CASE STUDY

Lotus Clinical Research achieves excellence in clinical research and quality management with Octave Reliance

Key facts:

Company: Lotus Clinical Research

Industry: Clinical Research/Contract Research Organization

Country: United States

Octave products used: Reliance *(ETQ Reliance)*

Key benefits:

- Automated document control and CAPA workflows replacing Excel spreadsheets to achieve audit-ready status at any time
- Enabled global scaling with growing client base without need for additional full-time quality professionals
- Created single source of truth for monitoring, managing and resolving quality issues across 20+ clinical research sites

Lotus Clinical research is a scientifically driven, full-service contract research organization (CRO).

Since its inception in 2001, Lotus has strategically leveraged its services, expertise and regulatory knowledge to help its biopharmaceutical partners succeed in clinical trials across all phases - from phase 1 through phase 4.

Lotus is owned by Emerge Holdco, LLC, which also owns Evolution Research Group, LLC (ERG). ERG is a leading clinical site organization with over 20 wholly owned clinical research sites across the U.S., conducting early- and late-phase complex trials in both healthy volunteers and highly specialized, diverse populations. What sets Lotus apart is its exceptional ability to mitigate risk at the site and study level, achieved through its therapeutic expertise and a superior level of talent across the medical, operational and support functions.

Addressing the challenges of a changing landscape, a scaling organization

As the complexity of clinical development and the regulatory landscape continues to grow, Lotus has encountered several key challenges. These include the need to automate its infrastructure for Standard Operating Procedures (SOPs), Work Instructions and standard documents, to ensure compliance with FDA regulations and prepare for ICH (E6r3) guidance in order to mitigate quality and compliance risk. Additionally, hosting and managing audits have become a rising client focus, and Lotus must work with multiple pharmaceutical clients with differing requirements, deliverables and processes.

To address these challenges, specifically the need to automate Lotus's infrastructure, the company recognized the necessity of implementing an automated quality management system (QMS) which could help digitize previously manual functions and streamline processes for drafting, approving and re-assessing SOPs while also enabling enterprise-wide visibility.

Lotus also knew that by automating core quality functions, such as document control and corrective and preventative actions (CAPA) plans, as well as training documentation and management, it would be able to streamline operations, boost quality and improve efficiency.

"We were successful for a long time with manual processes, but as we grew, it was becoming very difficult to manage all of these things manually," said Chris Bowman, Vice President, Quality Operations, Lotus Clinical Research.

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The solution: Reliance for document control, CAPA and training management

After vetting several vendors, Lotus selected Reliance initially because of the rapport with the Reliance team. "They clearly understood where we were coming from, where we were going and what we needed to reach our goals," added Bowman.

Lotus took a phased approach to its quality journey, first identifying high-risk elements to prioritize and validating them internally. It began by deploying the Reliance document control module, which enables the management, creation, review, distribution and archiving of enterprise-wide documents in a centralized framework. By automating document control, Lotus can build processes for an unlimited number of record types (e.g. procedures, templates, and work instructions) and define unique workflows, such as defining escalation and notifications.

Given the importance of Corrective and Preventative Actions (CAPAs) for risk management and driving continuous improvement, Lotus then rolled out the Reliance CAPA module. This module helps to quickly discover the root cause of issues and implement resolution plans, playing a key role in regulatory compliance management and preventing recurring quality issues.

Gaining a single source of truth, efficiency and control

Today, all Lotus employees and contractors have access to Reliance enabling them to perform process, guidance and standard document reviews, as well as a automated CAPA workflows. Reliance offers a multitude of reports that produce current



metrics providing valuable information in support of client audits and agency inspections.

"As a CRO that works with multiple clients, a key question that we're frequently asked is if we use an automated QMS. Reliance allows us to definitively say yes, demonstrating our commitment to quality and risk management," added Bowman.

Thanks to Reliance, Lotus Clinical Research has achieved a more automated approach to its culture of quality enterprise wide. Bill Martin, Ph.D., Lotus President, said, "The intuitive nature of the Relianceinterface has led to broad adoption and very high compliance rates across our organization, and as a result we are now audit-ready at any time. It has allowed us to move beyond Excel spreadsheets and other manual systems and gain a single source of truth for monitoring, managing and resolving quality issues."

Additionally, as Lotus continues to scale, expanding globally and with a growing client base, the efficiency and automation enabled by Reliance allows it to address rising workloads without the need for additional full-time quality professionals.

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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