

COMPANY CASE STUDY

Providing Sustainable Compliance Services and Solutions

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BACKGROUND

A leading Indian CRO company, also having their operations in the UK and had complete laboratory setup with various analytics software such as LCMS, GCMS, SAS, WinNolin, etc. The UK unit was expecting an MHRA audit and being governed under GCP, full validation and compliance as per 21 CFR part 11 and EU Annex 11 was expected.

SOLUTION

The solution offered has been based on GAMP5 guidelines which are well-accepted industry best practices for computerized system validation. For creating a validation package, other GAMP good practices guide such as Laboratory Computerized System had been referred.

The validation package contained the following documentation:

- Support for User Requirement Specifications
- Validation Plan
- Functional Risk Assessments
- Test protocols -IQ, OQ, PQ for all software
- Complete test execution and reporting
- Traceability matrix from URS to Testing
- Compliance checklist with 21 CFR Part 11 and Annex 11

BENEFITS

1. Regulatory Compliance

Configuration and validation of controls for data integrity compliance. Audit ready.

2. Consistent Quality

Full CSV as per GAMP5 to demonstrate intended use. Risk-based strategies to reduce redundant paperwork. Traceability to compliance. trustworthiness of data/records.

3. Economical Solution

Optimized onsite and offsite (at India) work enable client to derive maximum cost benefits.

AT A GLANCE

CHALLENGES

- Being Audit Ready
- Computer System Validation
- Knowledgeable resources

write to us at sales@ingenicotech.co.in for details.



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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."