

CASE STUDY

Enabling a CDMO to Modernize Validation and Save 1.5 FTE Annually

CUSTOMER PROFILE

A contract development and manufacturing organization (CDMO) operating across multiple sites, supporting life sciences customers who depend on rigorous GxP compliance. The company had a clear ambition: to become a tech-forward industry leader with the validation infrastructure to back it up.



CHALLENGE

Despite that ambition, the company's validation processes hadn't kept up. Most systems still relied on paper or paper-on-glass approaches, and a growing backlog of more than five releases made it difficult to keep pace with operational demands. With no common validation platform across sites, there was limited transparency and little ability to control or coordinate validation activity at an organizational level.

The company recognized that its existing approach put it at a disadvantage with regulators and with the customers it served. Modernizing wasn't optional; it was a competitive and compliance imperative.

SOLUTION

Sware deployed the Res_Q Validation Management Platform to give the company a consolidated, modern foundation for all validation activity. Historical validation packages were migrated into the unified system, eliminating the scattered, siloed records that had made audits and change management difficult.

From there, Res_Q established standardized validation processes across sites, streamlining day-to-day operations and creating a single source of truth for all validation documentation. The result was full traceability at every point in the validation chain, with audit-readiness built in rather than bolted on.



What impressed me most was their ability to provide both a sleek, modern validation tool and skilled resources who can hit the ground running to deliver results quickly. Their team really understands the unique challenges CDMOs face when it comes to GxP validation.”

Head of Quality
Global Biologics CDMO

RESULTS

The impact was measurable. The company is projected to **save 1.5 FTE annually** on ERP validation efforts alone, and is now FDA audit-ready with modernized, data-first validation that can be traced end to end. The partnership with Sware continues, with ongoing collaboration to refine existing processes and onboard new Res_Q capabilities as the company sees further into what compliant, future-proofed validation can look like.

Talk to a Sware expert to see how Res_Q can help your organization forge a new path in life sciences compliance.

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