

Warning Letter / Process Validation Remediation Project

Background

A large multinational medical device company was challenged with significant validation issues in a warning letter from the FDA. The company needed to remediate validations for more than 500 products to address deficiencies in process validation and develop a comprehensive risk-based validation program for sustainability. Most processes had no formal documentation of validation. Findings also included deficiencies in traceability of label claims to design validation activities. Remediation activities needed to be completed by the next series of FDA inspections.

Objective

Remediation needed to occur during continued manufacturing, and significant training was required to maintain sustaining capability. Gaps in availability of design and process risk analyses and specifications, test method validations (TMVs), and equipment qualification needed to be addressed prior to process validations.

Enhanced Compliance Engagement

Numerous subject matter experts were deployed across two manufacturing sites to augment local teams over a 24-month engagement. The project team supported the remediation effort with the following tasks and activities:

- Creation of Master Validation Plans and Master Validation Reports.
- Update of Product Specifications
- Creation of Product /Manufacturing Fixture /Testing Fixture Drawings
- Development of Risk Management Files: DFMEA and PFMEA
- Drafted/Executed OQ, PQ, PPQ Protocols and Reports
- Drafted/Executed Packaging Validation (OQ/PQ/PPQ)
- Creation of Test Method Validation Plans
- Created and executed Test Methods (Development and Validation)
- Updated Manufacturing Work Instructions
- Developed Process Flow Diagrams (PFDs)
- Addressed Non Conformance Reports (NCRs)
- Remediated Corrective and Preventive Actions (CAPAs)

Result

The client's processes were brought into compliance through an efficient, cost-effective effort. The FDA removed the Warning Letter status. Continuing use of the validation procedures and templates developed during this project has resulted in leaner, compliant operations for the client company.