VALGENESIS™

Validation Lifecycle Management System (VLMS)

Robust, end-to-end solution that manages the Validation Lifecyle Process

Validation programs are still almost entirely manual or consist of a number of separate, uncoordinated systems. Inefficiencies caused by human error cost manufacturers millions of dollars annually, increase product time to market, and introduce quality problems and data integrity issues. As the industry moves to PHARMA 4.0, companies are looking for a total validation management solution that ensures best practices and data integrity governance, enforcing them across all validation processes.

The ValGenesis VLMS is a 100% paperless Validation Lifecycle Management System that has been adopted as a system of record for validation since 2006. An end-to-end modularized system, the ValGenesis VLMS manages all types of validation processes, including CSV, Equipment, CQV, Method, Cleaning, and Process. It is packed with unique features yet unmatched in the industry. Over 50 top global life sciences companies testify to its efficacy after being audited and approved by global regulatory bodies as a system for validation processes across the organization

ValGenesis VLMS: Efficient CSV Lifecycle Management

Enforcing approved VMPs and Validation Plans in the corporate validation program – Lack of standardization and enforcement in the corporate validation process

Inefficient manual process to generate validation deliverables – Lack of a single collaborative environment in which an author can leverage existing validation content and data across the organization.

Once a document is authored or executed, it must be physically sent to the corresponding reviewers/approvers through interoffice mail or other delivery methods. Paper documents can easily be misplaced or lost causing time to be spent in searching/replacing documents

Compliance of Validation execution with ALCOA and FDA Part 11/EMA Annex 11 – Further compounded in a manual process that compromises data integrity

Offline execution – Unable to execute test cases in clean rooms and manufacturing floors without network connectivity

Creating end-to-end, Models and trace matrices – Time consuming manual generation and maintenance of trace matrices, and a lack of traceability in complex software systems

Risk based validation – Conducting risk assessment at the system and requirement level is difficult to manage in a manual process

Requirements Level Impact Assessment – Productivity is impacted as many resources are required to maintain validation status where each change may take weeks/months to close

Accessing, recording and archiving data and sample test results – Manual process to capture and archive data from instruments/equipment during validation and CPV, which leads to potential data integrity issues

Multilingual support – Lack of local language support in GxP systems hampering the ability to convey work instructions and operating procedures

Unique Features and Advantages of ValGenesis VLMS

Enforce approved Validation Plans, procedures and best practices – A decision tree driven validation assessment process helps define the validation requirements for GxP systems and processes as per the approved validation plan and procedures. Real-time validation status of these GxP systems and processes are available in the dashboard

Efficient process to generate validation deliverables – ValGenesis VLMS provides functions to reuse content across the organization. It supports parallel, serial and hybrid workflows for review and approval to expedite the final approval process

Comply with ALCOA and Part 11/Annex 11 requirements – Upon clicking the record button during validation execution, data and content populate contemporaneously across rows with exact date and time stamps, along with screenshots/attachments

Offline execution support through Mobile Apps – Test case execution is supported via tablets/ mobile, with or without network connectivity, objective evidence are dynamically captured in accord with the spirit of FDA 21 CFR Part 11 and EMA Annex 11

Dynamically generate many types of trace matrices with minimal effort – Create references for requirements and test cases with a simple click. Dynamically generate any type of trace matrix: comprehensive end-to-end, V model, one-to-many, and many-to-one traces of all artifacts. The VLMS supports forward and backward traces

Efficient Risk based validation – Conducting risk assessment at the system and requirement level becomes easy to implement. The entire process is guided by the system. Any type of risk model can be adopted to conduct the risk assessment

Requirement Level impact assessment - Reduce change management effort by up to 80% as a validation summary of all impacted artifacts is dynamically generated

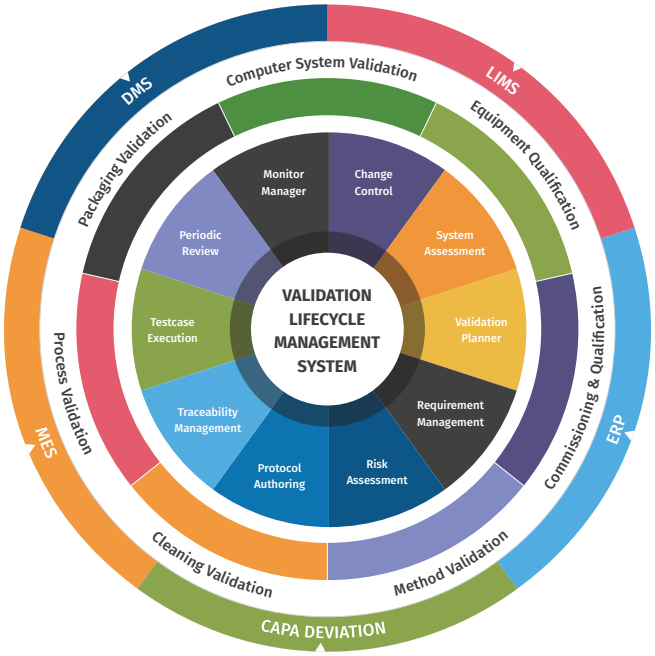
Access and archive dynamic data through IoT and OPC – IoT enabled access/capture of temperature, pressure, and humidity data in clean rooms, freezers, etc. The VLMS further supports shipping and cold chain validation. Data can be collected from instruments (pH meter, weigh balance, etc.) and directly populated in validation protocols, batch records, and log forms

Robotic validation execution support – The VLMS leverages the power of test automation tools for robotic validation execution and reduces validation execution time by up to 90%. Validated connectors for commonly available automation testing tools including UFT, MS Coded UI, Leapwork, Tosca, etc. are provided

Multilingual support – At site and user level. Any language can be supported. German, French, Japanese, Portuguese, Spanish, and Chinese are currently supported by default

The ValGenesis VLMS is designed to electronically manage the entire validation lifecycle and remove the inefficiencies that plague paper-based processes. ValGenesis reduces the cost of the validation process by allowing the optimization and stabilization of existing processes along with electronic management (document authoring, test execution, review and approval) of validation process and procedures. This reduces the cost of the validation process as much of the paper-based documentation and process/ procedure approvals are eliminated.

ValGenesis VLMS is expected to reduce the cost and time of the validation lifecycle process by at least 50% if it is specifically configured to meet your validation process requirements, with adequate training of the users.



VALGENESIS™

SAN FRANCISCO · TAMPA · CHENNAI · SCHIPHOL · MUNICH · TORONTO

info@valgenesis.com | (510) 445-0505 | www.valgenesis.com

Follow us on:

Valgenesis-Inc ValgenesisInc

Valgenesis.Inc ValgenesisIncVG