

Case Study – Re-aligning a Solution with Evolving Business Needs



The Challenge

An early, clinical-stage biopharmaceutical company was naturally focusing much of its resources on its drug research, so they invested in a 'turnkey' or 'one size fits most' quality management solution. Initially, one administrator was able to manage the lifecycle of policies and procedures effectively. The solution met the needs of their small team of less than a dozen scientists and lab technologists when the existing knowledgeable resources remained in their roles.

Over time, employee turnover and increased workloads resulted in disintegrated processes. The staff grew (and sometimes shrunk), including changes in the number and type of employees, contractors, and academic and consulting alliances. Their system and processes became time and resource-intensive and

included many manual workarounds. As a result, the company's compliance and reputational risks were exponentially increasing.

Our Approach

To uncover the historical context as well as emerging and unmet requirements, the 2030 Consultant Quality Management System experts interviewed the client team members and assessed the capabilities of their current solution. We found that employee changes and shifts in roles and responsibilities contributed to an ever-growing database of content and frequent adjustments to processes. Eventually, the employees were no longer using the software as initially intended. Many tasks, such as record reviews and approvals, were occurring outside of the system.



The Solution

We helped the client better understand their evolved quality management needs and addressed many of their immediate requirements with configuration changes, updates to roles and responsibilities, and modifications to streamline processes. The client's changing needs called for the quick and efficient reconfiguration of the technology and supporting processes.

The Result

By exposing scalable options within the software and business process, the client was able to renew their compliance efforts while getting more from their original technology investment.

