



Process Development Project

Background

A large multinational medical device company was challenged with developing process to set up a pilot manufacturing line to build a very complex surgical device for first in human use. The device consist of a platform, a guide tube, a controller and multiple single used hot and cold instruments. The client wanted to start clinical trial on time, so they could bring this device to the market with an accelerated timeline.

Objective

We were contracted to provide Process Development oversight which included following tasks:

- Direct and Manage team consisting of ECI consultants and Client Employees.
- Establish critical path task list to drive appropriate resource plan.
- Build strong communication and trust with R&D counterparts in Division which prior to our involvement was problematic.
- Responsible for all client "Management" activities / requirements as Full time Product Development Manager

Enhanced Compliance Engagement

The project team supported the following tasks and activities:

- Master Schedule and Core Team Task List development and monitoring
- Process Flow Diagrams (PFDs)
- Process Specifications
- Risk Management: PFMEA
- Equipment / Technology Assessment and Procurement
- Introduced site to Laser Welding and establishing Plant expertise in this technology
- Fixture Design, development and procurement
- Design of Experiments
- IQ, OQ, PQ Protocols and Reports
- Test Method Development
- Test Method Validation Plan, Protocols & Reports
- Manufacturing Work Instructions

Result

Delivered 1st working unit on time and as originally scheduled.