CASE STUDY

QMS REMEDIATION

OVERVIEW

Our client, a Class III medical device company, was issued an FDA 483 due to product field failures and QMS issues posing life threatening risks to implant patients.

CHALLENGE

The Square-1 SME team was brought in to identify & correct systems and process issues across six (6) functional departments and two (2) manufacturing locations domestically. Our clients' situation was dire due to several implant field failures.

ACTION

Square-1 deployed a team of 23 SME's, across two (2) facilities, to perform a system wide gap analysis while devising a company wide remediation plan to address clients' 483 warning letter. Plan included a collaborative effort between our team and clients executive management team.

Square-1 Team 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

Square-1's work on this project helped our client successfully avert plant closures, 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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