

# COMPANY CASE STUDY

Providing Sustainable Compliance Services and Solutions

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## BACKGROUND

The client has multiple (10+) formulation facilities spread across India. The majority of exports are to the USA and hence face strict regulatory audits around the year. Being a quality-conscious organization, they initiated a global computer system compliance assessment and remediation program.

## SOLUTION

We developed a protocol-based assessment program. Identified unit wise core team members and trained them in protocol execution. The protocol covered assessment towards:

- 21 CFR part 11 compliance of all computerized systems
- Computerized system validations as per GAMP5
- Governing framework for lifecycle management

The core team executed the protocol for all computerized systems at each unit with our assistance.

- For each system gaps and remediations were identified.
- A common remediation plan was created.
- Centralized Computerised System Compliance Framework was enhanced with Policies/SOPs.
- Internal Trainers and Auditors were identified and were provided full training to independently handle the duties.

## BENEFITS

### 1. Centralized Consistent Practices

Uniform policies, consistency in compliance expectations and documentation.

### 2. Audit Ready

Readiness of internal SMEs for continuous monitoring, coaching, and improving CS compliance practices. Internal auditing makes units always audit-ready.

### 3. Trustworthy Records

•Data reliability, confidence in data/records and enhancing company's image

## AT A GLANCE

### CHALLENGES

- Inconsistent and diverse compliance practices
- Project Management
- Skilled Resources

write to us at  
[sales@ingenicotech.co.in](mailto: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."