

Building a Compliant Foundation for Commercialization Success



ABOUT THE COMPANY

SomaLogic Inc. is a leader in AI-data driven proteomics technology. The company seeks to deliver precise, meaningful, and actionable health management information that empowers individuals worldwide to continuously optimize their personal health and wellness. With the ability to simultaneously measure thousands of proteins over a wide range of concentrations, SomaLogic's groundbreaking platform is designed to help drive better insights and improved clinical outcomes.

BUSINESS CHALLENGES

To stay ahead in the highly regulated and competitive life sciences market, SomaLogic needed to fast-track innovation and demonstrate compliance with various industry regulations and standards.

Previously, SomaLogic relied on a content management tool to maintain their product and quality records.

AT A GLANCE

Mission

Create a world where everyone can routinely monitor health and accurately diagnose, effectively treat, and proactively prevent disease

Best Thing About Arena

Provides single source of truth for teams to have complete control over product and quality processes

Bottom-Line Impact

Helps SomaLogic achieve compliance goals

Key Benefits

- Provides control and traceability of product and quality information
- Meets regulatory requirements for maintaining electronic records
- Reduces compliance risks
- Accelerates collaboration to speed new product introduction
- Scales with rapidly growing business

Because that system primarily focused on document management, it did not provide SomaLogic visibility and traceability across the full product record. This made it harder for SomaLogic to drive compliance and meet their new product development and introduction (NPDI) goals.

THE SOLUTION

Arena provides SomaLogic a product-centric framework to manage quality processes

SomaLogic needed a system that they could easily adopt without the burden of a costly IT infrastructure or a lengthy implementation. "We chose Arena's cloud-based quality management system (QMS) for its ease of use and ability to scale with our growing business. Because we did not have to rely on internal IT resources or invest in additional hardware and software for the initial setup, we were able to hit the ground running," stated Angenette Nordqvist, Senior Manager of Quality Assurance at SomaLogic.

Unlike traditional document-based systems, which fail to manage the complete product record, Arena QMS links all of SomaLogic's product information and quality processes in a single platform. By managing linked relationships between bills of materials (BOMs), quality records, design files, and any changes or quality issues, this product-centric approach to QMS provides SomaLogic greater visibility, traceability, and control throughout the entire product lifecycle and reduces compliance risks.

The ability to access Arena QMS anytime and anywhere and drive real-time collaboration keeps SomaLogic's dispersed teams on track with their product work and helps speed compliance.

Consulting with Arena's solution architects, customer success coaches, and other industry experts also enables SomaLogic to utilize Arena QMS to its full potential and keep their processes running smoothly.



KEY BENEFITS

Drives compliant practices across dispersed teams

Although SomaLogic was forced to transition to a hybrid remote-work model because of COVID, Arena has enabled their dispersed teams to stay connected and drive compliant quality processes.

Product teams can easily create, review, and approve electronic change orders through automated notifications and routings. They can also quickly access nonconformance reports (NCRs), corrective and preventive actions (CAPAs), and other outstanding items through a convenient dashboard and automatic alerts.

SomaLogic's quality team leverages Arena Projects to develop internal audit plans and schedules. Tasks and due dates are assigned to team members for easy tracking. Nonconformances are also linked to the audit schedule for greater visibility and quicker issue resolution.

“ Arena provides a traceable audit trail for all of our remote processes through electronic documentation, approvals, and signatures. This enables us to comply with FDA CFR Part 11 and similar regulations.

—Angetette Nordqvist, Sr. Manager Quality Assurance, SomaLogic

ESTABLISHING A ROBUST SYSTEM FOR COMPLIANCE

Now that teams across the organization have fully embraced Arena QMS, SomaLogic continues to ramp up good manufacturing practices (GMPs) and other areas of its quality system to ensure compliance with the Food and Drug Administration (FDA), International Standardization Organization (ISO), European Union (EU), and other regulatory bodies.

SomaLogic is acquiring Arena's software validation package (i.e., Arena Validate) to help speed FDA Part 11 and Part 820 compliance. By covering the critical elements of document management, change management, design controls, electronic signatures, quality management, and requirements management, Arena Validate saves SomaLogic significant time on in-house software validation and provides audit-ready results.

The quality team has developed a custom workflow in Arena to record and track injuries, exposure to hazardous substances, and other workplace incidents that impact employee health and safety. This enables the company to assess trends and implement the necessary counteractive measures.

They are also building a complaints workflow in Arena that will integrate with their downstream Salesforce customer relationship management (CRM) system. All customer complaints and feedback that meet certain criteria will be pushed into Arena QMS to better inform product development processes and improve customer satisfaction.



“ Arena has become our one-stop solution for all things product- and quality-related. We no longer have to access multiple, disconnected systems. With just a few simple clicks, we can do the work that's needed to reach our product development milestones.

—Angetette Nordqvist, Sr. Manager Quality Assurance, SomaLogic