SQUARE-1 ENGINEERING

CASE STUDY

EU MDR COMPLIANCE

OVERVIEW

Our client, a Class III global medical device manufacturer, needed to bring eight product lines into full compliance with EU MDR requirements. With regulatory deadlines approaching and multiple systems requiring updates, the company partnered with SQR1 to manage documentation, validation, and production readiness across its portfolio.

CHALLENGES

- Tight EU MDR transition timeline with eight product lines requiring documentation and manufacturing updates.
- Complex coordination across vendors, approvers, and the client's PMO.
- Integration into organization's EU MDR systems and processes while maintaining quality and compliance standards.

SQR1 IMPACT

Solutions:

- Deployed a two-person team to manage MDR compliance across eight product lines.
- Processed and released updated GTINs, drawings, BOMs, and manufacturing procedures through DCO.
- Executed software validation protocols and coordinated IFU component qualifications.
- Partnered with vendors to update materials and specifications in line with MDR requirements.
- Created and tracked Gantt chart; coordinated with approvers and vendors; updated PMO

Hear From Our Client

"I wanted to take a moment to thank you for all the effort and support to deliver results the right way by completing all activities related to NV-DR EU MDR. We have had many challenges; however, as a team we have been able to face it together to achieve great results. Now we are getting closer to being commercially ready and I couldn't be more excited to work along with you to see successful implementation of these changes. Your commitment and hard work have made this possible. Thanks!!!"

- Senior Program Manager

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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