SQUARE-1 ENGINEERING

CASE STUDY

GLOBAL PRODUCTION EXPANSION

OVERVIEW

Our client, a Class III medical device manufacturer, was scaling from early-stage commercialization into a global operation. Demand outpaced production capacity, driving the need to expand across five strategic locations. With a competitor moving aggressively into their market, the client needed rapid, dependable growth supported by stronger validation, compliant operations, and scalable manufacturing processes.

CHALLENGES

Production facilities had to be upgraded and retrofitted without interrupting ongoing manufacturing.

SOPs and compliance documentation needed to shift from general pharmaceutical standards to full device cGMP.

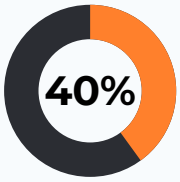
The client required a structured validation framework to reduce regulatory risk and support future FDA audits.

SQR1 IMPACT

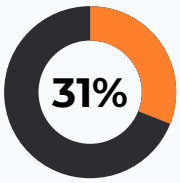
Solutions:

- Deployed a team of three medical device SMEs to lead scale-up across three facilities while keeping production active.
- Built the client's first formal device validation program.
- Completed IQOQPQ on 200+ pieces of equipment.
- Redesigned cleanroom and facility layouts for higher throughput.
- Led cGMP compliance gap analysis and equipment acquisition efforts.
- Implemented targeted process improvements that accelerated production and strengthened long-term compliance.

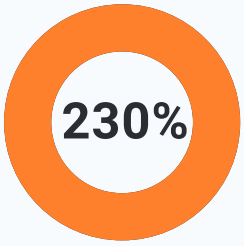
Results:



Production Volume: Production volume increased by over 40% year-over-year after facility upgrades.



Yield Improvement: Defects reduced by 31%, significantly improving overall yield.



Validation Speed: Equipment validation completed 230% faster than the original goal, freeing time for strategic investments.

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.

www.square1engineering.com
info@square1engineering.com
SQUARE-1 ENGINEERING