



SQUARE-1
ENGINEERING

CASE STUDY

SYSTEM BUILDS



OVERVIEW

Our client, a stroke treatment developer, faced significant delays after two prior suppliers underperformed. Component automation failures, UI issues, and lack of transparency stalled progress, threatening both international shipping timelines and internal Board expectations.

CHALLENGES



Previous vendors failed to deliver, requiring a trusted partner experienced in complex system builds.



Systems required embedded software programming and full system-level verification and validation.



Two hydrophilic coating systems needed to be fully functional on schedule to meet international shipping and Board requirements.



SQR1 IMPACT

Solutions from SQR1:

Square-1 deployed a focused team (1 Electrical Engineer, 1 Software Developer, 1 Project Manager) to rescue the project:

- Reverse engineered the full system and rebuilt each subsystem from the ground up.
- Reviewed, edited, and verified all code while creating a new UI with integrated safety mechanisms.
- Developed a troubleshooting protocol to simplify system-level adjustments for operators.

Performance Rating



2 Weeks Ahead of Schedule

The SQR1 team's efforts allowed our client to internationally ship its hydrophilic coating system on time while meeting Board expectations.

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.

