

VirtualScopics Gains Enhanced Product Development Visibility

AT A GLANCE

Organization:
VirtualScopics

Web Site:
www.virtualscopics.com

Headquarters:
Rochester, NY

Description:
VirtualScopics implemented TestTrack to gain greater visibility into their product development lifecycle and improve their compliance efforts.

Clinical trials are used to determine if a new drug or medical device is safe and effective. These trials often generate several MRI, CT, ultrasound, and x-ray images, and it's critical to the success of the trial that these images are analyzed and interpreted correctly.

To obtain reliable results, pharmaceutical and medical device companies turn to VirtualScopics, a leading imaging core lab providing central reads and quantitative imaging solutions for drug and medical device clinical trials.

The company has created a suite of image analysis tools and applications that are used for detecting and measuring specific anatomic structures and metabolic activity using medical images. Its proprietary software and algorithms provide measurement capabilities designed to improve clinical research and development. VirtualScopics focuses on applying its imaging technology to improve the efficiency and effectiveness of the pharmaceutical and medical device research and development process.



Growing Pains

Companies involved in the production of medical devices must maintain compliance with FDA regulations—particularly 21 CFR Part 11, which governs electronic records. Due to the company's desire to register its

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software application as a medical device, the software development team was starting to feel the pinch from the product development software they were using. They also needed greater visibility into their product development lifecycle.

“VirtualScopics has a lot of small projects that go concurrently in a fairly agile environment, so keeping them all straight and working out the implementation timeframes can be a bear,” said Colin Rhodes, Director of Software Development, VirtualScopics. “We used to use disparate software for issue and project management, but as we grew to a midsize company, those tools just didn’t cut it anymore. Every time a commitment date changed, updating and charting these changes was difficult; everything moved in an unpredictable way. Searching for relevant information was an absolute nightmare when you get over 16,000 artifacts/items. In short, there was no way to get a sensible answer about where you were on a given day. Every manager’s nightmare!”

Staying Compliant with FDA Regulations

In addition, Rhodes noted that previously, the only way to maintain compliance with 21 CFR Part 11 was to print the records. “The FDA is enforcing the electronic signature rules now. As part of the new regulation, if you make real decisions using an electronic system, that system needs to be compliant.”

After an in-depth look at some of the lifecycle management tools on the market, Rhodes decided on Seapine TestTrack.

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As a result of this greater visibility, VirtualScopics feels they are more prepared for audits and demonstrating their validation efforts to their clients.

Keep It Simple

Rhodes’ project management philosophy is to keep it simple and stick to the basics: what you have to do, when you have to do it, and what it’s going to take to get the project completed?

“Using Seapine’s software, we answer these three questions by configuring a bunch of custom fields to the high level request and then using the reports function to get good answers.”

“The most important aspect of management is making decisions based on good information,” Rhodes said. TestTrack’s reporting and actionable view increased Rhodes’ access to the right information, as well.

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When Rhodes needed a report showing the order of his outstanding projects ranked by custom fields and priority, he found that TestTrack's reporting module made it a "snap." He simply chose an appropriate filter, applied it to the report, checked some fields, and TestTrack generated the report.

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Easily Import Requirements

Because VirtualScopics has 10 years of requirements documentation, Rhodes was apprehensive about the amount of effort it would take to move the documents over to the new system. "My guys said it was easy, but I wasn't so sure. So I decided to try doing one of the documents myself."

Rhodes began with an existing requirements document, which was in Microsoft Word. He stripped it to just the primary requirements tables, converted the tables to text, and set header styles for business requirements and functional requirements.

"Then I ran the TestTrack import wizard, setting the option to treat each occurrence of the headers as a new requirement. It sucked the data in and showed me a preview, which I could then adjust as needed. I clicked OK and wham! A new requirements document was created."

It only took Rhodes about 30 minutes of work to transfer a 150-page requirements document from the old system to TestTrack. "The pictures came over fine," Rhodes said. "Tables within requirements looked great. The import was really fast! No complaints here."

Painless Implementation

All in all, Rhodes said the implementation of Seapine's products was surprisingly smooth. "It's been absolutely painless, and that's unusual. It would be nice if all implementations go that well, but they rarely do."

Rhodes said he was surprised at how well Seapine's products fit with VirtualScopics' needs. "It's the best software investment I've made in a long time."

About Seapine for Life Sciences

Founded in 1995, Seapine Software is based in Mason, Ohio, with sales and support offices located in Europe, Asia-Pacific, and Africa. Hundreds of leading medical device, pharmaceutical, biotechnology, and clinical research organizations rely on Seapine to streamline their core development processes, drive innovation, and gain a competitive edge.

Learn more at life-sciences.seapine.com.

