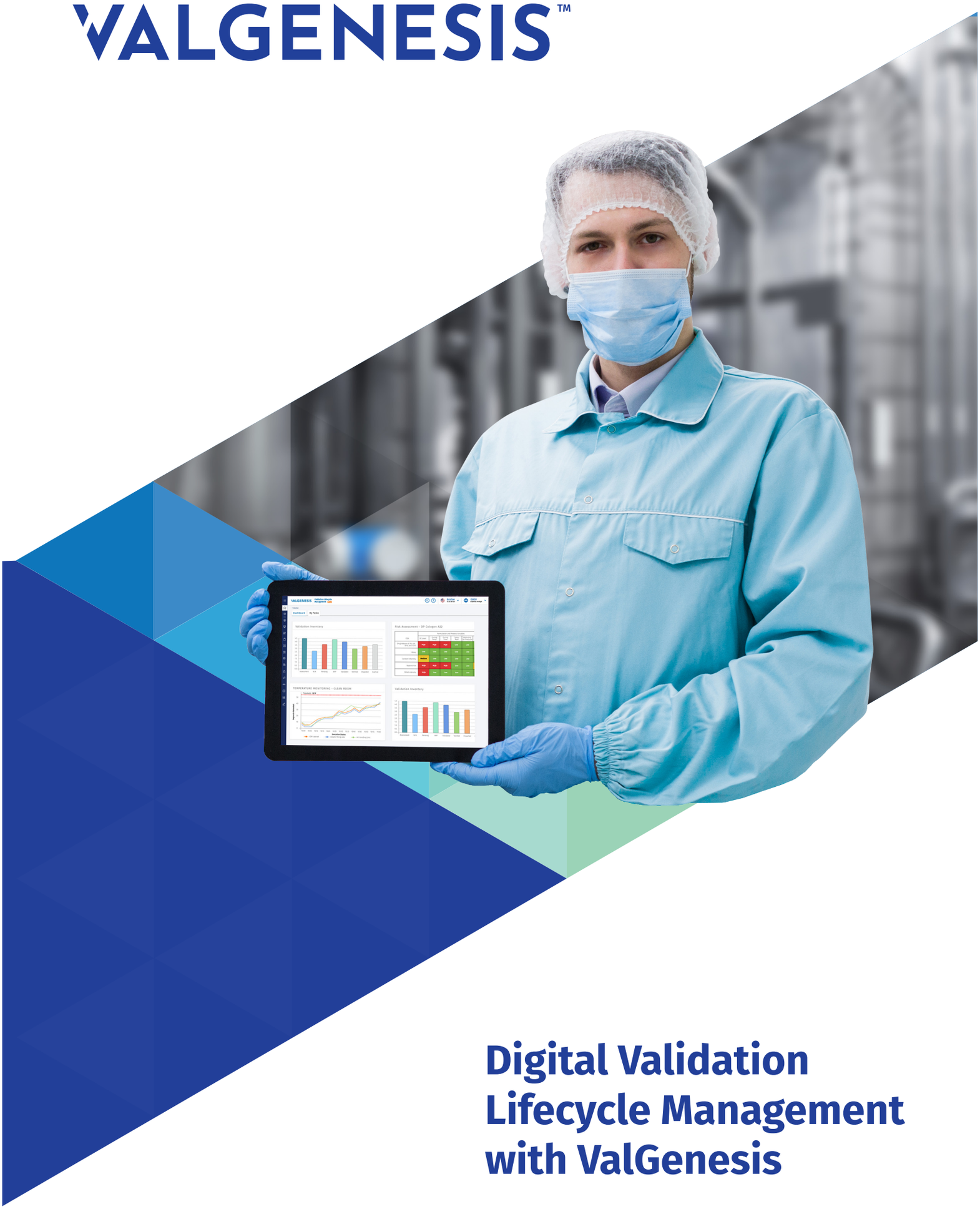
VALGENESIS™



Digital Validation Lifecycle Management with ValGenesis

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

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

Validation is a significant cost, effort and resource burden. Typically, it accounts for 20% of any project's budget. The ValGenesis Validation Lifecycle Management System (VLMS) helps you reduce validation cycle time by 50% (or more). For over 15 years, life sciences companies like yours have used the ValGenesis VLMS to standardize, digitize and automate their validation activities and deliver life-changing therapies 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
- Trying and expensive audits caused by missing records or illegible data

Solutions 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. A cloud-based platform, it can digitize and simplify all areas of your company's validation needs, including:

- Computer System Validation (CSV)/Computer Software Assurance (CSA)
- Equipment and Instruments Validation
- Analytical Method Validation
- Cold Chain 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, each module 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.

Validation Plan and Framework

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

Content Lifecycle Management

The Content Lifecycle Management module automates the assigning, authoring, reviewing, approving, storing, and binding of documents regardless of the software used to create them (e.g., Microsoft® Word, Microsoft® Excel). The system's 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.

Change Control and Management

The Change Control and Management module integrates change management and validation with a closed-loop change management process. The system tracks both requirement- and system-level changes electronically, identifying validation impact across the lifecycle in real time using a patented digital process. These features significantly reduce change process effort and cycle time up to 80%.

Risk-Based Validation

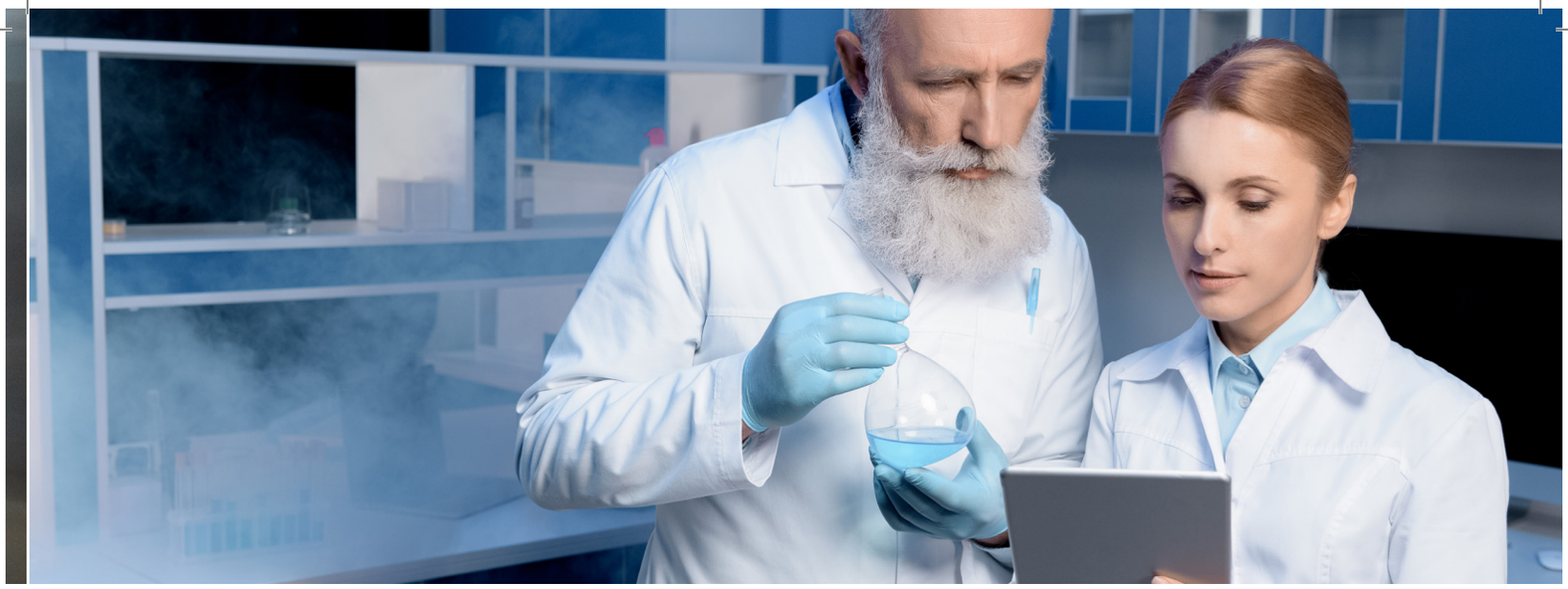
The Risk-Based Validation module provides a structured and documented approach for assessing risk in computer systems, equipment, instruments and processes. Users can leverage pre-built risk models, templates and decision trees to determine the appropriate level of testing and documentation required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

Electronic Test Case Execution

The Electronic Test Case Execution module allows users to execute test cases faster and more securely. Content is inputted electronically, directly to the document, helping to avert spelling errors, illegible handwriting, and other common validation protocol challenges.

GxP Asset Management

The GxP Asset Management module 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.



Validation Projects

The Validation Projects 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

The Periodic Review Management 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 Matrix

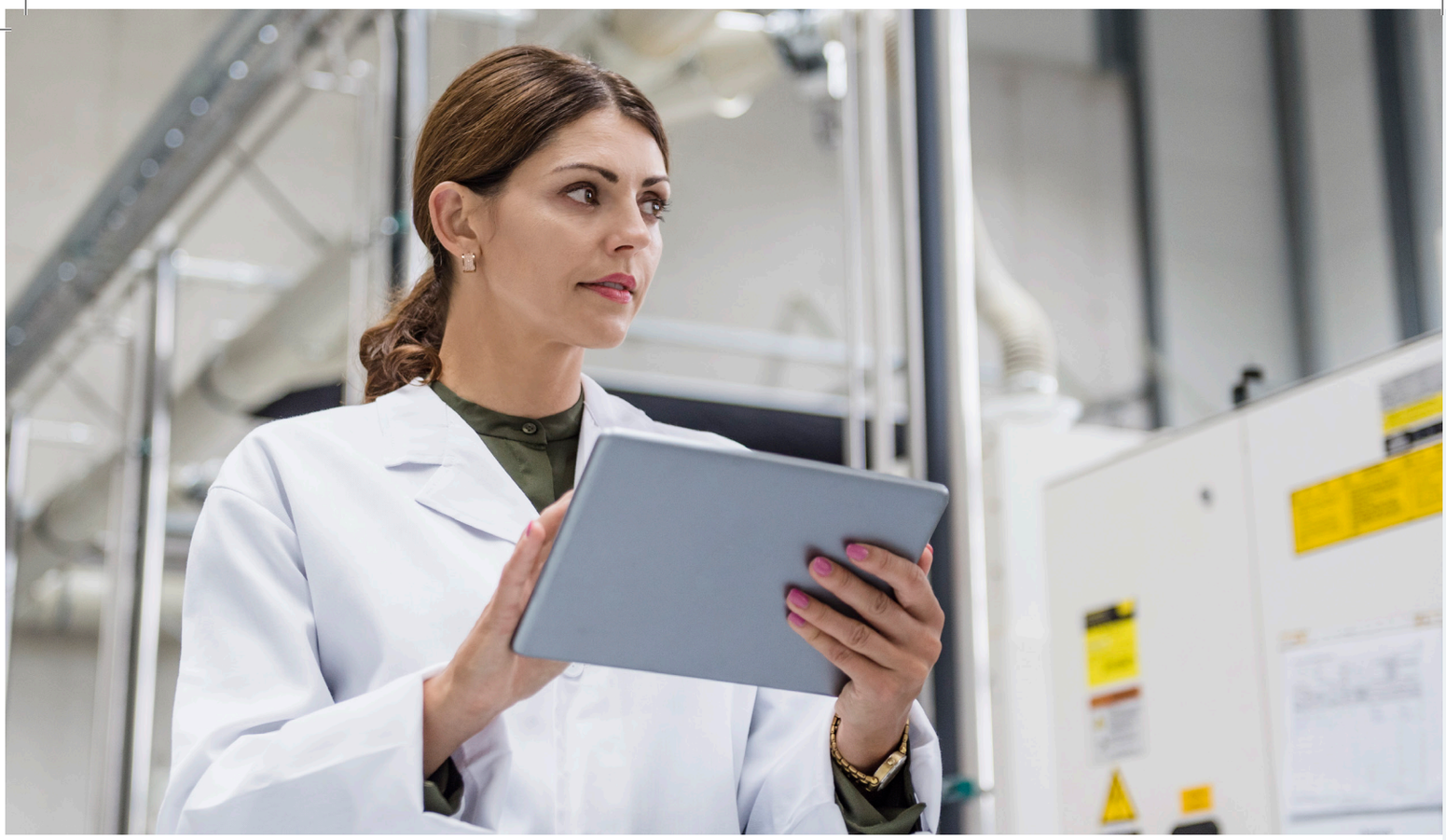
Building traceability matrices is an essential part of the validation process. The Dynamic Trace Matrix module expedites the trace matrix generation process and efficiently performs precise, easily understandable coverage analysis by showing the relationship between related items. ValGenesis supports one-to-many, many-to-one, 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 Management module allows users to modify, add or delete requirements and route any 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 minimizes compliance risk and saves a great deal of time and effort.

Retirement and Decommissioning Process

With the Retirement and Decommissioning Process module, users 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.



e-Logbook

With ValGenesis e-Logbook, users can electronically capture and route equipment, cleaning, preparation, and many other GMP logs. The Log Form Library houses more than 100 ready-to-use forms which authorized users can modify to meet their business needs, dramatically reducing form design time. Offline operation is supported, as is the ability to create business rules and task dependencies to force standardization. e-Logbook works with iOS, Windows and Android mobile devices. It can be deployed as a stand-alone solution or as part of the VLMS platform.

Robotic Test Case Execution

The Robotic Test Case Execution module combines the power of automated testing tools, such as Leapwork and Tosca, with the ValGenesis system to reduce test execution time by more than 90%. Users can execute more tests in less time with fewer resources. The integrated system is fully compliant with regulatory requirements.

Process Manager

The Process Manager module empowers users to develop robust cleaning programs that manage risk and ensure the safety and efficacy of products from development through manufacturing. Users can quickly and easily establish and monitor clean and dirty equipment hold times, conduct worst-case product and equipment assessments, automate MACO calculations and perform a host of other important cleaning validation lifecycle activities in a consistent, compliant manner.

Design Manager

We built the Design Manager module to support the Agile software development methodology. Users can define product backlogs and user stories and choose which user stories to include in a release. Requirements, specifications, and tests can also be created in the system as objects and dynamically linked with user stories, requirements, specifications or test objects. Including this module within the ValGenesis platform ensures that a truly object-based Agile methodology is applied to validation.

Validation Team Benefits:

- Enforces consistent, GDP-compliant template-driven standards for document authoring with e-signatures
- Captures objective evidence and automatically adds a timestamp, watermark and hyperlink
- Routes documents to the next user with task notifications
- Instantly manages test failures with built-in workflows
- Produces clear, concise audit trails

IT Team Benefits:

- Reduces the overhead of system management with a cloud-based system with built-in fault tolerance
- Standardizes all validation activities on one unified platform
- Secures and encrypts data from outside access
- Solidifies disaster recovery plans and ensures business continuity
- Leverages a unified identity system with single sign-on

Executive Team Benefits:

- Helps avoid reputation/brand damage due to regulatory action and recalls
- Minimizes the time, money and resources spent on non-value-added activities
- Improves employee engagement and morale
- Increases speed to market
- Reduces the overall cost of compliance

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 ValGenesis with their digital transformation efforts:

- We're the industry's first proven 100% paperless VLMS
- We're the industry's only VLMS to leverage augmented reality (AR) technology for hands-free validation
- Our solutions cover the entire validation lifecycle from conceptualization to retirement
- World-class professional services and technical support
- In-house industry and process expertise
- Work whenever, wherever with our easy-to-use mobile app
- Available in six languages (English, French, German, Spanish, Chinese and Japanese)

Accelerate time to market and your journey to Pharma 4.0 with the industry's de facto standard VLMS.

To learn more about how you can manage the entire validation lifecycle in one unified solution, contact a ValGenesis representative.

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