CASE STUDY

CLEANROOM EXPANSION

OVERVIEW

Our client, a Class III medical device manufacturer, was transitioning from an early stage commercialized business into a full-fledged international device manufacturer. Its cleanroom production capabilities were falling short of global demand causing this OEM to make a major investment to scale its global operations across five (5) strategic locations. The need for growth was further bolstered as a rival OEM was aggressively targeting their market share.

CHALLENGE

The Square-1 Engineering team was brought in to facilitate and advise our client through the scaling of three (3) regional cleanrooms, retrofitting each with state-of-the-art automation equipment; company was also transitioning its production SOPs and compliance docs from general Pharma standards to those based on device cGMP; work also included advisory support on proper validation protocols to avoid future FDA warning citations.

ACTION

Square-1 deployed a team of 3 medical device SME's (1x PM, 2x Mfg Eng) to facilitate the scaling efforts of each facility as follows:

- Cleanroom layout design (Class 7)
- cGMP compliance gap analysis
- Supply chain mgmt & equipment acquisition
- Production time studies
- Production process improvements
- IQOQPQ of 175+ pieces of equipment: ovens, tumblers, tube benders, ultrasonic cleaners, fume hoods, chillers, autoclaves, hot plates, machine room tooling
- Developed clients' 1st formal device validation program

SOLUTION

Square-1's efforts successfully helped our client retrofit all three (3) of it's regional manufacturing facilities ahead of schedule while keeping production going at all times. Volumes increased as strategically planned by >40% YOY while reducing yields by 31%. Equipment was validated at a rate of 230% of goal allowing our customer to use the extra time to invest in its international facilities ahead of schedule.

230%
Exceed Goal

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