



**GoVal**  
PAPERLESS VALIDATION

# Paperless Validation Case Studies

# Equipment validation & Electronic Data Capture using IoT devices

The customer is a **KSA based quality consulting** company-providing consultancy to health care and food industries. The company established in 2013 and have group of consultants located globally from varied expertise and backgrounds. The customer wants to implement GoVal solution for one of their Pharmaceutical customer to automate equipment validation and maintenance activities

## Business need - Automation in validation process

Ability to maintain the equipment inventory across multiple sites. Eliminate **100% of paper-records** for temperature and humidity logs.

Maintain equipment register and equipment related status with their periodic review activity

**Integration of IoT based devices** to capture temperature, humidity and various data points for equipment

Electronic review of logs, system generated calculations, Notifications & alerts for equipment



# Our solution and Business Benefits

## Digital Validation & Qualification

The platform helped to digitized validation approach for their Commissioning and Qualification processes.

Electronic Data Capture integrated with Rombee IoT devices for temperature and humidity

Allows users to perform calibration and preventive maintenance activity for all the equipment across multiple sites.

**Digitizing** facilitates the speed, accuracy, transparency and management of validation process. Achieve Quality Assurance (QA) best practices, improve productivity and reduce go-to-market cycle time.

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## Compliance & Standards

Helps to implement GMP standards, perform GxP assessments for GAMP classification

Electronic records, electronic signatures, role based access management and audit trail to comply with 21 CFR Part 11 and Annex 11 regulations

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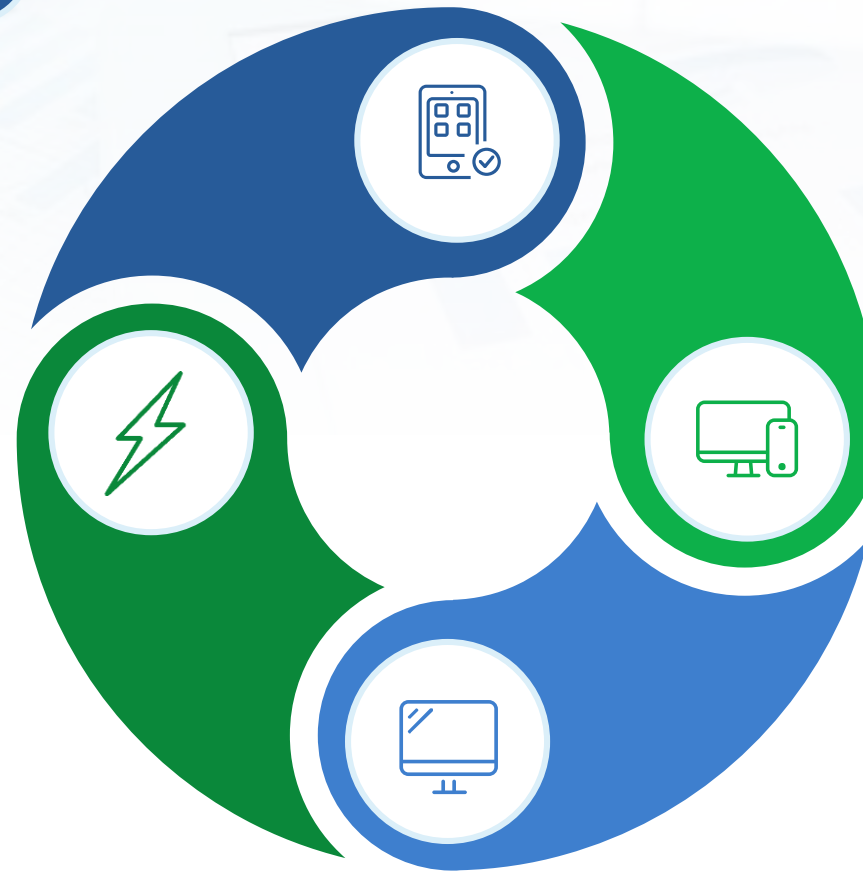
## Mobility and Central Reporting

Accurate & real time data of temperature and humidity data with auto generation of charts and reports.

Enabled the user to avoid any human error during data entry or calculations.

IoT & Mobility solution made field inspections easy and audit ready.

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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

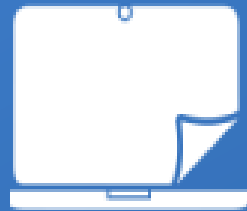
- Identify the project which needs to be implemented using paperless validation tool
- Identification of key users for product training.
- Enabling a pilot project to showcase the product features to the identified users
- Dedicated Account manager will help in URS preparation, project planning and task 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.
- Providing 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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