



## Case Study

# Electronic Validation Solution Implementation of JDE System Upgrade of 33+ Sites, for Leading US-Based Pharma Products Manufacturer

## Client

Drug manufacturer and global provider of drug delivery technology and development solutions for drugs, biologics, and consumer health products.

## Challenges

Our client had been following manual CSV process, which was hard to manage across its 33+ sites. As the market is flooded with number of CSV tools, handling different aspects of CSV, the client wanted us to understand their needs, and suggest a best-suited tool to address the following key requirements:

- The strenuous effort and time spent in sending, co-ordination for documents review/approval across various teams/sites involved in projects
- The huge amount of paper being wasted to store documents and its complexity to relocate documents at time of FDA audits
- Effective handling of Test Deviations, Change controls, and Risk Assessments all in parallel
- The effort and complexity involved in building a paper-based Requirement Traceability Matrix document
- Timely review and approval of documents, lack of proper oversight of review/ approval status
- Secure storage on sensitive data, which needs to be submitted to FDA when required
- Streamline its document development, assigning, review, and approval process across sites
- One stop to build and store documents, execute, handle deviation, change controls, manage risk assessment, apply traceability matrix, and workflow configurations

Therefore, the client decided to implement and adapt an electronic validation solution to effectively address the above business challenges.

# LTIMindtree Solution

LTIMindtree had detailed requirement understanding sessions with the client to understand its business process, and accordingly analyzed suitable tools available in market



Based on client requirements, we recommended ValGenesis Validation tool, as it is capable of end-to-end integrative support to handle various components of Validation



Enabled automated planning, managing, electronic execution, electronic signatures, and controlling of different validation entities



Smooth process of archiving and visibility to audit trails



Quick traceability check and retrieval of information at time of audits



Management Dashboards to have a quick view of Validation status at organization and application level



LTIMindtree has assisted the client to implement and adapt 100 % paperless validation approach, allowing Catalent users to manage documents in a controlled environment and streamline its review and approval process



Role-based authentication and views.



Daily task home page and alerts/reminders for pending activities to each user



## Business Benefits

- 100% paperless validation
- Improved Compliance with conformance to GxP guidelines and 21 CFR Part 11 requirements
- 75% reduction in manual errors, which are caused due to manual validation approach
- Enhanced security features with single sign-on capability through integration active directory
- Reduced validation cycle time by 30-50%
- Cloud-based pay-per-usage service
- Enhanced view of Traceability Matrices
- Risk Management
- Management Dashboards

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