

# COMPANY CASE STUDY

Providing Sustainable Compliance Services and Solutions

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## BACKGROUND

A leading Indian multinational company engaged in providing skills and talent development solutions. To support their Pharma clients, they need to establish GxP compliant framework and validate software platforms being used to provide such services including IT infrastructure compliance.

## SOLUTION

A Core team consisting of QA, users, and IT has been formed. The team has been coached for computerized system compliance and validation expectations. The program covered expectations of GAMP5 CSV, 21 CFR Part 11, EU Annex 11, ALCOA+ DI, and lifecycle management procedures.

The following has been achieved with us:

- Computerized System Compliance Framework, linked to existing QMS
- Inventory of computerized systems.
- Complete CSV documentation for all GxP software
- IT infrastructure qualification documentation
- Document Automation using Sharepoint, CSV of same

All these have been achieved remotely during the pandemic within less than a year and before customer audit.

## BENEFITS

### 1. GxP Compliance and DMS

Standardization of all GxP documents, management, traceability and electronic signatures based authorizations

### 2. CSV Framework

Complete CSV framework, SOPs and documentation for all GxP Software. Traceability to regulatory compliance

### 3. Audit Ready

•Sustainable GxP compliance led to huge new business from global pharma companies.

## AT A GLANCE

### CHALLENGES

- No in-house expertise for GxP compliance
- Time-bound business critical project
- Achieving compliance during pandemic

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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."