REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Process Validation Remediation

Client

Medical Device Manufacturer

Industry

Medical Device

Business Challenge

Develop a risk prioritized remediation plan emphasizing regulatory and business risk.

Project Time-line

18 months

Background

A large global medical device manufacturer received a Warning Letter from the FDA as a result of repeat 483 observations for process validation deficiencies. The company needed to remediate validations for more than 500 products and develop a comprehensive risk-based validation program for sustainability. Remediation needed to be completed by the next series of FDA inspections.

Challenge

Remediation needed to occur during continued manufacturing, and significant training was required to maintain a sustaining capability. Gaps in availability of both design and process risk analyses and test method validations (TMVs) needed to be addressed prior to process validations, and software validation studies were needed for automated manufacturing and data collection systems.

RCA Approach

Regulatory Compliance Associates® Inc. developed a risk-prioritized remediation plan with emphasis on regulatory and business risk. Following a survey of existing design and validation data, risk analysis documents for each major product line were generated. A validation program was developed in concert with the operating requirements of 14 global manufacturing sites. Training was developed and deployed, and RCA provided validation teams at each site to execute validations in conjunction with local professional staff.

Result

The 18-month project delivered 24 updated risk management files and over 1800 unique IQ / OQ / PQ and test method validation studies for the company. RCA provided both classroom and hands-on training to worldwide sites. FDA inspections at client sites resulted in no additional 483 findings related to validation.

"A validation program was developed in concert with the operating requirements of fourteen global manufacturing sites."

References

1. FDA Code of Federal Regulations, Title 21, Parts 210, 211, and 820.70. April 1, 2010.

2. Global Harmonization Task Force SG3, "Quality Management Systems—Process Validation Guidance," Edition 2, January 2004.

3. U.S. Department of Health and Human Services, Food and Drug Administration, "Guideline on General Principles of Process Validation," May 1987.

4. U.S. Department of Health and Human Services, Food and Drug Administration, "Guide to Inspections of Quality Systems," August 1999.

5. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, "Design Control Guidance for Medical Device Manufacturers," March 11, 1997.

6. U.S. Department of Health and Human Services, Food and Drug Administration, "Guidance for Industry: Q9 Quality Risk Management," June 2006.

7. International Standards Organization, ISO Standard 14971: Medical Devices—Application of risk management to medical devices. 2007.