SQUARE-1 ENGINEERING

CASE STUDY

QMS | POST-ACQUISITION REMEDIATION

OVERVIEW

Following a recent acquisition, our client faced immediate regulatory and quality challenges across its U.S. and European operations. They needed to stabilize and align their Quality Management System (QMS) to comply with EU MDR requirements and meet MDSAP audit criteria. With an audit looming and only six weeks to prepare, the priority was to deliver a structured, controlled, and auditable QMS package while addressing deficiencies in both the legacy and newly acquired systems.

CHALLENGES

Over 100,000 documents and inconsistent RA/QA processes across U.S. and European operations.

U.S. and European quality systems needed urgent alignment with MDR and MDSAP standards.

Critical document control, training, and high-priority deficiencies required remediation in six weeks.

SQR1 IMPACT

Our team of five quickly assessed and remediated the client's fragmented QMS, standardized procedures, and updated documentation to meet EU MDR and MDSAP requirements. We delivered a fully auditable QMS package gearing for the six week due date, ensuring they were prepared for the upcoming audit.

Key Deliverables:

- Gap assessment report highlighting high-risk deficiencies
- Standardized SOPs, work instructions, and procedures
- Updated training records and document control processes
- Fully compiled audit-ready QMS package

Estimated Length of Time to Complete Project
with vs without SQR1 Services

100,000 Documents

Our team is actively integrating and standardizing over 100,000 documents across U.S. and European operations, ensuring audit-ready compliance every step of the way.

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

MedTech Consulting: Stay compliant with FDA and ISO regulations, support design projects, and streamline manufacturing processes.

CAD Services: Ensures design accuracy, traceability, and full alignment with regulatory standards at every stage.

Technical Training: Our subject matter experts deliver targeted training to keep your team sharp, compliant, and confident.

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