REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Manufacturing Automation

Client

Medical Device Manufacturer

Industry

Medical Device

Business Challenge

To validate software of assembly and to validate equipment that had been recently built.

Background

A medical device manufacturer designed and built automation equipment to assemble and weld medical-grade check valves. The automation component of the equipment consisted of a PLC, an HMI, a vision system, and an ultrasonic welder. An ISO audit found that the software driving the client's automated assembly equipment had not been validated. Additionally, new, urgently needed equipment had recently been built and needed validation, but the client did not have sufficient software validation expertise available in-house.

Challenge

Regulatory Compliance Associates® Inc. (RCA) was contracted to develop validation documentation and provide validation services to ensure software was adequately validated and the valve assembly machine was prepared for production. The entire process required completion within an aggressive time frame.

RCA Approach

RCA provided software validation as an integral part of equipment validation. A risk assessment was performed to determine which user and functional requirements represented the greatest risk to product quality and patient safety (per GAMP 5). The functions that presented the greatest risk received the highest level of testing to ensure that the automation equipment consistently assembled components to meet critical product specification requirements. This approach provided a robust validation and reduced the overall validation project time-line.

Result

The validation was completed within the aggressive time frame, and the validation effort focused on equipment functionality that represented the highest risk to product quality and patient safety. The client received a dependable validation and the new equipment was available for production by the project target date.

"RCA provided a robust validation and reduced the overall validation project time-line."

References

1. U.S. Department Of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, “General Principles of Software Validation; Final Guidance for Industry and FDA Staff,” January 11, 2002.

2. International Society for Pharmaceutical Engineering (ISPE), Good Automated Manufacturing Practices 4 (GAMP4), December 2001.

3. International Society for Pharmaceutical Engineering (ISPE), Good Automated Manufacturing Practices 5 (GAMP5), April 2008.

4. International Standards Organization, ISO Standard 13485: Medical devices—Quality management systems—Requirements for regulatory purposes. Second Edition, July 15, 2003.