Client receives zero FDA Form 483 observations.

Case Study

Compliance Review for Medical Device Manufacturer

INDUSTRY

Medical Device

SERVICES

Remediation

Corrective & Preventative Action (CAPA)

SKILLS

FDA Compliance

Gage R&R

Receiving Inspection Review

Test Method Validation

Calibration & Metrology

The Challenge

A medical device manufacturer needed to complete a retrospective review of the tools used on their manufacturing floor as a part of their response to an FDA inspection observation. Although only a few pieces of equipment/tools were identified in the observation, our Oxford team recommended that the manufacturer expand their review across the entire facility to understand whether or not they had a systemic issue. Together, they opened a Corrective Action/Preventive Action plan (CAPA) to document their actions, findings, and results.

The Solution

We identified 4 consultants and had them ready to work on site within 2 weeks. Rapid and thorough completion of all activities was mission critical as production was halted during the project.

Our Oxford project team completed extensive reviews of the client's state of compliance surrounding Gage R&R studies, Receiving Inspection Forms and Test Method Validation Qualifications for every piece of equipment/tool utilized in the production of their products. In order to capture all instances of non-compliance, our Oxford team created a Trace Matrix for our client. The team also assisted with creating a more robust Gage R&R program, a Calibration program and a thorough "special" process validation program.

Our Oxford team enabled our client to become compliant with company and industry requirements, thus enabling production to resume.

The Result

Our Oxford team enabled our client to become compliant with company and industry requirements, thus enabling production to resume. Following the project, a subsequent FDA inspection resulted in zero FDA Form 483 observations. The Trace Matrix and CAPA that our team completed allowed the manufacturer to successfully demonstrate compliance with Quality Management System requirements and Industry Regulations.

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