

BUYER CASE STUDY

Speeding the Cure: Kalypsys Deploys Xerox DocuShare CPX to Accelerate Drug Development

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IDC OPINION

Compliance applications often serve as the camel's nose under the tent — a strategy for introducing a content management platform that proceeds to transform business operations. Kalypsys, a clinical stage pharmaceutical company, rapidly deployed an enterprise solution for managing the content for regulatory operations and clinical trials, thus enabling itself to demonstrate compliance with U.S. Food and Drug Administration (FDA) regulations. Not only did the application work as expected but the company learned from the experience and has proceeded to expand its content management capabilities into many other business functions. Among the lessons learned:

- ☒ It's important to choose an extensible and flexible platform, one that can easily adapt to various operational situations.
- ☒ Quick wins breed success. Solving the compliance problem can be a good first step toward deploying content technologies more broadly across the enterprise for improved business process management.

IN THIS BUYER CASE STUDY

This IDC Buyer Case Study examines how Kalypsys, an innovative pharmaceutical company, is leveraging the capabilities of a content management platform to address a broad range of business functions. Ensuring compliance with FDA regulations for clinical trials was the driving force behind the company's decision to invest and deploy Xerox's DocuShare CPX content management system. But this is only the beginning of the story. DocuShare CPX is now being used to support the flow of business-related documents in many other areas.

SITUATION OVERVIEW

Organization Overview

Kalypsys, a clinical stage pharmaceutical company, blends cutting-edge science with innovative business processes for rapid drug development and testing. Founded in 2001 by a team of seasoned researchers, the company leverages a proprietary, state-of-the-art, fully automated, robotic ultra-high-throughput screening and profiling system to accelerate the drug discovery process. The bench science is paying off.

Kalypsys has already identified several promising molecules to treat cardiovascular/metabolic diseases, pain/inflammation, and particular types of cancer.

Kalypsys must now move these compounds through a series of clinical trials and translate the laboratory discoveries into real therapies for real patients. Managing the flow of scientific and clinical documents associated with these trials is essential to the success of the company's efforts.

Challenges and Solution

The Operational Challenges of Drug Development

When they launched the company, Kalypsys executives were well aware of the operational challenges of drug development — scientifically proving the effectiveness and safety of a compound to the satisfaction of the FDA. As they prepared for clinical trials, senior managers decided to focus on what they needed to do to comply with FDA requirements.

Kalypsys was determined to avoid the pitfalls of managing clinical trials and needed a systematic solution for tracking electronic documents. The company needed an adaptable environment capable of supporting the documentation and auditing requirements for an investigational new drug (IND) application and then, if the initial trials proved successful, seamlessly managing the extensive information required for a new drug application (NDA). "Many small companies don't address requirements for FDA compliance until clinical trials are well under way, when paper-based document tracking processes become overwhelming," observed Dr. Paul Grint, chief medical officer and executive in charge of clinical trials at Kalypsys. "We're a technology-driven company and have a number of people who've seen first-hand the value of content management systems. So we decided to invest in a compliance system up front."

Beyond Compliance

Although compliance was the initial driver, Kalypsys also sought an extensible platform whereby the company could manage content across the enterprise. Senior managers knew that HR, corporate IT, finance, legal, and many other company functions needed to capture, organize, store, produce, and archive business documents. As they planned for the company's long-term growth, they anticipated that researchers and staffers alike would need to share content with various partners — including other pharmaceutical firms and university-based research organizations with which they would collaborate on a variety of codevelopment activities. Kalypsys needed a flexible environment capable of addressing its broad range of enterprise requirements.

In addition, Kalypsys leaders knew their core competencies and limits. Kalypsys focused on the bench science and innovative business processes of medicinal chemistry and translational medicine. (These emerging disciplines seek to facilitate interactions between researchers and clinicians, often by pursuing multiple drug development tasks in parallel and sharing information electronically.) Kalypsys maintained a bioinformatics staff to develop sophisticated computer-based

applications for its drug development activities and initially considered developing a clinical trials tracking system on its own. But managers quickly realized that this kind of system was only one instance of a more general business need to manage content across the enterprise. They concluded that building an extensible content management platform required specialized knowledge and skills, beyond the company's immediate area of expertise. The smart business decision was to buy the solution and services that would meet the company's needs, rather than try to develop them in-house.

Making the Xerox DocuShare CPX Decision

Senior managers proceeded to rely on their years of industry experience to develop the requirements for a comprehensive, enterprisewide solution. The evolution of Web-based technologies had a profound impact on their options. They knew that going into 21st century drug development, the right Web-centric platform would enable company researchers to easily and securely share content with colleagues across an extended enterprise.

Kalypsys reviewed the capabilities of several leading content management offerings before selecting Xerox DocuShare CPX together with the DocuShare Compliance Module from Sitrof Technologies. "We were looking for a system that would meet the FDA requirements, that we could leverage in other areas, and that we could rapidly implement at an affordable cost," John Graf, associate director of IT, explained. "We concluded that the Xerox solution would provide us with the best value for our investment." Xerox delivered the essential technology platform, while Sitrof contributed the technical components required to comply with 21 CFR Part 11 (the detailed electronic records management requirements mandated by the FDA).

Implementing a Comprehensive Solution

DocuShare CPX gives Kalypsys a central repository that securely stores and manages all types of content objects — including electronic documents, spreadsheets, pictures, multimedia files, email messages, and wikis. All of these objects are fully indexed and permission controlled. They can be put under corporate governance via an integrated records management module. DocuShare CPX also has features for content collaboration, content assimilation, and content-centric business processes.

Thus, business teams can securely share content over the Web. Researchers with appropriate access rights and permissions can access and add documents to sets of shared folders that are indexed and stored within the repository. Through the content rules feature of DocuShare CPX, adding or changing any document can invoke predefined actions on that document when specific criteria are met. With the XML processing capability enabled, copies of these documents are converted to XML and indexed in a way that allows individual paragraphs or content chunks to be accessed and reused in other documents.

In addition, business process owners can easily access template libraries and process steps to define workflow activities. Application developers can, in turn, use a visual development environment to design the templates and process steps. Sitrof relies on this development environment to deliver its Compliance Module, including a

customized collection of templates, process steps, business rules, audit trails, and electronic signature functionality that meet FDA requirements.

Results

The IT group at Kalypsys was able to install and deploy DocuShare CPX within a few days. The group then worked with Sitrof Professional Services over a four-week period to define the steps for the compliance-related business processes, develop the templates, implement the workflow activities, and deliver the necessary documentation to complete the computer systems validation process. The operation of the platform can be audited and tested by an independent third party or by the FDA, as required, to verify compliance with the standards.

DocuShare CPX (together with the Sitrof Compliance Module) now serves as the central repository for clinical research and regulatory operations. It is storing and tracking all of the documents related to the company's current IND studies. It can easily manage additional compliance studies as needed — these become separate sets of named folders within the repository. Each study systematically accumulates thousands of documents, messages, reports, and other items over a multiyear period. Finally, DocuShare CPX can produce the necessary reports, on demand, to satisfy IND submission requirements.

For example, DocuShare CPX tracks successive versions of the study protocol document — lengthy instructions that describe how the drug is going to be administered and how the results should be reported. When it is initially developed, the protocol goes through a review and approval process; DocuShare CPX manages this workflow process and captures the approvals in a permanent and auditable manner. Then, when the protocol is amended and the instructions are modified, DocuShare CPX again manages the amendment process and captures the approvals. Should the FDA decide to verify compliance or track who changed what and when, the agency will find a complete record of the documents and procedures — including explanatory notes for change justifications and electronic signatures for approvals.

Now that the compliance solution is up and running, the IT group is addressing the content management needs of other corporate functions. More than 40 employees at Kalypsys (roughly one-third of the company) are using DocuShare CPX to manage documents for clinical studies, develop the documentation for IT projects, and control financial reporting activities. The legal, procurement, and HR departments are looking to this platform to track contracts, archive email messages, and manage a wide range of routine business processes. Researchers can anticipate developing innovative workflows for easily sharing documents with colleagues and partners over the Web. The IT group, in turn, is able to build on the initial experiences supporting clinical trials and adapt DocuShare CPX to other corporate requirements.

ESSENTIAL GUIDANCE

This case study illustrates the importance of a compliance-related application as the driver for technology change and business innovation within the pharmaceutical industry in particular, and other regulated industries in general. Companies know that complying with administrative regulations — such as clinical trials procedures mandated by the FDA — is just part of the cost of doing business. But solving the compliance problem in an extensible fashion can lead to significant business benefits for improving content management within the company.

The key is investing in a scalable and robust content management platform, becoming experienced in its use to solve an initial problem, and then adapting it to other business situations. While the platform begins as a central repository for storing content, it includes a wide range of content-related services for ensuring security, launching workflows, organizing metadata, and tracking review/approval cycles. Rather than trying to develop a specialized content application in-house, companies should define their requirements and then survey the market to find a suitable content management platform that meets their needs.

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- ☒ *Worldwide Applications 2007 Top 10 Predictions: The Road to Applications 2.0* (IDC #205238, January 2007)
- ☒ *The Stars Align: Oracle Acquires Stellent* (IDC #204713, December 2006)
- ☒ *IBM to Acquire FileNet, Amidst Ongoing Consolidation in the Content Management Market—Who's Next?* (IDC #cUS20312706, August 2006)
- ☒ *Open Text Outbids Symphony for Hummingbird as Content Management Market Continues to Consolidate* (IDC #202494, July 2006)
- ☒ *Oracle Ratchets Up Its Content Management Initiative with New Strategy* (IDC #202451, July 2006)
- ☒ *Worldwide Content Management Software 2005 Vendor Shares* (IDC #202317, July 2006)
- ☒ *CA Acquires MDY and Strengthens Its Position to Compete in the High-Growth Areas of Compliance and Legal Discovery* (IDC #202124, June 2006)
- ☒ *Worldwide Content Management Software 2006-2010 Forecast: Continued Steady Growth* (IDC #201781, May 2006)
- ☒ *The Future for Content Applications: A Survey of Market Readiness and Technology Trends* (IDC #34831, February 2006)

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