CASE STUDY

Helping a Precision Medicine Company Implement Rapid, Scalable GxP Validation

CUSTOMER PROFILE

A biopharmaceutical company leveraging gene therapy to discover and develop innovative medicines to treat disease and improve patient lives safely and effectively.

CHALLENGE

As the company implemented more and more SaaS applications into its product development technology stack, its computer system validation (CSV) and GxP requirements increased in lockstep. Having made a decision to lean into technology to support their business goals, they implemented multiple industry accelerators for file storage and signature, supply chain management, and more. Factoring external system updates and internal process changes, their SaaS validation requirements ranged **between 25 to 30 releases per year**.

To accommodate this volume of releases, they **needed to reassign three full-time employees (FTEs)** from other mission-critical work to focus full-time on managing their validation needs. This had a significant impact on day-to-day operations and slowed down product development, leading them to look at validation solution providers across the country to reduce their validation burden and free up critical resources.

SOLUTION & PARTNERSHIP

Sware reached out to this biopharmaceutical company to kickstart discussions around Res_Q, Sware's leading-edge SaaS solution for validation and GxP compliance. Res_Q is cloud-native, fully scalable, and acts as a central control system for all validation processes, automating, unifying, and accelerating validation for life sciences companies. Sware also provides full support by functional domain experts with deep, specialized experience in life sciences validation and compliance.

> **Many of the solutions providers in the United States focus primarily on commercial validation, while others specialize in providing a platform to build your processes on. It was hard to find a winning product with deep human support behind it. Sware is a rare solutions provider in that it provides both disruptive technology and a team of true functional experts. Sware provides both the platform and people needed to excel at validation, saving us time and money and making our lives considerably easier."**
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> — Director, Clinical and Development Systems, Biopharmaceutical Company

RESULTS – BETTER TOGETHER

By partnering with Sware to implement the Res_Q platform, they:

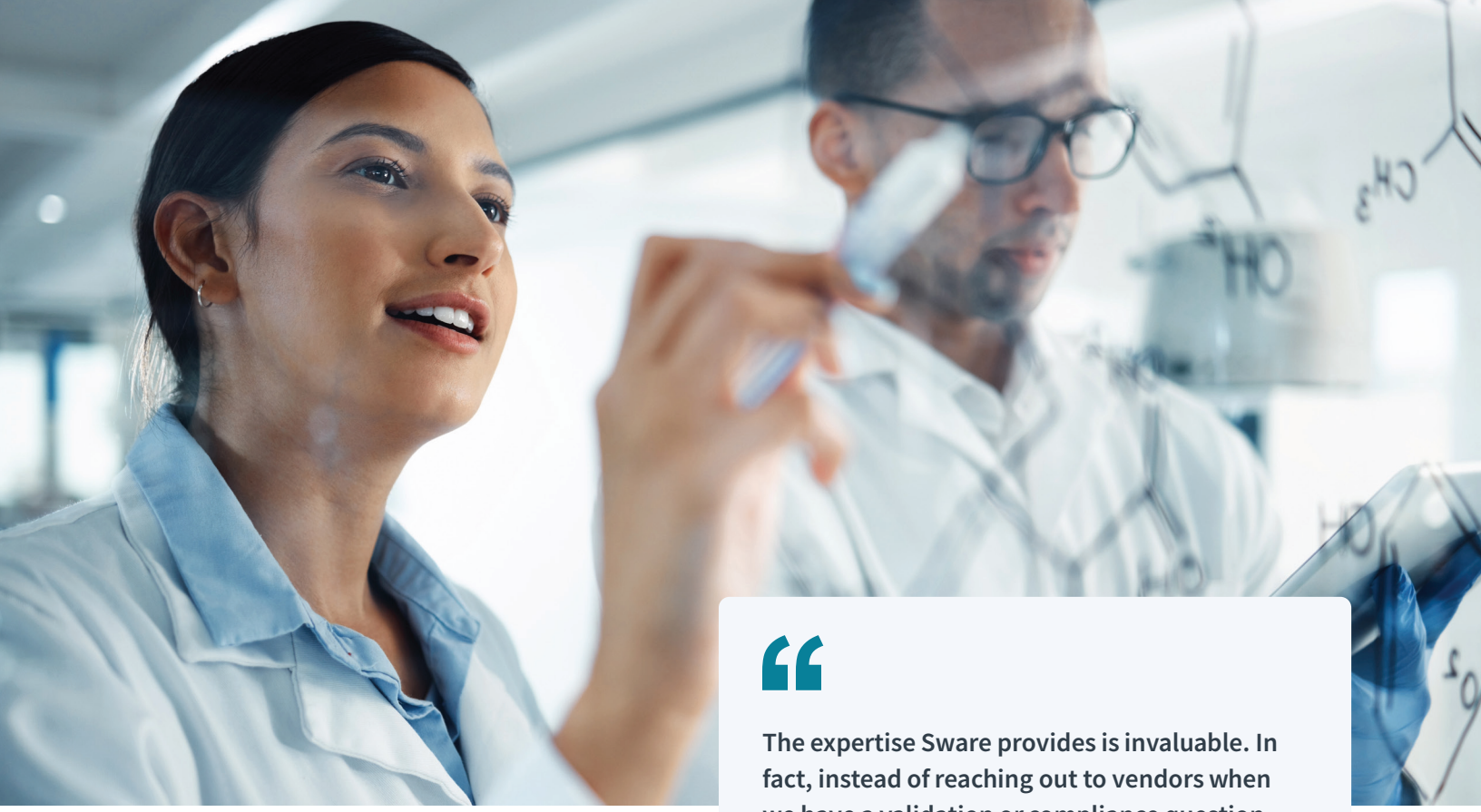
Save approximately 102 FTE hours per validation project, freeing their core team to focus on high-priority tasks.

Removed all paper-based processes, switching to a paperless, end-to-end ecosystem that enabled speed, transparency, and easier change management.

Scale rapidly and flexibly as new requirements emerge, enabling predictable TCOs and further accelerating mandatory activities.

Manage all validation processes in one location, increasing visibility, ease of access, and collection of deeper insights about process and quality.

Maintain audit-readiness, derisking validation and putting the company in a state of regulatory preparedness.



FUTURE COLLABORATION

The company partnered with Sware to develop a cohesive strategy for validation across their organization as they scaled business functions and supporting systems. Centered around Res_Q, they have a single point of visibility into the state of validation across the entire organization. In ongoing partnership with Sware's expert team, they are able to ensure they have the compliance expertise they need across their applications and accelerate system adoption.

> **The expertise Sware provides is invaluable. In fact, instead of reaching out to vendors when we have a validation or compliance question about their product, we reach out to Sware. They're typically able to give us a better answer because they work with the product in different life sciences ecosystems, including our own. There have been several instances where before reaching out to a vendor, we reached out to Sware, and were able to advance our project goals faster. Their collective experience and ability to think ahead is invaluable."**
>
> — Director, Clinical and Development Systems, Biopharmaceutical Company

Are you ready to accelerate validation and GxP with Sware and Res_Q?

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