CASE STUDY

MOLECULAR MEDICINE COMPANY

CUSTOMER PROFILE

The customer is a clinical-stage precision medicine company that harnesses experimental technologies to advance biotechnology research. They are focused on making small molecule medicines against precision medicine targets. Their objective is to make the discovery of medicines both more efficient and effective.

CHALLENGE

The customer's existing validation approach relied on digital file storage to manage documentation for validations with pen and paper. This traditional method of computer software validation (CSV) made it difficult to ensure GxP across the company's digital ecosystem, which included systems and applications from external vendors, such as Veeva and DocuSign®. As the frequency of software releases, regulatory changes, and other validation requirements increased, the company was accumulating validation debt, adding time, costs and risk exposure.

Validation Debt: the unpaid, accrued cost of new and unaddressed validation, testing, and GxP requirements.

SOLUTION

To solve this issue, the customer looked for ways to improve their validation process and decided to take a new approach, moving away from CSV and towards computer software assurance (CSA). This new model – based on a paperless automated workflow – would improve efficiency and risk assurance by eliminating manual, redundant, and risk-prone human processes.

The customer selected Res_Q, Sware's leading validation platform that automates, unifies, and accelerates validation for life sciences companies. Res_Q's out-of-the-box workflows helped change their systems and processes quickly and effectively, while Sware's collaborative engagement model educated and won over internal stakeholders. Within weeks, they rapidly implemented a scalable CSA solution with minimal disruption to existing validation workstreams.

The customer depends on Res_Q to:

- **Automatically advance** key validation procedures, reducing human time and labor
- **Manage risk** by exchanging batch testing with intelligent risk-prioritized testing
- **Interface directly** with industry-standard accelerators for Veeva and DocuSign®
- **Manage** all internal and external validation processes from a single, app-based point of control
- **Create and share** change records

> "I wanted to restructure our approach to CSV and GxP management. Our old system was based on storing and manually accessing documentation. As our business and validation needs grew, I knew we had to take a fundamentally proactive approach to validation. We couldn't afford to do things the old way."

OUTCOMES

By adopting Res_Q, the customer has reduced time to develop, validate, and deploy work that is done internally and externally. This has empowered the company to:

- **Move key personnel** from validation to other high priority tasks
- **Reduce time** to validate and deploy work related to internal or external systems
- **Align to emerging FDA recommendations** around GxP best practices and compliance digitization

> "Validation workstreams that weren't in Res–Q took days. Those same workstreams, once moved into the Res–Q system, take hours. It has helped us move from a reactive to proactive posture when it comes to cost and risk management and is a fundamental part of our bigger technology and compliance picture."

ONGOING COLLABORATION

Today, the customer uses Sware to manage more than 30 internal and external releases and changes per quarter. Sware's powerful, intuitive workflow engine allows them to accommodate this large (and increasing) volume of validation requirements with fewer dedicated staff and greater risk assurance.

Request a demo or learn more about Sware's Res_Q validation process automation platform at sware.com.