

COMPANY CASE STUDY

Providing Sustainable Compliance Services and Solutions

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BACKGROUND

An independent Mumbai-based CRO firm needed support for overall GAMP5 CSV and ALCOA+ DI compliance during digitizing their end-to-end lab automation solutions, namely analytical study management, Lab information management, document management, etc.

SOLUTION

The services covered the overall lifecycle management framework based on the GAMP5 guide. Procedures were established for vendor assessment, evaluation, and audit; computerized system validation and periodic review.

Following services were provided to the client:

- Vendor audit covering vendors' QMS, SDLC, and validation credentials
- Evaluation of software product for 21 CFR Part 11, Annex 11 features compliance
- Complete validation lifecycle documents including URS, FS, DS, FRA, CS, IQ, OQ, PQ, VSR, and RTM.
- Release of validated product into operations
- Establishment of lifecycle SOPs for Data backup/restore, audit trail review, System admin
- Classroom training to vendor and clients IQ, QA, user team

BENEFITS

1. Compliant Software Development

Integration of SDLC and CSV for built-in 21 CFR Part 11 and GAMP5 compliance. Major reduction in repetitive testing documentation

2. CSV Framework

Establishing CSV process for the company, periodic review mechanism to stay validated. Consistency in CSV linked to GAMP5

3. Trained Resources

Developing internal SMEs and training to handle audit independently.

AT A GLANCE

CHALLENGES

- Software Vendor Audit for SDLC and GAMP5 compliance
- Building CSV SOP
- Internal awareness and training

write to us at

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"For over a decade, our company has been building compliance into client's digitization journey to make the software experience delightful."