CASE STUDY

BIOTECHNOLOGY COMPANY

CUSTOMER PROFILE

A growing biotech company on a mission to develop groundbreaking treatments for cancer and infectious disease. Utilizing best-in-class technologies and delivery systems they have developed novel treatments that will revolutionize patient care.

CHALLENGE

- **A relatively small team** covering multiple site locations lacked a way to centralize and control validation processes
- **Validation processes** based on “digital paperless” data housing required manual file and resource exchange, draining time and resources
- **Outdated workflows** require employees to manually review assets and documentation to meet timelines and deliver crucial risk assurance
- **A growing volume of required validations** contributed to organizational validation debt and placed further pressure on IT and Quality personnel

SOLUTION

To address these challenges, the biotech company partnered with Sware to implement Res_Q, a technology platform that automates, unifies, and accelerates life sciences software validation using a single SaaS application. The two companies set several goals to eliminate bottlenecks, drive efficiency, and mitigate risk:

- **A single, SaaS-based application** to bridge validation gaps and offer a single point of control
- **Workflow automation** to expedite and prioritize curation, review, and approval of key documentation
- **API-driven, data first architecture** to interface with existing industry-standard GxP file storage architecture
- **Transparency, speed, and connectivity** to increase end-to-end visibility and mitigate risk

As the solution was implemented, Sware's functional expertise, proactive planning, and agile methodology helped the biotech company minimize implementation time, answer specific process questions, anticipate challenges, and eliminate the backlog.

"Res–Q has saved us significant time and resources, allowing us to focus on core business objectives and reducing validation time by 30-40%. I wholeheartedly recommend Res–Q to fellow industry professionals seeking to enhance their validation practices."

– Senior Director, IT Business Partner, GXP Systems

OUTCOMES

- **Reduced costs**, improved efficiency, and easy collaboration across multiple sites
- **Increased audit-readiness**, traceability, and state of compliance at all points
- **Increased focus** for IT and Quality staff on high-value, revenue-generating initiatives
- **30-40%** reduction in total validation time

"The Sware team is very knowledgeable regarding validation practices and regulations. They're always the first to provide insights or point out required plan deviations. Ultimately, they understand that every company is different, and they demonstrate the flexibility needed to provide deliverables that enhance our process."

ONGOING COLLABORATION

This biotech company has approached Sware to integrate its bespoke bioinformatic data into the Res_Q workflow. They are collaborating with Sware to ensure a successful implementation, understanding that the Res_Q platform will seamlessly accommodate these complex data streams as it automates, unifies, and accelerates their validation activities.

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