CASE STUDY

QMS REMEDIATION

OVERVIEW

Class III medical device company is issued FDA 483 due to product and QMS failures posing life threatening risks to implant patients.

CHALLENGE

Identify systems level issues across 6 business units including external field failures, develop enterprise wide remediation plan, implement plan and corrective actioning

ACTION

SQR1 deployed a hybrid team of 23 SME's across two facilities, supporting six (6) business units to perform a system wide gap analysis while devising a company wide attack plan to address customers 483 warning letter. Team consisted of:

Teammates Included:

- 7 – Quality Engineers
- 4 – Manufacturing Engineers
- 4 – Project Managers
- 3 – Complaint Handling
- 3 – Regulatory Affairs Specialists
- 1 – Configuration Manager
- 1 – Interim Site Quality Director

SOLUTION

Successfully averted plant closure, saving customer an estimated $4.5 million in potential missed revenue by addressing FDA observations, developed new enterprise wide SOPs, supplier full cycle CAPA processing, implemented new automated internal complaint handling system.

4.5M
SAVINGS

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