



RCA Case Study

Computer & Software
Validation

Manufacturing
Automation

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, HMI, 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 prepared for production. The entire process required completion within an aggressive time frame.

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 timeline.

Result

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

References

1. FDA Guidance - General Principles of Software Validation, CDRH, January 2002
2. GAMP4, Good Automated Manufacturing Practices, ISPE, December 2001
3. GAMP5, Good Automated Manufacturing Practices, ISPE, April 2008
4. ISO 13485 - Medical devices - Quality management systems – Requirements for regulatory purposes

Regulatory Compliance Associates Inc.

262-842-1250

www.rcainc.com

RCA-CS-251