Manual to automated, efficient and compliant in 7 months.

Case Study

CQV for a Medical Device Manufacturer

INDUSTRY

Medical Device

SERVICES

Automation

Equipment Development

Inspection Readiness

SKILLS

FDA Compliance

Business Analysis

Functional Analysis

Specification Development

Project Management

The Challenge

A medical device manufacturer was in need of help installing and qualifying a completely new piece of automated manufacturing equipment to replace aged equipment which utilized a manual process. Oxford's client sought a team with a robust understanding of inputs and outputs to develop specifications for the equipment manufacturer. These specifications would enable them to build the equipment needed in such a way that the subsequent installation, qualification, and validation activities could occur.

The Solution

To help the client fully automate the production process, obtain the new equipment, and perform the Commissioning, Qualification and Validation activities, our consultant team was responsible for completing the following activities within a seven month period:

- Performing Reverse Engineering studies to correlate manual outputs with automated inputs
- Identifying equipment that would be the best fit for their manufacturing application and esultant product
- Performing Engineering Analysis throughout the Commissioning and Qualification process
- Assisting with outlining User and Functional Requirement Specifications (URS and FRS)
- Drafting and executing all related Computer Systems Validation (CSV), Logic Test Cases and Installation/Operational/Process Qualification (IQ/OQ/PQ) activities

The Result

Oxford's team enabled the client to become compliant with both company and industry requirements. Custom equipment was purchased by the client based on the User Requirements Specifications and Functional Requirements Specifications development documents created by the engagement team, in collaboration with the equipment manufacturer, which allowed for the creation of a fully automated production process. Oxford's team efforts also allowed the client to bring a robust manufacturing process online to produce functional product with no product stock shortages or market disruptions.

Our client underwent a subsequent FDA inspection, in which the developed process was reviewed, with zero FDA Form 483 observations.

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