

COMPANY CASE STUDY

Providing Sustainable Compliance Services and Solutions

www.ingenicotech.co.in

BACKGROUND

A leading Canadian client has been using SAP BI for their inventory, purchase, quality assurance and sales distribution. The company has been governed under regulatory expectations of US FDA and Health Canada for software compliance. The enterprise application needed to be validated for 21 CFR Part 11 and EU Annex 11 compliance.

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 Global Information Systems and IT infrastructure compliance have been referred.

The validation package contained the following documentation:

- Initial gap assessment towards GxP, 21 CFR, and EU regulations.
- Creation of a validation strategy, validation plan, IQ, OQ, PQ, and a validation report.
- Risk management and checklist-based risk analysis.
- Traceability matrix from URS to Testing
- Validation training workshops.

BENEFITS

1. Regulatory Compliance

Configuration and validation of controls for data integrity compliance. Improved compliance by 75%, with reduction in manual errors.

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

- GxP Compliance
- Process, Solution & Compliance knowledge
- Project Cost

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



JAYDEEP CHHATRAPATI

Director

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