



Summary

TECHNOLOGY

Class III device indicated for reconstructive and cosmetic aesthetic surgery.

COMPANY

High growth publicly traded Aesthetic Medicine company.

CHALLENGE

Assessed and restructured contract manufacturer (CMO) supply chain capabilities, including manufacturing technology, GMP quality management systems, and operational effectiveness. Enhanced parent company governance to improve oversight of GMP-regulated operations, aligning with client demands for quality, service, and growth.

OPERATIONS RESTRUCTURE - AESTHETICS PORTFOLIO

Advisor to CEO / Interim General Manager

ENGAGEMENT

Extended consulting engagement offered dual-sided guidance to both the client and contract manufacturer (CMO) to enhance regulatory compliance, supply chain integrity, strategic decision-making, and operational performance. Phase 1 involved a comprehensive evaluation of operational standards, including quality, productivity, service, and resources. Phase 2 provided interim leadership to drive organizational transformation, core process improvements, and performance results.

OUTCOMES

- Aligned organizational priorities to enhance manufacturing performance, quality, and supply chain scalability.
- Achieved FDA GMP compliance by strengthening Quality System procedures and enforcing organizational accountability.
- Enhanced client relation through restructuring management in Manufacturing, Quality, Planning, and Finance .
- Reduced average unit cost >15% thru value stream mapping and productivity enhancements.

LESSONS

- *Robust CMO alignment on technical, management and cultural parameters is vital to successful business relations.*
- *Underleveraged Quality systems result in unacceptable risk levels and costly remediation.*
- *Corporate post-merger integration of GMP regulated CMO merit strong governance, technical leadership & talent expectations.*
- *Well executed Design Controls from Design Input thru Design Transfer and Validation drive optimal efficiency and cost.*
- *Employee orientation with product expertise, training and physician/patient experiences strengthen business culture.*
- *MedTech/Device contract manufacturing relations should be viewed more as strategic alliances than suppliers.*