CASE STUDY

Streamlining Validation to Save Over $130K Annually and Accelerate Compliance

CUSTOMER PROFILE

A global contract development and manufacturing organization (CDMO) operating across nine international manufacturing facilities, supporting the development and production of life sciences products for clients worldwide.

KEY CHALLENGES

- Validation processes varied widely across facilities, creating inefficiencies and a lack of visibility into compliance status.
- Spiraling FTE hours spent managing outdated workflows.
- Urgent need to validate critical SaaS systems during a major Microsoft Dynamics ERP implementation.

SOLUTION

Standardized Validation

Res_Q established a single source of truth for all validation documentation, replacing fragmented, facility-specific processes.

Unified Dashboard

Leadership gained full organizational visibility into validation status for the first time.

Scalable Platform

Res_Q supported Andelyn's acquisition-driven growth strategy, enabling new projects and facilities to onboard without adding headcount.

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RESULTS

- **53%**
  Reduction in effort per project using Res_Q
- **$130K+**
  Projected annual labor savings
- **2,070 hours**
  Saved annually—equivalent to ***1 FTE.***

- **Accelerated Compliance:** Test execution sped up by 20-40%, and approval cycles reduced from weeks to days.
- **Early Wins:** Three critical SaaS systems validated successfully, earning early FDA approvals.

> We highly recommend Res_Q for its simplicity and effectiveness. [The] software is exceptionally user-friendly, enabling streamlined audits through controlled auditor access. All validation activities are consolidated within a single app, ensuring consistency and transparency. The prebuilt templates simplify implementation and promote uniform validation processes."
>
> **Director of Quality**
> Global Gene Therapy CDMO

FUTURE COLLABORATION

- The CDMO plans to integrate Res_Q with equipment using BM RAM, further enhancing operational efficiency.
- The partnership will continue to evolve as the CDMO scales its operations, ensuring compliance and innovation remain at the forefront.
- Sware and the CDMO are committed to a long-term collaboration, leveraging Res_Q to meet future challenges and maintain the CDMO's position as a leader in gene therapy manufacturing.

Talk to a Sware expert to see how Res_Q can bring clarity and control to your validation program.

Book a Consult

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