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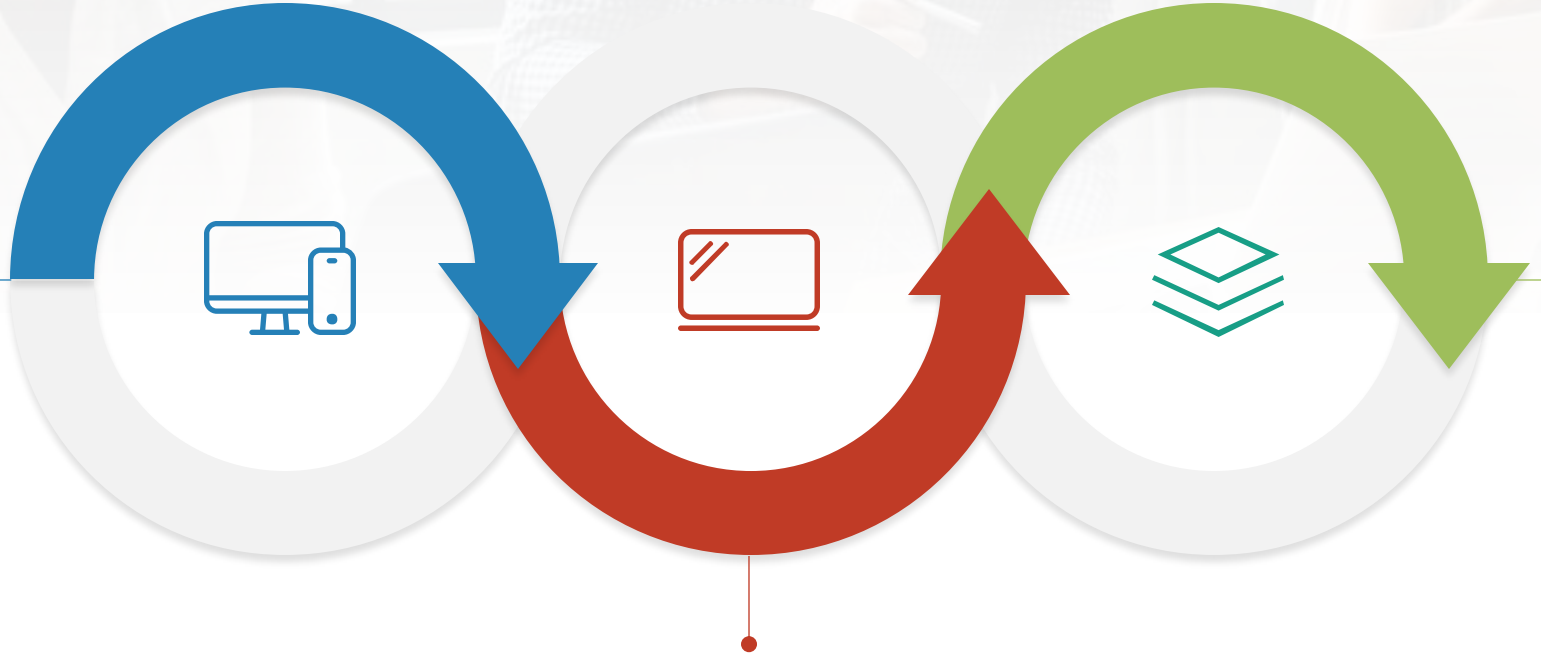
Paperless Validation Overview

H2-2023

GoVal is a Validation Lifecycle Management System (VLMS) for Life Science companies to implement paperless validation and fulfil regulatory compliance. FDA and other regional regulatory agencies mandates of validation of any computerized systems and software that automate device manufacturing, testing, component acceptance, packaging, or complaint handling, or to automate any other aspect of the quality system.

GoVal is a Validation Lifecycle Management System

Implement paperless validation and fulfil regulatory compliances.



Fulfill FDA 21CFR Part 11, EMA EU Annex 11, and GxP Assessments, Implement GMP

Validation of any computerized systems and software

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GoVal Overview

GxP System Validation
GoVal software helps organization to implement GxP system validation for computerized system as per GAMP methodologies.

1

2

Always On & Audit Ready Always-On & access across multiple devices which enables to track the progress on validation activities, thereby reducing the cycle time for validation.

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.

4

3

Monitor & Control Enables the visibility of validation tasks and provides management up-to-date information for monitor and control.

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Market Problem & Current Solutions

The Life Science Industry use paper based or manual processes to maintain validation records. Its often cumbersome and may not be accurate. The need for comprehensive Validation Life Cycle management system exists ever since FDA issued the guidelines for verification and validation computer systems.

The key things addressed by VLMS software :

1. Capability to maintain electronic records, electronic signatures.
2. Product and process meets pre-determined specifications and quality attributes.
3. Capability to validate IT systems, based upon risk assessment, current regulations (for example: 21 CFR Parts 11, 820, 210 and 211, EU/Annex 11, EMA ISO 13485), policies, procedures, and expectations

System Overview

Change Control

Change Control Management

CR Approval workflow, Tag CR to the projects

Impact Assessments

based on GxP checklists

GAMP categorization of system

FMEA based risk assessment

Validation Process

URS, FS, DS, Risk Management, Requirement Traceability, Test case setup & execution

Review & Approval Workflow

Periodic Reviews

GoVal Features – 1/3

Validation Master Plan (Project Setup)

- Define System, Sub Systems
- Introduction, Scope and Objectives
- List of documents / Forms / Templates
- Perform GxP Assessments & Define GAMP Category
- Workflow setup (Levels & Roles)
- PDF format, Notification & alerts setup

User Requirement Specification (URS)

- Gather Business functional requirement, helps to categorize various cross functional requirements.
- Map compliance and regulatory requirements.
- Clone or reuse the requirements from existing projects. Allow user to map URS to be Risk, FRS, IQ, OQ and PQ

Project plan & Task creation

- Create plans for each Document Type , assign owners
- Create task, assign and follow-up tasks
- Define task completion dates, track the progress
- Scrum board view
- Email alerts and notifications

Risk Assessment

- Define Risk Factor, Risk Scenario
- Map to requirements / specifications
- Define Probable cause of risk
- Probability of Occurrence , Severity Detectability based on rating scale
- Calculate RPN & Risk Priority
- Perform residual risk assessments

GoVal Features – 2/3

Test Management

- Test Cases for Installation, Operational & Performance Qualifications
- Define Test cases, Link URS , Specifications and Risks to Test cases
- Record test execution details, helps to update test steps with necessary evidences, status and Actual Results
- Allow user to screen capture, screen recording, upload images , documents
- Provide an options to create discrepancy for test failures.
- Auto generation of Traceability Matrix
- Allow user to perform **Unscripted testing** for out of box features and configurable specifications based on FDA guidelines

Validation Summary Report

- Validation Summary (Overall approval status, test case status)
- Overview of deviations
- Observation & recommendation
- Revalidation cycle (If applicable).
- Audit Trial
- Allow user to set a periodic review for the products and documents

GoVal Features – 3/3

Other features – 1/2

- Detailed Audit Trial
- Search documents and test case
- Bulk Import requirements & test cases. Create reusable components for URS, Risk, Test case, specifications
- Role based review & approval workflow , SLA for each level with Electronic signature
- Custom PDF export format. (Word templates can be mapped as export format)
- Discussion forum for each document type to have a team interaction and feedback.
- Integration to existing Document Management System (DMS) using REST API/ (Like SharePoint & OneDrive) , Import requirements from JIRA
- Inbuilt Knowledge base
- Enabling Single sign on (Integration to LDAP / Active directory / Office 365)

Other Features – 2/2

- Site wise project status, Document Summary, Timeline, test case execution reports
- Lowcode Form builder & Template builder
- Vendor Assessment
- Discrepancy Report
- Compliance Report
- Qualification Report
- Inventory Report
- Periodic Review Assessment Report
- Single / Multi tenant databases
- System Release Certificate
- Map Legacy documents for completed projects

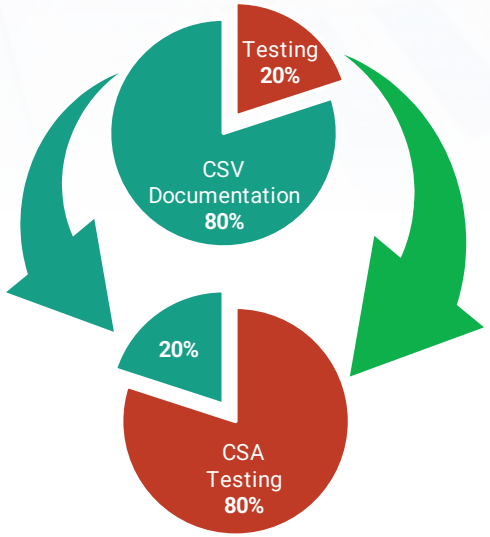
Computer Software Assurance (CSA)

Objective

- Risk-based approach focusing on critical thinking
- Using automated/unscripted testing
- Refocus on software quality, new technologies, reducing the traditional documentation and approval process

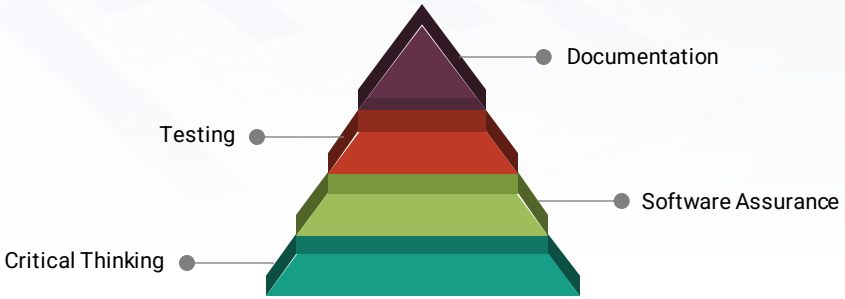
Our Approach

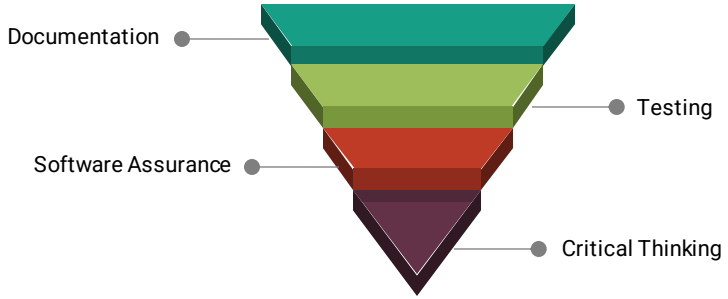
- Create requirements, specification
- Perform risk assessment
- Start testing against the requirements and record the evidences and test results.
- Create a electronic signed document with the following
  - Requirements
  - Risk assessment
  - Test data , result , business impact (if applicable)
  - Approval history
  - Audit trial
- Review and leverage supplier testing data.
- Limit scripted tests only for medium to high risk, and critical quality attributes
- Do a deeper test only in case of failures of these medium to high-risk attributes



Computer System Validation and Computer Software Assurance approach

Computer System Validation





Computer Software Assurance

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Application Deployment Models

1

GoVal Cloud

Customer accesses application from the GoVal dedicated cloud environment. Single or Multi tenancy options available based on customer need. Suits for the customers who don't want to go for the hassle of maintaining the software on their premises.

2

On-Premise – Datacenter Option

Customer accesses application from the GoVal dedicated cloud environment. Single or Multi tenancy options available based on customer need.

Validation Cycle

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Adaption of Paperless Validation

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 devices)

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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