

COMPLIANCE WEEK

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Case Study: Document Management At OSI Pharma.

By Matt Kelly — May 31, 2005

Jessica LeFur has plenty of experience developing systems for managing clinical and regulatory data for the pharmaceutical industry. A veteran of Andersen Consulting, LeFur had designed such systems at Johnson & Johnson and Bristol-Myers Squibb before joining OSI Pharmaceuticals in June 2001.

Which is why she had been recruited by OSI in the first place; LeFur was originally hired to help the company meet the Food and Drug Administration's notoriously exacting regulatory requirements. In part, that meant overseeing implementation of the company's first electronic document-management system, and she immediately saw opportunities for fundamental improvement.

But LeFur also grasped that the regulatory winds were blowing, and that additional requirements were looming. That meant the company would not only have more documents to manage—and that OSI would need to corral all that data into one electronic filing cabinet—but that fairly rigorous controls would need to be implemented to monitor and audit the data assets.

LeFur's project began in earnest in early 2002. Prior to her arrival, OSI staff generated and handled all documents manually, storing electronic copies on various servers throughout the OSI network. And because it was common for employees to edit and transmit data to peers, multiple copies of single documents proliferated; the company lost "version control," and staffers frequently came across information that was out-of-date.

It was clear to LeFur that OSI need a tool to control creation of documents and monitor updates. But considering the heightened regulatory environment, she also envisioned this tool controlling company policies—an interactive depot where employees could review procedures, submit to authorization approvals, and even sign attestations.

"We implemented [a tool] for regulatory documents at the start, knowing full well that we would expand it," LeFur says. "Everything surrounds content and generation of content. Whether it's a compliance requirement, a regulatory requirement, or some other requirement—the way we communicate is documentation ... You need a mechanism to manage that documentation effectively."

"A Lot Of Tools"

Despite the dozens of tools that have emerged in recent years to facilitate compliance with Sarbanes-Oxley and the SEC's rule 17a-4 (which requires certain financial institutions to archive records including email and instant messaging), LeFur found few that could also act as a more general document management tool. Would-be vendors included upstarts like OpenPages and Stellent, and technology stalwarts like IBM and EMC, which acquired content management firm Documentum in October 2003. But while "a lot of tools are out there," LeFur says, few could manage both drug-industry regulatory filings and SOX-related compliance filings.

As a result, LeFur spent most of 2002 scouting potential solutions. "At that time," she recalls, "there weren't that many tools out there that provided a more generic document need. Ultimately, she assembled a list of three possible

DETAILS

Company	OSI Pharmaceuticals
HQ	Melville, NY
Employees	452
Industry	Biotechnology
'04 Rev.	\$42.8 million
'04 Net	(\$260.4 million)

THE CHALLENGE

OSI Pharmaceuticals needed a system to automate management of the documents it generated for regulatory filings, storing all files in one location so employees could work with one set of current data.

SOLUTION CHOSEN

Enterprise compliance management solution from [Uumas Corp.](#)

vendors: Documentum; GX Pharma, a software suite based on Documentum but designed by IBM Life Sciences specifically for the pharmaceutical industry; and a broad-based suite of applications from Qumas Corp.

LeFur chose Qumas for simplicity and cost. Based on Cork, Ireland, with U.S. headquarters in Florham Park, New Jersey, Qumas offers a suite of compliance management applications have been developed specifically for regulated industries; its solutions facilitate compliance with regulations including The Patriot Act, Sarbanes-Oxley, and the record-keeping components of the Investment Company Act and Title 21 Code of Federal Regulations (Food and Drug Administration). Though less well known in the United States, the company has over a decade of experience working with financial and pharmaceutical companies in the United Kingdom and Europe; customers include London-based AstraZeneca and GlaxoSmithKline, as well as major U.S. players like Merck.

According to LeFur, part of the decision to go with Qumas was the fact that the solution was off-the-shelf, and that it didn't require massive configuration or extended implementation contracts. "That was critical, especially for a small company," she says. "We can't afford something that requires customization because of the initial upkeep and the continuing costs." As Compliance Week has reported in other case studies (see box above, right), it's not uncommon for public companies to spend close to—or over—seven figures for enterprise-wide document management systems. "I've seen multi-million dollar implementations with custom applications where you keep spending money on it because you keep maintaining it," acknowledges LeFur.

The cost to OSI: \$135,000 for the software, new servers, outside consultants, and training for the "first wave" of users.

Read And Understood

OSI began implementing Qumas' eDocCompliance application in the third quarter of 2002. Twenty participants were tapped for the first wave. Employees began utilizing the Qumas platform to manage basic functions when authoring new documents, like using its check-in and check-out procedures. Later, they added electronic "sign-offs."

As opposed to the pre-Qumas era at OSI, when multiple versions of documents were housed in disparate locations, the Qumas system now ensured all documents were housed in one centralized database accessible from any location on the Internet. LeFur's staff managed version-control, periodic review and sign-off.

However, LeFur notes that she held back on implementing some of Qumas' bells and whistles to ensure employees could adapt to the new system. "Even though there is tons of functionality in the tool, we were going from a paper process to an electronic process—so you really need to manage the change process with the people," LeFur explains. "You can have the best whiz-bang tool under the sun, but if people can't handle it and they're not ready for the change, it's going to be very difficult to succeed."

As users grew accustomed to using Qumas for FDA filings, the compliance staff added narratives for its Sarbanes-Oxley procedures to the database, so the company could take advantage of electronic signatures. In doing so, OSI wanted to convert its old paper-based methods of reading controls procedures and signing acknowledgements into an all-electronic process. LeFur then extended the ability to file "read and understood" statements to regulatory procedures stored in the database, eliminating another layer of hand-written bureaucracy. She will expand that function to its Sarbanes-Oxley procedures this year.

Roughly 200 OSI employees use the Qumas database today, LeFur says. So far the company uses the system for its critical document needs—principally, FDA filings and Sarbanes-Oxley attestations and procedures. But LeFur now expects other business units within OSI to come knocking. The sales force, for example, wants to add training materials, while the medical-affairs division wants to store promotional reviews. "We're going almost beyond things that require centralized control," she says, "to places where centralized control would be really handy to have."

When asked about return on investment, LeFur talks more about productivity than dollars. Approval processes that might previously have taken weeks as a paper document circulated among multiple executives are now done in a day. "That alone has sped up things like the validation process," she says. "Getting SOPs [standard operating procedures] up is not nearly as painful as it used to be." And as for a cash investment only in the low six figures, LeFur is quick to note that "I've done other implementations that cost millions of dollars."

To those ends, LeFur recommends that other executives pursuing similar goals work to keep any document-management overhaul simple. "Don't try to implement the world because you have this application," she warns. "People look at me and say, 'You bought all these servers and software, and you're only managing documents? You're only managing version control?' Well, yes. Right now that's what the user base can handle."