CASE STUDY

Design History File (DHF)/Technical Files/Design Dossier/Shonin Filing Remediation Program

Background

A large multinational medical device company received notification from a Notified Body that their CE certification would be withdrawn from a number of medical devices due to non-compliance with the Medical Device Directive 93/42/EEC unless all the gaps in the medical device technical files were addressed in a timely manner. CE certification is required to be applied to product labeling in order to market the medical device products in European countries where the CE Mark was required.

Objective

We were tasked to provide program management to bring Technical Files and Design Dossiers into compliance with the Medical Device Directive 93/42/EEC and most current harmonized standards in Europe within time line provided to notified bodies.

Enhanced Compliance Engagement

We managed the $100MM recertification program tasked with bringing Technical Files and Design Dossiers into compliance with the most current harmonized standards in Europe. This multi-year on-site Program Management of remediation effort required to coordinate activities including manage and provide direction to multiple resource pools from client employees and consultants, across several divisions and manufacturing sites. Due to the magnitude of remediation effort required, a phased, risk-based approach was used to ensure efficient progress in accordance with product risk, sales projection and budget limitations.

- GAP analysis performed
  - Initial GAP analysis to evaluate major gaps and basis for Project Proposal.
  - Secondary review to evaluate gaps against updated standards, etc. – "State of the Art" – update budgetary requirements.
- Program Planning:
  - Developed SOP for Technical Files and Design Dossier Recertification.
  - Developed quality plans for each Technical File/DHF.
  - Organized diverse functional and program resources to successfully bringTechnical Files and Design Dossiers into compliance.
  - Developed and managed plans, schedules, and budget for recertification program.
  - Developed and managed program risk.
  - Presented program progress to C-level executives on regular basis.
- Provided overall leadership and direction to the Remediation teams:
  - **Group A:** Sterilization, Biocompatibility Assessment.
  - **Group B:** Market Specifications, Design Validation, Risk Management – Use, Design &

Process, Essential Requirements Checklist.
    - **Group C:** Product Specifications, Test Methods and Test Method Validations, Design Verification strategy, Process Validation.
    - **Group D:** Packaging study and Product Labeling
    - **Group E:** Shelf Life Testing – Product & Package.
- Remediation included following activities:
    - Developed a detailed checklist to review Technical Files and Design Dossier.
    - All Technical File and Design Dossier elements were reviewed for conformity to "State of the Art" including Design Control Requirements.
    - Technical Files and Design Dossiers completely reformatted and rewritten to meet current Medical Device Directive Requirements including Essential Requirements Checklist and resigning of Declarations of Conformity.
    - All Products were evaluated against Japan Ministry of Health, Labor and Welfare (MHLW) PAL Reform requirements and updated in accordance with current JIS requirements, etc. PMDA Shonin filings were re-evaluated and addressed based upon new supporting data as generated.
    - All Document linkages were evaluated to insure cascade of requirements from voice of the customer (Market Specification) to Product Specification through to Process Documentation were adequate and supported by data.
    - Gaps in data were assessed for risk to patient safety, etc. to insure proper due diligence had taken place.
    - Data gaps were filled via protocols, testing and reports.

Project Matrix

- Total budget for the entire program: $100MM.
- Total Product Development Project: 150 DHFs
- Documents Created and / or upgraded: 11,000+
- Test Methods and Test Method Validations: 3000+
- Individual tests performed across diverse product lines: 180,000+

Result

All the Technical files/Design Dossier/DHFs for each medical device product family were updated and completed. The client has been successfully passed the audit by European Notified Body and FDA since completion of the program. The ECI Rx has cured the clients Medical Device Directive 93/42/EEC compliance health.