SQUARE-1 ENGINEERING

CASE STUDY

CLEAN ROOM EXPANSION

OVERVIEW

Our client, a Class III medical device manufacturer, was evolving from an early commercial operation into a global producer. Rapid growth and rising demand exposed a shortfall in cleanroom capacity, driving a large-scale expansion across five strategic manufacturing sites worldwide. Square-1 Engineering was brought in to guide and execute the cleanroom retrofits, integrate advanced automation, and ensure compliance readiness.

CHALLENGES

Existing cleanrooms lacked the capacity and automation needed to meet global production targets.

The company's production SOPs and compliance documentation were still rooted in pharmaceutical standards rather than medical device cGMP.

Needed to include advisory support on proper validation protocols to avoid future FDA warning citations

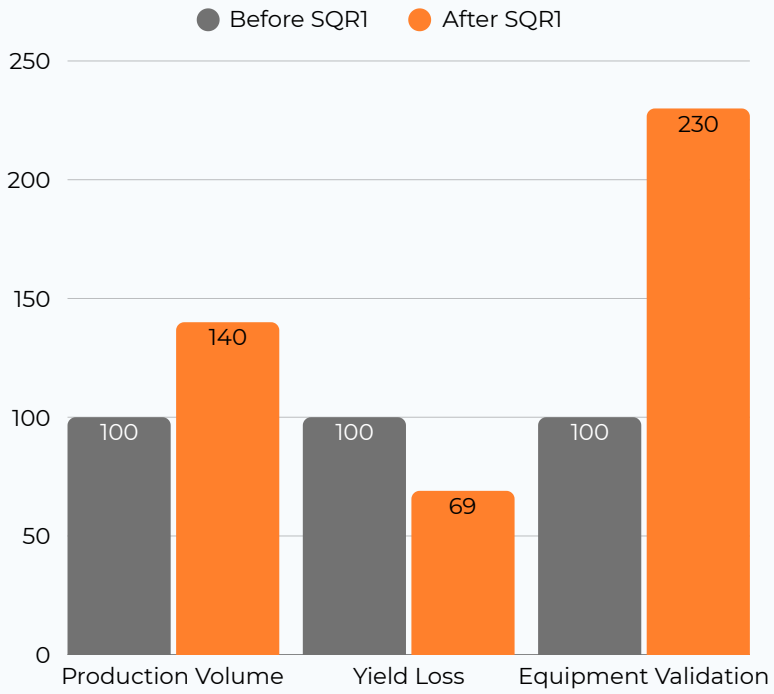
SQR1 IMPACT

Solutions from SQR1:

Square-1 deployed a focused team of three medical device SMEs (1 Project Manager, 2 Manufacturing Engineers) to lead cleanroom scaling efforts across three regional facilities. The team:

- Designed new Class 7 cleanroom layouts
- Conducted cGMP compliance gap analyses
- Managed supply chain and equipment acquisition
- Performed production time studies and process improvements
- Executed IQ/OQ/PQ on **175+ pieces of equipment** (ovens, tube benders, autoclaves, chillers, etc.)
- Developed the client's first formal device validation program

RESULTS



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

Engineering & Ops: Square-1 provides engineering and operational expertise needed across the entire product development lifecycle.

Regulatory & Compliance: We help clients build quality and regulatory practices which protect the business while enabling it to move forward.

Executive Strategy: Seasoned medtech executives who help organizations navigate growth, solve complex challenges, and execute strategic initiatives.

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