Brevitas
People, Process and Program Excellence

CASE STUDY

Data Integrity Compliance Project Completed Ahead of Schedule and Under Budget

An internal audit of a top generic pharmaceutical manufacturer identified deficiencies in their legacy computerized systems related to SDLC requirements (GAMP standards, FDA 21 CFR Part 11 & Data Integrity). Brevitas consultants were enlisted to deliver an effective solution to bring the existing systems into regulatory compliance.

AT A GLANCE

INDUSTRY
Pharmaceuticals

AREA OF EXPERTISE
Regulatory Compliance

SERVICES PROVIDED
- Project Management
- FDA 21 CFR Part 11 & Data Integrity Compliance
- Computer System Validation
- Organizational Change Management

DURATION
9 months

IMPACT
During Phase 1, 13 legacy systems were brought into FDA 21 CFR Part 11 and data integrity compliance, at par with industry best practices. These results spanned the Greater Toronto Area, and came in three months ahead of schedule and under budget.

Business Challenge

Following our client's internal audit, several technical & procedural deficiencies were identified, related to legacy computerized manufacturing & packaging systems, in relation to system security, audit trail, and electronic record management. These deficiencies rendered the equipment non-compliant with most FDA 21 CFR Part 11 and data integrity requirements. The challenge was to perform a comprehensive review of each system; each with widely differing software capabilities, and develop a software lifecycle management plan that would comprehensively address these issues, incite a perceptible change in organizational awareness, and spur adoption of industry best practices.

Our Scope

Brevitas was selected to prepare a complete compliance package for each of the impacted legacy systems. A total of 61 pieces of equipment were to be covered in a 3-phase project with stringent deadlines for each phase. The first stage of each project phase involved identifying as-built computer system capabilities, gap assessments, risk analyses, and development of a detailed mitigation plan. The second stage involved the execution and implementation of the mitigation plan to bring the legacy systems into FDA 21 CFR Part 11 and data integrity compliance, at par with industry best practices.

Value Added

- Raised awareness on the importance of data integrity and FDA 21 CFR Part 11 (going forward, all capital engineering projects are to include discussions with vendors to incorporate these regulatory requirements)
- Infused a system development lifecycle (SDLC) culture throughout Engineering, QA, and Production
- Established an efficient process for implementing changes to minimize the challenges of integrating best practices into client's operational ecosystem
- Received recognition from other international sites and set a successful example for similar future projects

Results Achieved

- Developed templates for use in system & equipment qualification, including:
  - URS integrated with computerized system requirements
  - Gap analysis and remediation plans for legacy computerized systems with emphasis on FDA 21 CFR Part 11 and data integrity compliance
  - Computerized system test procedures to be incorporated into qualification
  - Validation summary report with traceability matrix
- Updated internal policies & procedures for user access management and data back-up/ archival/ retention to ensure alignment with corporate SDLC standards
- Provided training to Engineering, QA, and Production on computerized system development lifecycle requirements

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