CASE STUDY: Leading CRO adopts Labwise as its Enterprise Quality Management Solution

Going Paperless

Founded in 1986, Ricerca Biosciences, LLC collaborates with pharmaceutical developers by providing a comprehensive, integrated suite of services to accelerate drug development.

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-Stephen Rogenthien, Director of Quality Assurance

Executive Summary

Ricerca Biosciences, LLC recently made the transition from paper to an electronic quality management system by implementing Xybion's Labwise product. This resulted in lower organizational risk and increased client confidence, allowing the company to focus on its core contract research service business.

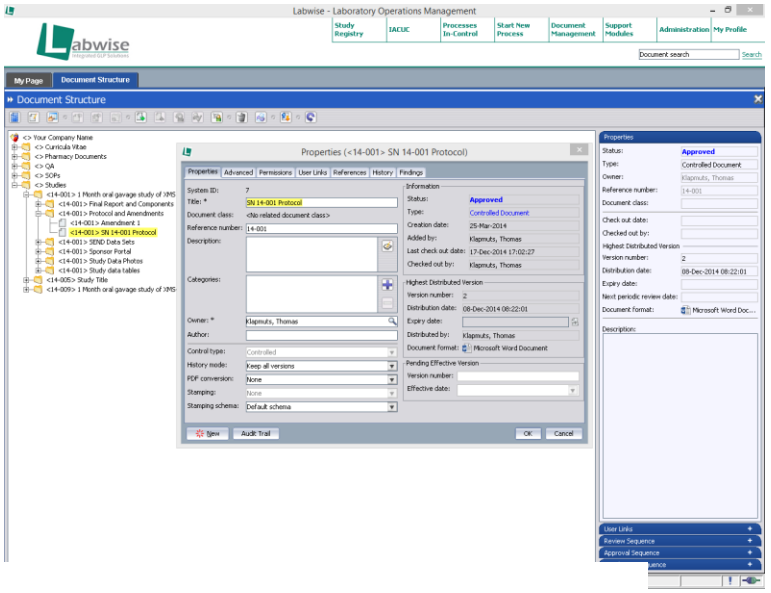
Challenges

Ricerca, a US-based nonclinical CRO, faced inefficiencies in managing its various regulated documents due to a highly manual, paper-based quality management system. The Quality Assurance department needed to find a way to respond to client audits more quickly. This required moving to an electronic quality management system. In addition, numerous process deviation types were in scope and needed to be addressed, preferably in one system.

Labwise from Xybion

Xybion's Labwise product was implemented in North America for the management and control of numerous policies, procedures, work instructions, and other documentation in a consistent manner. A well-structured folder system and permissions scheme was put in place, enabling users to find documents quickly. The configuration included PDF rendering and stamping configurations.

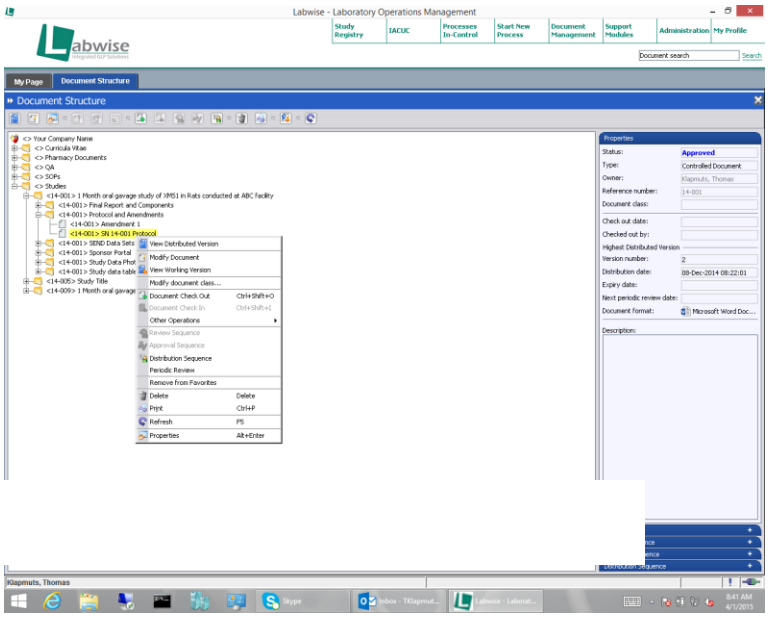
In addition, using Labwise's flexible process designer, numerous types of deviations were tracked, including process and lab deviations as well as Corrective and Preventive Actions (CAPAs). These critical workflows were used across departments to cover an array of specialized deviation tracking needs.



View and track document properties, including the audit trail.

Benefits

- Control and automated reporting over thousands of critical documents required by regulatory authorities, resulting in reduced risk.
- Multiple deviation types tracked in one system, resulting in lower IT costs.
- The flexibility of the Labwise platform enabled Ricerca to configure, migrate, and train on the system using in-house resources, supporting a lower TCO.



Access a variety of document management functions immediately from the folder system.

"We were able to configure our own process designs, including some specialized plug-in reports – a testament to the ease of configuring Xybion's Labwise platform. This allowed us to minimize ongoing maintenance costs."

-Stephen Rogenthien, Director of Quality Assurance