REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Gap Assessment Electronic Records

Client

Bulk Chemical Manufacturer

Industry

Pharmaceutical

Business Challenge

Preforming gap assessments of quality software systems and laboratory systems.

Project Time-line

6 months

Background

In preparing for an upcoming audit by the FDA, a pharmaceutical-grade bulk chemical manufacturer required a gap analysis to determine compliance of quality and laboratory software to requirements for Electronic Records (21 CFR Part 11).

Challenge

RCA was contracted to perform a gap assessment of eight quality software systems and twenty-nine laboratory software systems.

RCA Approach

Regulatory Compliance Associates® Inc. developed an assessment strategy that involved client interviews for each of the software systems to determine compliance with specific requirements of Part 11. Then a risk assessment was performed to determine highest risk software systems based on compliance with Part 11. Finally the software systems were prioritized based on the risk analysis. This prioritization was used to develop a remediation plan to bring all software into compliance.

Result

The results of the gap assessment, risk analysis, and prioritization were presented to the client. Within a month, the FDA visited the client and reviewed the assessment and remediation plans. The FDA determined that the client had adequately demonstrated that they were in the process of complying with Part 11, and did not make a regulatory observation.

"After reviewing remediation plans, the FDA chose not to make a regulatory observation."

References

1. FDA Code of Federal Regulations, Title 21, Part 11, “Electronic Records; Electronic Signatures.” Final Rule, March 1997.

2. U.S. Department of Health and Human Services, Food and Drug Administration, “Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application,” August 2003.

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

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