



SQUARE-1
ENGINEERING

CASE STUDY

NPD QUALITY ENGINEER



OVERVIEW

While transitioning into its first New Product Introduction, a Class II medical device manufacturer was simultaneously advancing multiple R&D programs toward near-term 510(k) submissions. With limited internal bandwidth and growing regulatory pressure, the team needed experienced support to stabilize documentation, maintain compliance, and keep development moving without delay.



CHALLENGES

Managing multiple concurrent NPD programs with overlapping verification and regulatory timelines.

Ensuring DHF, verification, and quality documentation met FDA and cGMP expectations ahead of submission

Maintaining document accuracy, traceability, and version control while teams scaled and priorities shifted



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SQR1 IMPACT

Solutions from SQR1:

- Supported two projects with hands-on technical documentation ownership
- Conducted detailed reviews of verification reports, DHF files, and quality documentation to confirm FDA compliance
- Improved document accuracy and traceability through formatting updates, version control, and cGMP-aligned practices

Performance Rating



Client completed their 510(k) submission by the end of the year.

Teammate Feedback from Client:
“Square-1 provided two strong candidates back-to-back and we are highly satisfied with the partnership. I am disappointed we couldn’t keep [the teammate] for longer.”

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.

