

COMPANY CASE STUDY

Providing Sustainable Compliance Services and Solutions

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BACKGROUND

The USA-based company had implemented an Oracle-based ERP solution a decade back. ERP upgradation and additional MES module have been planned. As the initial CSV had been internal & over the decade regulatory expectations have gone through much change, client opted for independent subject matter expert opinion of their planned ERP upgradation and validation documentation.

SOLUTION

Secured FTP drive access was established for document sharing. Microsoft TEAMS platform was used for video conferencing and system walkthroughs with functional SMEs where required.

The following services were provided to the client:

- Review of initial and revalidation documentation for ERP and MES as advocated by GAMP5 guidelines and company SOP
- Mapping of Validation documentation against the currently implemented system.
- Review of applicable Data Integrity Aspects into Validation Documentation including US FDA 21 CFR Part 11 / EU ANNEX 11
- Gaps in CSV approach and recommendations.

BENEFITS

1. Updated CSV documents

CSV documentation and approach in line with current GAMP5 and regulatory expectations.

2. Effective Time Management

Time difference between India and USA has been used for faster project management

3. Audit Ready

Confidence in new implementation and controls. Traceable CSV documents to support intended and authorized usage.



AT A GLANCE

CHALLENGES

- Remote Assessment
- Time difference
- Business Process, Oracle software and GAMP5 expertise

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."