CASE STUDY

PHARMACEUTICAL RESEARCH COMPANY

CUSTOMER PROFILE

The customer is a pharmaceutical research company focused on solving urgent patient needs. The company was created to deliver lasting impact for patients using innovative treatments.

> We are a virtual organization with experts across the country. We needed a validation solution capable of bridging time and knowledge gaps, driving our processes forward without relying on archaic, manual processes."

CHALLENGE

Validation Slows and Debt Grows

To support a growing pipeline of drug candidates, the customer augmented its existing tech stack with multiple industry-standard SaaS applications. These applications increased the company's software validation requirements significantly; as of today, the customer is tasked with validating 8-10 software releases per app, annually. As the organization grows, this number is expected to double, or even triple.

Validation Debt: the unpaid, accrued cost of new and unaddressed validation, testing, and GxP requirements. As companies progress through lifecycle stages, validation debt continues to accumulate, affecting timelines, and increasing risk.

The company's standard software validation process was executed using a hybrid, “paper-paperless” system. Digitally stored computer systems validation (CSV) files were printed, scanned, and signed by team members in disparate physical locations around the country. These files were then manually scanned and uploaded back into digital storage, costing IT & Quality teams unnecessary time and effort. They relied heavily on vendor developers to provide validation packages.

Eventually, the added time, effort, and external dependencies led to a backlog and subsequent validation debt, wherein two major systems were being validated using manual processes. This cost the customer additional time and resources to maintain a state of compliance, forcing personnel to redirect focus away from mission-critical initiatives and towards ongoing validation work.

SOLUTION

Res_Q by Sware

To increase efficiency, shorten validation time, and eliminate validation debt, the customer partnered with Sware to implement Res_Q, a modern life sciences SaaS validation platform that automates, unifies, and accelerates validation processes. Today, they use Res_Q to create a fully digital validation ecosystem, automate key workflow elements, maintain superior risk assurance, and drive critical efficiency at all points in the validation lifecycle.

By implementing Res_Q, the customer is now able to:

Automatically advance validation requirements from stakeholder to stakeholder

Build risk management steps directly into the end-to-end workflow

Establish risk criticality and create ranked risk management priorities

Unify 5 industry-supported app validation processes in a single dashboard, including Veeva, Argus, and Optel

Create and finalize signed, audit-ready packages without printers, paper, and ink

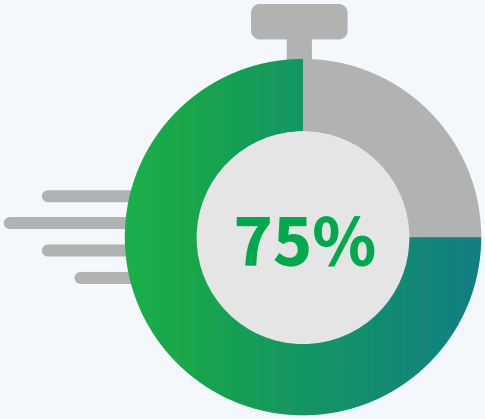
Execute proper change management and ensure traceability at all points

As life sciences validation experts, Sware was able to provide the customer with critical strategic planning, challenge anticipation, and solutions mapping. Sware helped meet their current validation needs as well as anticipate future validation requirements, implementing a system capable of scaling to accommodate the customer’s growth trajectory.

OUTCOMES

As a result of the operational changes facilitated by Res_Q, the customer has:

- **Eliminated** its validation debt
- **Reassigned labor hours** equivalent to one full-time employee (FTE)
- **Accelerated validation** by 75%



"The old way involved more documentation and less critical thinking. The shift from CSV to computer systems assurance (CSA) turned this model on its head. Now, we succeed with less documentation and more critical thinking. With Res–Q, a project requiring 15 validation packages has now been reduced to less than 10."

"The difference pre- and post-Res_Q is simply night and day. What used to take us weeks or months now takes us days or weeks. We've essentially eliminated GDP issues by removing the hand-written aspect of document alteration. The system enforces controls, eliminating the long chain of corrections we needed to manage using paper-based processes and communication by scan."

ONGOING COLLABORATION

In the future, the customer plans to utilize Res_Q to manage validation for an increasing number of industry apps to support their growing portfolio of drug candidates. Their validation needs are expected to double soon; fortunately, by using Res_Q as its modern validation solution, the customer will be able to accommodate this significant scale-up with minimal disruption and improved overall efficiency.

The Res_Q platform by Sware is helping the customer automate, unify, and accelerate its validation processes. Sware's mission is to change the way life sciences companies see and eliminate validation debt within their organization, reducing overall CSV costs and ensuring peace of mind in an increasingly complex compliance environment.

Now, we'd like to help you.

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