GoVal
PAPERLESS VALIDATION

# Paperless Validation
## Case Studies

# Paperless validation for an Indian based Pharma Company

The **customer** is one of the **leading pharma companies** India and ranked amongst the leaders in therapeutic segment of cardiovascular (CV), central nervous system (CNS), gastro-intestinal (GI) and women healthcare (WHC).

## Business need - Improve and fully digitize CSV

- The customer was looking for a software solution to transform existing manual way of validation to paperless Computer System Validation (CSV). In specific, the customer wants to eliminate the manual errors during the testing, **streamline the review and approval processes.**
- To bring down the validation and approval process timeline and looking to improve **operational efficiency.**
- Execution of test protocols, record deviations, automatic generation of **traceability** matrix and Validation Summary Report (VSR)

# End to end digitization

The platform was configured and validated **within 12 weeks**. The CSV and Change management process was set up on the platform and **user acceptance testing (UAT) completed** in a month time.

End to end validation Life cycle including project setup, URS, Risk assessment, test protocols, electronic review and execution, electronic signature, traceability matrix and validation summary report.

The complete solution was live **within 3 months**, including training and all validation deliverables. This streamlined paperless CSV had a substantial impact on the business by enabling greater productivity, shorter cycle times and a higher compliance standard.

## Key Benefits

- Eliminated 100% of paper-records & VLMS through GoVal solution. FMEA based **risk assessment**, GxP assessment as per their existing SOP, GAMP categorization and suggestion of validation documents as per impact assessment.
- In-depth analysis of test case and their results and discrepancy management. Parallel execution of test scripts with screen recording, **uploading of instrument results and screenshots**
- Provides validation project plan, enabled the task allocation and follow-up within the system. Document management System (DMS) to store all the generated PDF documents.
- Collaborate in real time with multiple users. Complete transparency during validation cycle and **automated workflow** for each document
- Provides Validation Summary Report (VSR), system release certificate and **enable periodic review** process for all the approved documents
- Enabled leveraging and reuse of previous validated information and systems. Provides **inventory** of all validated records during audit.
- Improved audit preparedness. Improved metrics on all aspects of the process like dashboard on **real-time validation status** based on deliverables.

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# Our Approach

## Discovery Phase

Understanding existing paper based manual system

Analysis on current organization Validation Master Plan (VMR)

Inventory of exiting GxP systems. (Both software, hardware and Instruments)

Understanding on existing Audit reports by various regulatory bodies

Review of existing SOPs

Understanding IT organization policies related to infrastructure and security requirements

## Planning Phase

Identify the project which needs to be implemented using paperless validation tool

Identification of key users for product training.

Enabling a pilot project to showcase the product features to the identified users

Dedicated Account manager will help in URS preparation, project planning and task allocation.

## Implementation Phase

We offer multiple deployment & costing models that suit our customer's internal and external needs.

GoVal software can be deployed at the customer's data center (on-premise) as well as public cloud such as AWS and Google Cloud Platform.

Proving single point of contact for immediate query and support

Consultant will ensure the smooth project execution.

In case of any support, the consultant provides online / email / screen sharing support.

User acceptance and end user sign off

## Support & Audit Phase

Defining clear SLA during the contract phase which will help for the customer to get a single point of contact during support.

In build Knowledge base with videos of training material for immediate assistance

On demand CSV consultant for ongoing project support if required

On demand support during regulatory audits to showcase the paper less validation.

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# THANK YOU

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