VALGENESIS®

Case Study

A specialty pharmaceutical company streamlines computer system validation for a successful ERP upgrade.

noven

"Our ERP upgrade would touch every department in the company. This was the ideal opportunity to transition from paper-based to electronic validation, and now we're reaping the benefits: signoff documents organized in one place, simplified review and approval, no more issues deciphering handwriting, one-click access to deviation reports, reduced printing costs — all totaling up to a successful outcome."

— Mabel Santana,
Compliance Manager,
IT Business Solutions,
Project Management Office

Case in Brief

Customer Profile

Noven Pharmaceuticals, a specialty pharmaceutical company and wholly owned subsidiary of Hisamitsu, the world's largest manufacturer of transdermal patches, is engaged in the research, development, manufacture, marketing, and sale of prescription pharmaceutical products. The company is headquartered in Miami, Florida.

Mission

To develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery.

Noven was embarking on a major enterprise resource planning (ERP) system upgrade. Through a rapid implementation of the ValGenesis Validation Lifecycle Management System (VLMS), the company launched a new computer system validation (CSV) process for the rollout — on time and fully compliant with FDA 21 CFR Part 11 requirements.

The pharma leader plans to expand the VLMS functionality to other GxP systems integral to the research, development, manufacture, marketing, and sale of prescription pharmaceutical products.

Seizing the Opportunity to Go Paperless

About the ValGenesis VLMS

The ValGenesis VLMS is the de facto standard of life sciences companies worldwide as a global, purpose-built validation platform. The complete suite delivers unmatched functionality that supports the unique needs of regulated companies for digitizing the entire validation lifecycle, from conceptualization to retirement, in a single solution.

ValGenesis VLMS empowers users to enforce best practices andstandards to ensure data integrity and compliance throughout its corporate validation process. The solution has been implemented in more than 300 manufacturing sites and used to validate more than 100,000 GMP systems.

Noven provides commercialized oral and transdermal products for women's health and central nervous system disorders, including ADHD. The company maintains state-of-theart FDA-approved transdermal manufacturing facilities that the US Drug Enforcement Administration also approves to produce controlled substances. An upgrade of its ERP system provided the IT business solutions team with the opportunity to digitize and automate its CSV efforts for a fully paperless process.

Noven needed a consistent way for all departments to develop, route, review, and approve validation plans, requirements, risk assessments, protocols, traceability matrices, and deviations. This simply wasn't possible with the existing paper-based approach. The IT business solutions team hoped to implement a fully digital, end-to-end validation lifecycle management system that could eventually scale to other departments and GxP processes, including equipment validation.

However, to ramp up quickly, the initial goal was to eliminate manual validation systems and introduce a risk-based approach for 100% digital CSV to support the ERP upgrade, then roll out the new VLMS system to other departments as the ERP upgrade progressed.

The Vendor Selection Process

Industry Insights

The FDA has advised life sciences companies to take a risk-based, least burdensome approach to CSV for two decades. Unfortunately, many regulated users and software suppliers struggle to understand CSV and perform it effectively. Computer software assurance (CSA), a simplified method for performing CSV, is the Agency's attempt to "rightsize" validation by placing the focus on what directly impacts patients or product quality.

Choosing a full featured digital validation tool like ValGenesis VLMS that manages both CSV and CSA processes is critical as it allows users to drastically improve efficiency and direct documentation and testing efforts to the areas of greatest need. The streamlined approach facilitates innovation and strengthens acompany's ability to bring products to market on time or even ahead of schedule.

Noven selected ValGenesis over other vendors for its ability to provide real-time access to tasks, inventory, and work in progress — and the resulting reduced cycle times in the range of 30% to 50%. ValGenesis also offered built-in functionality and round-the-clock solution support.

- **Real-time Visibility:** The ValGenesis VLMS provides a holistic view of the entire validation process. Users can monitor the validation status of all GxP assets and processes across sites, remotely and in real time.
- **Reduced Cycle Time:** By eliminating non-value-added activities that waste both time and skilled human resources, the ValGenesis VLMS expedites the entire CSV process, resulting in an average 30% to 50% reduction in overall validation cycle time.
- **Built-in Functionality:** Applying risk assessment procedures to CSV ensures that all critical requirements are tested and documented appropriately. The ValGenesis VLMS supports a risk-based approach with pre-built risk models, templates, and decision trees.
- **Round-the-clock Support:** ValGenesis' globally distributed support staff is available around the clock to resolve issues quickly, minimizing any interruption to validation operations.

For effective CSV, ValGenesis documents all processes in the validation lifecycle and, after the initial validation, continuously maintains the validation status for each computer system. The solution can be delivered in six weeks from configuration requirements gathering to going live.

Users can develop protocols and requirements in Microsoft Word and Excel and manage them electronically through controlled workflows. All task alerts are routed through email. Users simply click on embedded hyperlinks to open the tasks and then author, execute, review, or approve.

The Implementation Process

5-Phase Rapid Implementation Model

Successful and timely deployment is crucial to meeting compliance goals and overall competitiveness in the market. Through hundreds of successful customer installations, the ValGenesis professional services team has developed a proven implementation framework that consists of five phases:

(1) Initiation, (2) Specification, (3) Configuration, (4) Validation, and (5) Transition.

ValGenesis offers a host of add-on services, such as data migration and integration services, for customers who desire more assistance throughout the implementation process.

After selecting ValGenesis, Mabel Santana, Noven's compliance manager of IT business solutions, worked closely with the ValGenesis professional services team to ensure the rapid implementation was successful.

Santana was highly engaged in defining the system requirements. After ValGenesis provided the qualification documents, she adapted them for the Noven format. Noven's implementation made maximum use of the out-of-the-box functionality available through ValGenesis.

The initial project in IT was managed collaboratively through phases:

- Validation plan and project
- Specifying requirements (author, review, approve)
- Risk assessment (author, review, approve)
- Authoring design and test case protocols (DQ, IQ, OQ, PQ / author, review, approve)
- Creation of traceability matrices (create, review, approve)
- Execution of test cases
- Summary report (execute, review, approve)
- Management of execution deviations (initiate, assess, review, approve)
- Change control and management periodic review

Powerful Business Benefits

Using ValGenesis for all CSV activities in the upgrade of its ERP system has had a substantial impact on the business, allowing Noven to streamline work processes, shorten cycle times, and apply consistency and structure companywide. Specific benefits noted by the client include:

- A 100% electronic approach to validation lifecycle management for CSV related to a significant ERP system upgrade throughout the company.
- Convenient, real-time access for the authoring, execution, review, and approval of GxP assets across seven departments.
- Easy virtual collaboration, visibility, accountability, and time savings through simultaneous review and approval of validation documents by various users.
- Automatic audit trails and electronic signatures that support electronic workflows.
- Document consistency via templates for planning, protocols, qualification, reports, requirements, and other processes.
- The ability to scale to additional departments and applications.

As Noven continues to lead the way in the specialty drugs category, the company plans to use ValGenesis to digitize its equipment validation efforts next.

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ValGenesis, Inc. is the creator of an innovative software platform that serves as a foundation for managing compliance-based validation activities in life science companies. ValGenesis, Inc. is the provider of the first enterprise application that manages the corporate validation lifecycle process. This solution is fully compliant with U.S. FDA 21 CFR Part 11 and Annex 11 requirements.

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