



CASE STUDY



EyePoint Pharmaceuticals,
a Leader in Retinal Disease
Therapeutics, Partners
with AssurX to Replace
Paper-Based Processes





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David Vario
Vice President of Quality

EyePoint Pharmaceuticals is an innovator committed to developing solutions for retinal disease, including sustained delivery systems DURASERT®.

FDA-regulated as both a manufacturer of combination products and a CDMO, the company's reliance on paper-based processes put serious constraints on its productivity and visibility across the quality chain.

DISPARATE QUALITY PROCESSES CREATE PRODUCTIVITY AND VISIBILITY CHALLENGES

When Vice President of Quality David Vario joined EyePoint in 2021, the company was using a collection of disconnected processes to manage quality activities. These included separate software solutions for document management and learning management, plus inefficient paper-based processes for everything else.

"It just took forever to execute processes," says Vario, who notes that change control alone required five sets of signatures to process a change. "It was taking up a lot of everybody's time."

Furthermore, their existing document management software only did lifecycle documents, leaving a gap in terms of records management for reports and protocols.

Originally, the company considered purchasing additional QMS modules from its document management software vendor. It was clear, however, that this would quickly become costly compared to an all-in-one solution, especially considering the number of processes Vario would ultimately move to the QMS.



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Vice President of Quality

SEEKING A PROVEN PARTNER IN ASSURX

While the company worked on improving its paper processes, Vario began the search for an integrated QMS capable of meeting EyePoint’s needs. As it turned out, he didn’t need to look far.

“This is my eighth install, and I’ve used AssurX at very small companies as well as very large companies,” Vario says, adding that he’s been using AssurX for 18 years.

Having already implemented AssurX in previous roles, he knew that the system’s high degree of configurability and scalability would provide significant advantages over their existing approach.

Within three months of purchasing AssurX, EyePoint had fully validated solutions in place for document management and change control. With AssurX, they not only were able to manage lifecycle documents, but also records management, reports, and protocols.

EyePoint also validated AssurX for training management and began using it for on-the-job training, while still using the previous learning management system (LMS) to verify training materials were read and understood.



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FINDING NEW EFFICIENCIES

The company was in the process of deploying corrective and preventive action (CAPA) in AssurX when concerns began to surface about upcoming renewal costs for the existing LMS. What leadership wanted to know was whether AssurX could handle all of the company’s training management needs.

For Vario, the answer was easy.

“I told them all we needed to do was import the content from the LMS and we’d be ready to go,” he says, pointing out that they also needed to rewrite SOPs which were stored in yet another tool. In three weeks, the entire process was complete.

Today, document changes are automatically linked to training tasks assigned by the QMS, rather than requiring added work to upload documents, create courses, and assign them to employees.

In addition, Vario developed an internal lexicon containing all terms and definitions used in company documentation. That means, for example, the term “corrective and preventive action” is generated automatically in any document where the CAPA acronym is used. Anytime a definition is changed, that too cascades automatically across all documents.

FROM ZERO TO 60 IN ONE YEAR

Vario says the hardest part of implementing was overcoming resistance to change, but that happened relatively quickly once people saw how easy it was to use AssurX.

Over the course of a year, EyePoint went from having separate solutions for document management and training to a fully integrated QMS. Solutions deployed in AssurX include:

- Document management
- Training management
- Supplier quality management
- CAPA
- Internal and external audits



“It’s about the people,” he says. “They always resolve issues quickly.”

**David Vario
Vice President of Quality**

IMPROVING VISIBILITY WHILE REDUCING COSTS

Vario estimates that replacing multiple software systems with AssurX has helped the company save at least \$100,000 annually in licensing costs alone. However, he says the bigger impact has been gaining real-time visibility into processes.

“Even after we updated our paper processes, we were still having to route things through DocuSign for everything,” he says. “Now the system instantly tells someone when a task is due, and they can sign it directly in AssurX.”

With the AssurX solution, Vario’s team is now able to:

- Store and access all records in a secure, centralized repository, with permissions-based rules to prevent unauthorized access or editing
- Automate document routing, approval, and signatures, with escalation rules to keep the process moving forward efficiently
- Ensure compliance with FDA requirements via time-stamped records and audit trails

The new process reduces delays associated with waiting for people to complete and sign off on tasks, while providing improved visibility into the entire process. Vario says once the base system was up and running out of the box, it was easy to configure AssurX to their needs.

For example, Vario configured the system to be able to add and update documents directly from the change control solution, without having to make a separate change request.

On top of these new efficiencies, Vario says the system has also accelerated the reporting process.

“When it comes to generating metrics, all it takes is the click of a button to get my results for management review.”

As for what he and his team liked best about working with AssurX, Vario says it comes down to support.



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David Vario
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ABOUT ASSURX INC.

With decades of expertise built into our extensive quality management and regulatory compliance software, the AssurX Quality Management Software Platform helps companies maintain quality and compliance standards, streamline workflows, and better manage any enterprise. Our configurable software and understanding of users' needs produce a unique system that easily adapts and scales as a customers' business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant. [Learn more.](#)

FUTURE PLANS WITH ASSURX

Vario is currently using AssurX to develop a computerized maintenance management system (CMMS) to manage preventive maintenance and calibration tasks for both GMP and non-GMP equipment. In addition, electronic logbooks will be built-in for all equipment that requires them.

“Any equipment used in production will have preventive maintenance, calibration records, and due dates automatically generated, so people don't have to record them by hand,” says Vario.

He adds that the new CMMS will allow them to eliminate yet another separate system that was previously only used for preventive maintenance tasks and calibrations.

The company also plans to open a new commercial facility in 2024, with nothing more than an internet connection needed to get the AssurX system up and running.

“We'll probably have as many as 60 people there in a couple of years, and we only need licensing as we add people,” he says. “They can log into the system using their laptop and access it from anywhere.”

SCALING UP WHILE MEETING COMPLIANCE

Vario notes that AssurX has been a key part of maintaining a state of compliance while both preparing to launch a Phase III program and taking on more CDMO work.

He says that the company has been able to take on roughly 20% more work as a CDMO—all while utilizing existing staff.

“Automated systems are what help us manage those clients without adding more bodies,” he says. Simplifying their processes and deploying them on AssurX has helped shorten the learning curve, with actions, tasks, and forms consistent across trainings, documents, and CAPAs.

“It truly is a harmonized solution,” says Vario.

SEE ASSURX IN ACTION

