VALGENESIS®

# The Gold Standard of Digital Validation Lifecycle Management

# Life sciences companies face unique, complex regulatory challenges when bringing their life-saving drugs, devices, and biologics to market.

## ValGenesis VLMS is the solution.

Peerless in capability, ValGenesis VLMS provides a unified, data-centric platform for digitizing the entire validation lifecycle, enforcing standardization, ensuring data integrity, reducing risk, lowering the cost of quality, strengthening compliance, and more.

### The gold standard of standardization

Strengthen your compliance stance and lower the cost of quality with enforced standardization and absolute data integrity.

### Knowledge integrity to data integrity

Gain total peace of mind with a single source of validation truth with documentation aligned to ALCOA+ standards.

### One platform, boundless scale

Start small or start global. VLMS scales effortlessly to support new systems, new sites, new products, new languages, new validation processes.

**ValGenesis VLMS is the industry standard for digital validation across life sciences.**

The road from concept to commercialization is lengthy and expensive. Operational inefficiency in meeting stringent regulations can delay market delivery, costing you millions of dollars each day and eroding your competitive advantage.

Validation is a major resource drain, typically accounting for 20% of any project's budget. The ValGenesis Validation Lifecycle Management System (VLMS) helps you reduce validation cycle time by 50% (or more), allowing you to deliver innovative drugs and medical devices to patients faster and more cost-effectively.

## Paper-Based Validation Challenges Solved with ValGenesis

- Lack of standardization and enforcement in corporate validation processes
- Data integrity issues caused by human error
- Burden on internal resources
- Data silos that hinder productivity, visibility, and decision-making
- Lack of real-time collaboration across departments, sites, and projects
- Increased compliance risk
- Time-to-market and innovation delays
- Stressful and expensive audits caused by missing records or illegible data

## Purpose-Built for the Life Sciences

The ValGenesis VLMS is the proven industry standard for digital validation, trusted as the validation system of record for over 100,000 GMP systems around the globe for nearly two decades. A cloud-based platform, it can digitize and simplify all your validation needs, including:

- Computer Software Assurance (CSA)
- Computer System Validation (CSV)
- Equipment and Instruments Validation
- Analytical Method Validation
- Commissioning Qualification Validation
- Process Validation
- Cleaning Validation

**Unmatched ROI: ValGenesis customers report a 13% reduction in time to market, 20-30% reduction in validation costs, and 80-90% reduction in audit prep time.**

### A system that can scale and grow with your business

The ValGenesis VLMS is a suite of integrated, configurable modules that work together to help you reach new levels of productivity, efficiency and collaboration. Dynamic and scalable, the platform can be implemented in a phased approach on your timeline as your business needs evolve. Our Rapid Implementation Model ensures a smooth onboarding experience. And our comprehensive off-the-shelf API stack makes it easy to integrate with other software applications commonly used by regulated companies, including ERP, QMS, and MES.

# Components and Features of VLMS

**Validation Plan and Framework**

Consistency is a key factor in any validation process and critical to regulators. The System Manager module is designed to enforce consistent execution of the Master Validation Plan (MVP) by allowing you to define validation standards and deliverable requirements that validation staff can apply to one or more GxP systems.

**Content Lifecycle Management**

The Content Manager module automates the assigning, authoring, reviewing,approving, storing, and binding of documents regardless of the software used to create them (e.g., Microsoft® Word and Excel). The centralized repository simplifies and expedites search and retrieval during inspections and audits. A reusable content library reduces authoring time by more than 50% while improving consistency.

**Design Manager**

Design Manager enables compliance with the FDA's computer software assurance (CSA) guidance. Develop risk-based requirements upfront and perform both scripted and unscripted testing to reduce unnecessary documentation to "right size" validation efforts.

**Change Control and Management**

The Change Manager module integrates change management and validation with a closed-loop process. The system tracks both requirement and system-level changes, identifying validation impact across the lifecycle in real time using a patented digital process. This can reduce change control effortsand cycle time up to 80%.

**Risk-Based Validation**

The Risk Manager module provides a structured and documented approach for assessing risk in computer systems, equipment, instruments, and processes. You can leverage pre-built risk models, templates, and decision trees to determine the appropriate level of testing and documentation required to satisfy validation and compliance requirements.

**Electronic Test Case Execution**

The Execution Manager functionality allows users to execute test cases faster with guaranteed integrity. Content is inputted electronically, directly to the document, helping to avert spelling errors, illegible handwriting, and other common validation protocol challenges.

**Validation Projects**

The Project Manager module empowers project leaders to manage complex project tasks and the team members assigned to those tasks. The system automatically updates the project plan, eliminating manual intervention. The result is enhanced compliance, improved team efficiency, and consistency in execution.

### Periodic Review Management

Our Scheduler Manager module allows users to create periodic review schedules for any previously validated GxP system, asset, or process. The system manages the schedule and automatically alerts users/groups of upcoming or delayed periodic review tasks via corporate email. These features ensure that all GxP assets, systems, and processes are operating as expected.

### Dynamic Trace Matrices

ValGenesis VLMS automates the trace matrix generation process and efficiently performs precise, easily understandable coverage analysis by showing the relationship between related items. ValGenesis supports one-to-many, many-toone, many-to-many, and V-Model relationships at the requirements level as well as forward, backward, and end-to-end traces.

### Requirements Management

The Requirements Manager module allows users to modify, add or delete requirements and route changes through an approval process. Once modified, the system automatically updates the requirement status in the traceability matrix to ensure changes are tested. Maintaining a closed-looped requirements change management process saves time and minimizes compliance exposure.

### Retirement and Decommissioning

Within the Scheduler Manager module, you can create and approve retirement schedules for GxP assets, templates, validation documents, and associated records. Users can specify retention periods and schedule task alerts to notify affected user groups of planned or required retirement activities. Documents associated with retired assets are always available in real time for audits.

### Robotic Test Case Execution

Our robotic test case execution capabilities combine the power of automated testing tools, such as Leapwork and Tosca, with the ValGenesis system to reduce test execution time by more than 90%. You can execute more tests in less time with fewer resources. The integrated system is fully compliant with regulatory requirements.

### GxP Asset Management

The GxP Asset Management component allows users to seamlessly track, manage and monitor all GxP assets — including facilities, instruments, equipment, computer systems and analytical instruments — throughout their lifecycles. Maintaining a centralized, up-to-date asset inventory that is accessible from any location ensures consistency in corporate validation and quality processes.

# Benefits for the Entire Team

## Validation Teams

- Apply agile methodologies to validation
- Assess risk at the requirements level
- Capture objective evidence directly in the protocol
- Speed approval with routing and compliant e-signatures
- Manage test failures via predefined workflows
- Produce clear, precise timestamped audit trails

## Quality Teams

- Enforce correct template usage — every time, at all sites
- Avoid tediously recreating traceability matrices
- Ensure ALCOA+ data integrity
- Deploy technical controls to enforce SOPs
- Eliminate illegible handwriting and encourage GDocP
- Initiate and perform quality by review (QbR)

## IT Teams

- Cut system management burden with a cloud-based system
- Standardize all validation activities with a unified platform
- Keep information and processes secure
- Support disaster recovery and business continuity plans
- Extend your single sign-on (SSO) identity management system
- Perform forensic analysis of data

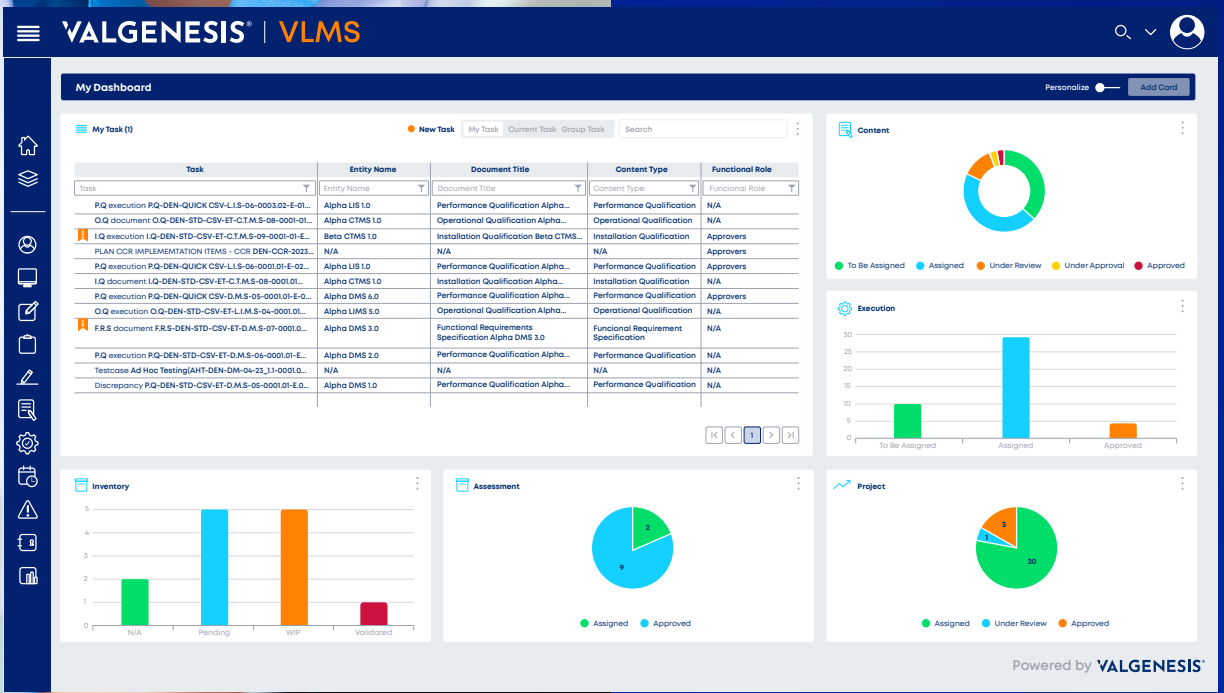
## Executives

- Avoid observations, warning letters, and consent decrees
- Reallocate staff time and budget to value-added activities
- Get to market faster by reducing validation cycles by > 50%
- Attract a modern workforce with best-in-class digital tools
- Adhere to regulatory requirements

## Why 30 of the World's Top 50 Life Sciences Companies Use ValGenesis

ValGenesis is the leading provider of enterprise VLMS solutions. We have successfully implemented hundreds of customer sites, including systems for pharma, biotech, medical device, nutraceutical, GxP labs, CROs, CMOs, and CDMOs. Here's why organizations trust us with their digital transformation efforts:

- The industry's first and most complete 100% digital VLMS
- Innovation leaders and the first with AI capabilities
- A full validation lifecycle approach, from conceptualization to retirement
- World-class professional services and technical support
- Unmatched in-house industry and process expertise
- CSA-ready out of the box
- Mobile app to work wherever, even offline



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