CASE STUDY

QUALITY SYSTEM REMEDIATION

OVERVIEW

Our client, a Class III medical device company, received multiple FDA 483's as a result of Class-I product recall due to several system wide nonconformances, both major and minor, ranging from QMS, Operations, and R&D Sustaining. Nonconformances included product performance issues, personnel training, complaint handling and various other cGMP compliance documentation shortfalls.

CHALLENGE

The Square-1 team was brought in to help build out the overall strategy to address our clients' nonconformities while also facilitating the hands-on work to correct their systems, processes and internal communications across two (2) facilities and six (6) departments. This included 1k+ change orders across a dozen product families. Key to the success of this project was ensuring business continuity for our customer.

ACTION

Square-1 aided our customers' executive team in identifying the root cause of its product recall and operational challenges, developed a system wide corrective action plan as well as deployed a team of 26 SME's within 3.5 weeks. The Square-1 team encompassed both management and hands-on engineers working in collaboration with our customer onsite:

- 1 – Program Manager
- 3 – Project Managers
- 11 – R&D Engineers
- 7 – Quality Engineers
- 4 – Manufacturing Engineers

SOLUTION

Square-1's work on this project helped our client successfully avoid a warning letter while keeping it's $1B+ business operational. As a result of Square-1's ability to dive into the project quickly and solve problems in rapid fashion the project was successfully concluded ahead of time, shortening the initial project scope by 33%, or 6 months, while saving our customer 13.5% off initial budget.

33%
TIME SAVINGS

SQUARE-1
THE MEDTECH PROBLEM SOLVERS