SQUARE-1 ENGINEERING

CASE STUDY

QUALITY SYSTEM REMEDIATION

OVERVIEW

A Class III medical device manufacturer faced multiple FDA 483 observations following a Class I product recall, with nonconformances spanning QMS, Operations, and R&D Sustaining. Square-1 was brought in to quickly address the systemic issues while protecting business continuity across the organization.

CHALLENGES

System-wide nonconformances across QMS, Operations, and R&D, including product performance, training, complaint handling, and cGMP documentation.

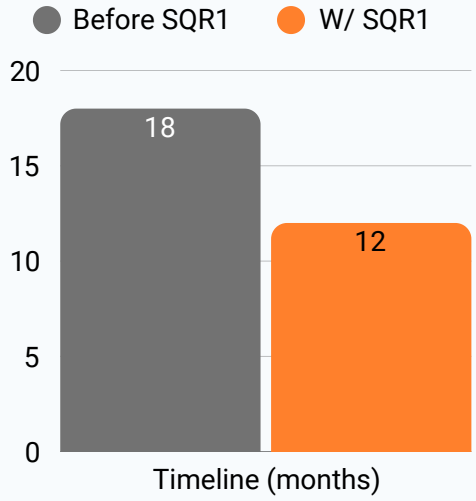
1,000+ change orders spanning 12 product families across two manufacturing facilities and six departments.

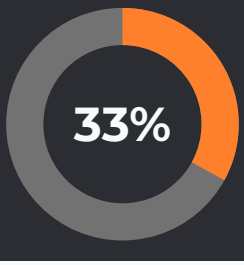
Urgent remediation without disrupting operations, requiring both an enterprise-level strategy and hands-on execution.

SQR1 IMPACT

Solutions from Square-1:

- Deployed 26 SMEs within 3.5 weeks, including Program and Project Managers, R&D, Quality, and Manufacturing Engineers
- Partnered with executive leadership to identify root causes behind the recall and broader operational challenges
- Developed and executed a system-wide corrective action and remediation plan
- Provided hands-on support across two facilities, six departments, and 12 product families
- Coordinated and executed 1,000+ change orders while maintaining business continuity





TIMELINE REDUCTION

Completed in 6 months less than the originally projected timeframe.

ABOUT SQR1

At Square-1 Engineering, we provide technical consulting services across the entire medical device product life cycle from product ideation to obsolescence. Our skilled engineering and compliance teams take on projects of all sizes in R&D Engineering, Quality & Compliance, Regulatory (RAQA) and Manufacturing Engineering.

When Companies Need Us:

Regulatory Events
Loss of Key Personnel
Rapid Company Growth
Lacking SME
Audit Preparedness
Bandwidth Constraints
Next Gen Development
M&A Support
Facility Moves & Transfers
Change in Supply Chain

Capabilities

Engineering & Ops: Square-1 provides engineering and operational expertise needed across the entire product development lifecycle.

Regulatory & Compliance: We help clients build quality and regulatory practices which protect the business while enabling it to move forward.

Executive Strategy: Seasoned medtech executives who help organizations navigate growth, solve complex challenges, and execute strategic initiatives.

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