CASE STUDY

Design Development Project

Background

A large multinational medical device company was challenged with developing a very complex Endo-surgical device and bringing the device to the market with an accelerated timeline. While the employees of the group were still in the development phase of the project, a resource shortage was identified to begin work on the design control elements that would be needed to complete design Development phase Product Development Process.

Objective

We were contracted to provide assistance with Design Development phase tasks (Design Freeze, First Human Use through clinical Product Development Process and Clinical Product Qualification, and manufacturing site transfers).

Enhanced Compliance Engagement

Enhanced Compliance team members supported the following tasks and activities:

- Solid Works support
- Technology /Equipment Assessment and Procurement
- Prototype Development
- Product Specifications
- Product Specification sources documentation
- Created Design Capability Matrix (DCM)
- Performed Tolerance Analysis
- Risk Assessment: Use FMEA and Design FMEA
- Fixture Design, development and procurement
- Test Method Development
- Equipment & Automated System (E&AS) Life Cycle for Test Method Equipment
- Test Method Validation Plan, Protocols & Reports
- Drafting product build Procedures.
- Feasibility run
- Design Freeze Protocol
- Design Freeze testing
- Design VerificationProtocol
- Worked with Process Development team for manufacturing site transfer.

Result

Completed all assigned Design Development activities on time and as originally scheduled.