only 10% of CAPA records would have gaps in documentation. Based on this information, he expected the assessment and remediation to be complete in 3 months!

GForce provided them with (4) Quality Assurance consultants to begin CAPA remediation efforts and perform a retrospective review of CAPA records from almost 5 years of records (over 200 records). There were 58 different CAPA Owners for the records assessed - many no longer employed at the client! Finally, 90% of CAPA records had gaps in the documentation, not 10%! We documented inadequacies and assigned a gap level (0, 1, 2, or 3) to each CAPA phase and record.

Within a short time frame, our team lead the effort to revise protocol to include specific remediation steps for each Remediation Recommendation category, an improved CAPA process with detailed reviews for CAPA Committee members, instructions for how to conduct root cause analysis and the use of other investigation tools, development of Remediation Plans for each CAPA record based on assessments, and prioritizing based on risk, aging, and the client's management requirements.

With respect to Corrective Actions, our team established interim controls for new CAPAs (per the Protocol) with **GForce consultants** mentoring and coaching CAPA Owners, procedures and work instructions were revised, and **GForce** instructor-led classroom training was conducted along with measures of effectiveness.

Our client engaged a 3rd party expert auditor to audit these assessments and activities and the results were **outstanding.** The 3rd party confirmed the **GForce's** assessments were accurate and examined thoroughly and the client recognized additional time was required to remediate records and to "do the right thing". Additionally, our client recognized the need to limit CAPA Owners to those that are capable and well-trained and they hired CAPA Engineers to support CAPA Owners in the newprocess with a tremendous amount of knowledge transfer from **GForce.**

Our client was left with an effective CAPA process compliant with 21 CFR Part 820.100 and ISO 13485 8.5.2, CAPA owners/team members well-trained and supported by CAPA engineers, and most importantly, the confidence that new records will pass FDA inspection or other 3rd party audits.