



RCA Case Study

Process or Test
Method Validation

Process Validation
Remediation

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 500+ products and develop a comprehensive risk-based validation program for sustainability. Remediation needed to be significantly completed by the next series of FDA inspections.

Challenge

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

Approach

Regulatory Compliance Associates, Inc. (RCA) 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. Classroom and hands-on training was delivered to worldwide sites. FDA Inspections at client sites resulted in no additional 483 findings related to validation.

References

1. Code of Federal Regulations (CFR), Title 21, Parts 210, 211 and 820.70
2. Global Harmonization Task Force SG3 "Quality Management Systems – Process Validation Guidance, Edition 2", January 2004
3. FDA Guidance – General Principles of Process Validation, May 1987
4. FDA Guidance - Inspections of Quality Systems, August 1999
5. FDA Guidance - Design Control for Medical Device Manufacturers 3-11-97
6. FDA Guidance - Q9 Quality Risk Management June - 2006
7. ISO 14971 (2007) - Application of Risk Management to Medical Devices

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