Case Study

Empowering Validation Consultants with SIMCO

Life Sciences Consultant Scales Client Delivery with Automated Software Validation

Overview:

The client, a medium-sized Next Generation Sequencing (NGS) company headquartered in the U.S., transitioned from research-use-only (RUO) products to FDA-regulated in vitro diagnostics (IVD) products and needed to validate their systems quickly to meet go-to-market deadlines without compromising on quality.

The company implemented Arena™, a cloud-based eQMS/PLM platform, and quickly realized how difficult it would be to validate the platform efficiently with limited internal resources. So, they turned to a Quality Consultant to lead the effort.

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The Challenge: Validating Fast with a Lean Team

With no dedicated validation team and a small, newly hired quality group, the priority was clear: validate the platform quickly and compliantly.

Faster validation would allow the client to move forward with production, regulatory submissions, and audits without delay. Traditional paper-based methods would only slow things down and stretch already limited resources during a high-stakes transition.

“With a manual validation process, these protocols required weeks of work, pulling skilled team members away from higher-value and strategic work, better aligned with their expertise,” said the Quality Consultant.

Seeking to accelerate the execution of multiple validations and head off a time-consuming, labor-intensive, and costly resource drain, the Quality Consultant brought in SIMCO.

Quality Consultants Facilitate Efficient Compliance, Safety & Market Access

Consultants help life sciences companies stay compliant, close gaps, avoid findings, and reduce risk by streamlining system validations. Their efforts ensure software used to manage data, quality processes, and production performs reliably and meets regulatory expectations. And by extension, they also enable patient protection, product quality, and market access.

The Solution: SIMCO Automated Software Validation

SIMCO's Automated Software Validation platform offered a smart alternative to managing each execution test case, by test case, or having to build out additional resources with the client's limited budget.

Instead, SIMCO handled the full PQ execution, delivering summary reports, screenshots, and a complete video recording of each test. This meant less coordination, no manual rework, and complete traceability, which accelerated timelines and enhanced client confidence.

The approach reduced test execution time by more than 90% and kept the project on schedule and on budget, even as the client scaled up for regulatory submissions.

From Bottleneck to Business Advantage

"As a consultant, customer satisfaction and on-time delivery are everything. SIMCO's Automated Software Validation exceeded customer expectations, juggling multiple projects while staying compliant. I was able to manage the project efficiently and deliver ahead of schedule, with full confidence in the results," said the Quality Consultant

Benefits at a Glance:

Delivered more, faster, and without overextending the team

- Eliminated weeks of manual PQ execution, reducing time to mere hours
- Scaled delivery without sacrificing quality or control
- Enabled simultaneous work across multiple projects and clients

Stayed compliant with less effort

- Delivered full traceability through embedded screenshots and execution video
- Automatically generated FDA-compliant reports with deviation tracking
- Reduced the risk of CAPAs, rework, and audit findings

A Win-Win for Consultants and Clients

The consultant helped the client meet aggressive timelines and market-readiness goals without exceeding budget or burning hours. SIMCO's automated platform enabled the consultant to deliver fast, audit-ready validation while managing other high-priority projects, and all without compromising quality.

By introducing a state-of-the-art, compliant solution, the consultant elevated expectations. The project moved forward faster, the team stayed focused on FDA readiness, and the consultant strengthened her reputation as a strategic partner.

"SIMCO gave me a technological advantage to deliver agile, compliant validation. It freed me up to focus on FDA readiness and internal training, without draining time on execution," said the consultant.

A Consultant's Competitive Edge

SIMCO's automation unlocked efficiency and delivered a competitive edge. It helped the consultant:

- Accelerate project timelines while demonstrating innovation
- Avoid bottlenecks and manual work
- Strengthen client relationships through operational excellence
- Deliver a modern solution clients trust—and remember

Why SIMCO? A Partner Consultants Can Trust

The Quality Consultant had prior experience with SIMCO's software and calibration services and recognized the opportunity to bring added value to the client, especially in FDA-regulated environments.

"There was already trust. SIMCO has a reputation for delivering high-quality services, so connecting SIMCO with my client felt like a win-win for both of us," the quality consultant shared.

SIMCO offers a strategic partnership, not just software. It serves as a true execution partner, offering deep domain expertise that far exceeds the role of a typical vendor. Its consultants maintain strategic oversight without detailed manual execution.

Looking Ahead

With Arena™ pushing 3–4 updates per year, the consultant sees long-term value in continuing SIMCO's Automated Software Validation Solution for her client. Each update may require revalidation, and SIMCO ensures fast, low-friction re-execution, without straining resources unnecessarily, enabling the client to succeed in the long term.

Revalidation requires only minor updates to the automated test scripts, which speeds up future releases and builds on the work already completed, delivering even greater ROI.

About SIMCO's Automated Software Validation

SIMCO's platform empowers consultants and internal teams alike with:

- PQ execution with customer-provided protocols
- Screenshot and full video evidence
- Summary reports with deviation tracking
- Confidential sandbox execution
- Seamless support for frequent software updates

Whether you are a consultant or manage a validation team, SIMCO empowers you to achieve greater results without increasing your workload.

Reach out, we'd love to tell you more.

SIMCO is the leading provider of calibration and software services for technology organizations, bringing over 60 years of calibration industry leadership. Our experience enables us to develop exceptional solutions for service management.

Founded in 1962 to service NASA and high technology firms in Silicon Valley, SIMCO is committed to delivering life-saving quality leaner, by providing the highest level of quality and customer service.

Learn more at **www.simco.com**
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