Oliver-Tolas

OnDemand Document Management:

Expedited, compliant control & increased productivity

AssurX®

OLIVER-TOLAS HEALTHCARE PACKAGING
ONDEMAND DOCUMENT MANAGEMENT:
EXPEDITED, COMPLIANT CONTROL + INCREASED PRODUCTIVITY

Oliver-Tolas is a leading medical packaging provider, developing innovative sterile-grade packaging materials for more than 30 years. Oliver-Tolas' 240 employees serve more than 500 customers in 40 countries from ISO 9001:2000 registered headquarters in Grand Rapids, Michigan, USA; an ISO 9001:2000 registered, class 8 clean room facility in Venray, the Netherlands; and a sales office in Suzhou, China. Oliver-Tolas provides the unique package of inventive products, superior adhesive, flexible customer service, and expert support to medical device manufacturers worldwide.

The Company's Goal

Being Oliver-Tolas' Vice President of QA/RA Lora Keena is a person who wholeheartedly understands the importance of operating at the highest possible level of safety, efficiency and efficacy. "It's a core value of mine and that of our company, too," she says. "It's important to us that our standards for quality are at least as high as those of everyone we work with - both our customers and our vendors," she says. But the challenge is to help Oliver-Tolas grow and expand while making certain that all electronic records are maintained properly and that all employees have access to the latest procedures, protocols and other operational forms, Lora says. That's why she embarked on a vendor/partner search two years ago. The goal? Establish real-time procedures that are easy to understand, train, and update anywhere, anytime Oliver-Tolas personnel need to do so.

Quality Assurance Raises the Bar

As Oliver-Tolas' Vice President of QA/RA, Keena is responsible for initial FDA and ISO registration, inspection, and compliance for US and European facilities. Her areas of expertise include international auditing; quality systems; and supplier, product, and process validation. She has extensive experience and proficiency in FDA cGMP, QSR, MDD, FDA and ISO 13485 registration and inspections, 510(k) pre-market notification, international medical device registrations, supplier management and related regulatory affairs. She's been with the company for over

seven years. She's also a respected industry expert and frequent speaker. For example, in June 2008 she addressed the Medical Design & Manufacturing (MD&M) East conference in New York City. Keena's presentation was so well received at MD&M, prompting conference organizers to invite her to speak again at MD&M East. Keena's presentation, "Root Cause Package Failure Analysis," provides a guide to analyzing package failure, including a discussion of fishbone analysis (including the "6 Ms") and 'five-why' root cause analysis. She also speaks widely on how to address many anomalies that may result in seal failure, providing case studies and several specific examples of seal defects. She clearly understands the importance of QA and is passionate about making the right decisions to raise the bar higher.

Background: From Good to Great

Three years ago Lora and her team started looking for an electronic documentation system that would help them speed operations, improve operational efficiencies, and cut review times. Using a paper-based system, Oliver-Tolas personnel had struggled to fax and keep track of numerous documents. And getting signatures "took forever," says Lora. "Three years ago we were looking for an electronic document control system. But that system not only had to perform at a high level, it also had to be easy to operate, and adaptable enough to function in different countries and different situations. "All the quality systems—

from Grand Rapids, Michigan—to China—had to be consistent," Lora says. They knew they had to move everything—forms, testing, and all quality systems—from paper to electronic. And their customers also demand that an electronic system be 21 CFR Part 11 compliant, adds Lora. "Our old way was time consuming and cumbersome...we were faxing hard copies back and forth and it took forever," Lora recalls.

The Vendor Search

Lora's team ultimately spent several months on a relatively quick and certainly efficient vendor search. A key to the success of their vendor effort, Lora says, was the simple fact that they know what they wanted to achieve from the very outset. There were four requirements Lora demanded of her eventual system. It had to:

1. Be priced reasonably. Some were extremely expensive, she says.

2. Be Part 11 compliant

3. "Meet our needs" for document control

4. Be ready to roll and implement quickly

"We didn't have 12-18 months implementation time," Lora says. "I didn't want that kind of delay." During the three-month search, Lora and her team looked hard at four vendors. "AssurX rose to the top right from the beginning," she says. "After speaking with several AssurX customers in the pharmaceutical and medical device industries, we felt they were the best choice for our requirements," Lora reports. "We were impressed by their capabilities such as configurability, ease of use and better ROI when compared to other solutions. The other systems required heavier IT support and did not appear as user validation-friendly." "Our expertise in the life sciences industry helps companies such as Oliver-Tolas implement their electronic quality and compliance systems quickly, efficiently and effectively. Prior to AssurX, Oliver-Tolas was using paper based and legacy computer systems. Easy transitioning and short deployment times are key to successful regulatory compliant systems, and that's what we were able to provide to Oliver-Tolas," said Sal Lucido, Vice President, Enterprise Solutions.

A 'Compatibility': AssurX, Oliver-Tolas & Other Customers

Another reason Lora ultimately went with AssurX is that several of Oliver-Tolas' customers were already happy AssurX customers—including Boston Scientific and Bausch & Lomb. Familiarity and recommendation drove this over the top for final selection. Since Oliver-Tolas' customers were using it, they felt it was best to keep things consistent, and since they had good recommendations from those customers, that was perhaps the "final deciding factor" that compelled Oliver-Tolas to choose AssurX. "We are audited by our customers all the time," Lora says. "This compatibility helps a lot...it really is a bonus when customers know we are using the same system they are using," she says. So, how have Oliver's audits gone? "We've passed every audit," she says proudly. That's some 30 audits in the past two years and it's an enviable track record.

Oliver-Tolas and AssurX OnDemand

Oliver-Tolas elected to go with AssurX OnDemand (Software as a Service) delivery model because it helped to get them up and running faster and more cost-effectively. "First, it was the quickest route to have the project completed," Lora notes. OnDemand was also cost effective for Oliver-Tolas because it allowed them to test the system and see how much they liked it, instead of purchasing a system which would've been more costly.

The Verdict

After implementing AssurX, signatures and other approvals now come in the same day, Lora reports. Instead of waiting days and even weeks for a signature on paper to come back, Oliver-Tolas has leveraged AssurX to Com Oliver-Tolas to make certain that most current releases of procedures and documents are on the floor and available to all employees in real-time, Lora says. It's especially important for Oliver-Tolas because they have operations in several different locations—with more expansion on tap. "Using AssurX , our operators, inspectors and engineers now have access to the most current document at all times," Lora says. "Better safety and

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effectiveness is the immediate result." "This is especially important because it allows us to instantly add current releases on the floor everywhere in real-time," she says. AssurX "allows us to know when we are opening anything that it is the latest release and that it is correct," Lora stresses. Thanks to AssurX, there is now no possibility of using old or obsolete forms or systems. Lora is relieved by this improvement. "In today's environment, we can't afford that delay of even 1-2 days as it used to be in old days." Virtually all of the company's employees are now using AssurX in some form or another, she adds. She says about 40 are heavy users today, and that number is likely to rise in 2009. The benefits of AssurX are already wide-ranging...literally. For example, Oliver-Tolas' regional sales managers regularly use AssurX for demos in a customer or prospect's office. They can log into the system from any Web browser and show them test procedures and other screen shots, Lora says. "There's no need to carry around loads of documentation, they can pull it right up there in the customer's office." What's the final verdict? AssurX has easily "met expectations company-wide," Lora notes.

Easy Training

Lora also reports that the training program for AssurX went very well and employees adapted to it very quickly. It has reduced document wait-time by three to five days, and that means Lora and her team can train others much sooner. "We also used to use hundreds of copies of paper forms, and the paper reduction has been phenomenal." "It's fantastic now because terminals are setup at each site and everyone has access to the latest approved documents and procedures at all times," adds Lora. Document transition from paper to electronic wasn't that hard, either. She hired two temps who worked for two weeks over the Christmas break to come in and transfer paper documents onto the electronic system. After uploading some 250

documents—ranging from Quality Manuals, QS System Procedures, and Test Methods and other forms—Lora says the system was helpful on day one. The key is "getting people comfortable using it, and that comes with using it on a regular basis," she says. AssurX also makes training employees easier and faster, too, reports Lora. "There is no more waiting for documentation, or dissemination of paper copies" of procedures, training and other forms, she notes. That means everything—including employee training—is done in real-time. "We have no delays, no hang-ups" any longer, thanks to AssurX, she says. The result? AssurX's built-in dashboards and metrics allow Oliver-Tolas to anticipate potential bottlenecks or problems before they manifest themselves. And that means they are hitting deadlines faster and keeping a much closer eye on their vendor partners, too.

Future AssurX Uses

Sometime in 2009 Oliver-Tolas will use AssurX for internal and external CAPA, audit findings and supplier and complaint handling findings, Lora says. "We're looking forward to putting all of this into AssurX," she says. "I'm looking forward to being able to sort information so much faster, and our overall information assessment capabilities should be greatly expedited," Lora notes. Her prediction: "I anticipate the time savings here will be significant."

Conclusion

Oliver-Tolas and QA/RA Medical Director Lora Keena put a premium on getting the job done well and on time. It's a personal and professional mission for Lora that is clearly reflected in how seriously she takes her responsibilities at Oliver-Tolas. Harnessing a solution like AssurX has helped Lora and her team to raise the quality bar and improve operational efficiencies across the company—with more great things to come.