CASE STUDY

Duke University

Duke University Quality Assurance Team scales research portfolio while staying compliant with AssurX

AssurX

Overview

As Duke University Medical Center research labs ramped up participation in vaccine trials, the Quality Assurance for Duke Vaccine Immunogenicity Programs (QADVIP) was faced with QMS constraints around managing document approvals and tracking employee training. Today, QADVIP uses AssurX to automate document workflows and centralize training data, with real-time visibility into compliance tasks across numerous internal and external labs.

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Rebecca Beerman
QA Manager, QADVIP

THE ORGANIZATION

The QADVIP team sits within the Duke University School of Medicine and supports a complex network of clinical research labs, most of which are involved in vaccine research.

QADVIP oversees the quality and compliance components of regulated projects at Duke, including those that require compliance with standards such as:

- Good Clinical Laboratory Practice (GCLP)
- ISO/IEC 17043 for proficiency testing programs
- ISO/IEC 20387 for biobanking
- ISO/IEC 17020 for inspection bodies

The quality unit has seven people supporting more than 150 users working in diverse internal and external collaborations and consortia. Some collaborators are outside of Duke entirely, requiring varying degrees of system access and document distribution workflows.

"Our quality management system is where we track all of these projects in different labs, many of which have different requirements and regulatory standards they have to meet," says Rebecca Beerman, QA Manager at QADVIP.

COVID-19 DRIVES DIGITIZATION PUSH

The legacy QMS the organization had been using was originally implemented around 2005, when the QADVIP team only managed a handful of labs and projects. As their portfolios grew and projects became more complex, the team started running into challenges with their initial QMS.

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"It had the features that were critical for us, and it allowed us to maintain some of the features that worked well for us in our previous system," says Beerman. "Other systems didn't offer that."

Rebecca Beerman
QA Manager, QADVIP

Covid-19 in particular marked a turning point in terms of driving the shift to electronic processes. At the time, Duke labs were pivoting to participate in Covid-19 vaccine trials, which meant an increased workload for the QADVIP unit with more projects and more requirements.

"We were still doing a lot of paper signatures at the start of the pandemic," says Beerman, noting that the ability to use electronic approvals was a big motivator for QMS modernization.

"We had to manually export separate approval reports for every document as evidence of approval. It was a lot of extra steps," she recalls.

Configuring permissions for the different groups QADVIP works with was another cumbersome point. The legacy QMS was implemented as an on-premises application. Local IT support was required to install and maintain the software on individual computers, or users accessed the system through the Citrix platform. The current implementation of AssurX is cloud-based, which allows users to access the system through an internet connection and a standard web browser.

"We have groups that interact in complex ways in terms of what can and can't be shared," says Beerman. "There were limitations in the previous QMS on how we could set up those permissions."

Finally, the system also had significant constraints around reporting and tracking training. For example, it was difficult to generate a comprehensive training record for a single user, and instead required cross-checking against lists of who was trained on individual documents.

As these challenges became more pronounced, QADVIP decided it was time to modernize its QMS to support the growing clinical research operations.

FINDING A PURPOSE-FIT, COST-EFFECTIVE QMS

In 2021, Duke began the search for a new QMS, demoing systems from several different software vendors. AssurX was selected based on its configurability, feature set, and cost-effective pricing.

"The system included the features that were most important for our organization, needed to meet our workflow and compliance requirements," says Beerman.

Beerman says AssurX's license model has also better aligned with Duke's user structure. "With our old system, login denials were common because of how licenses were tied to permissions. AssurX's licensing model aligns with our distributed user structure," she says.

QADVIP has implemented several AssurX solutions so far, including:

- Document Management
- Employee Training
- Asset Management
- Deviation Management

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"I've really enjoyed the ability to create the workflows that we want, get rid of the steps we don't want, and make it fit exactly for a purpose."

Rebecca Beerman
QA Manager, QADVIP

Beerman and her IT counterpart managed much of the system administration themselves, engaging AssurX professional services to support configuration and training.

She says that while there was a learning curve for configuring the system, the AssurX team has worked closely with her group to ensure they are building a reliable system they can maintain moving forward.

Beerman explains how, over time, her team has learned from AssurX the process of deploying different solutions.

IMPROVING EFFICIENCY AND VISIBILITY ACROSS QA PROCESSES

The move to AssurX has improved day-to-day efficiency for Duke's QADVIP team and the labs they support, which Beerman attributes largely to the system's configurability.

"AssurX increased the ability to create the workflows that we want, get rid of the steps we don't want, and make it fit exactly for a purpose," she says.

Where it once took several minutes to locate individual records and tasks, now team members can see all of their pending issues in one place.

"The fact that AssurX notification emails contain a hyperlink directly to the record and action item has been very efficient for laboratory end-users," she says.

Beerman noted that these features save time and effort for both the laboratory end users and the QA team, so people can stay focused on completing compliance activities rather than looking for information. Custom dashboards and visual alerts also help to highlight overdue items and urgent records to keep labs and QA teams aligned.

"Our previous system didn't have options to develop custom flags and email notifications when specific actions that we deemed important, needed to be addressed,"
Beerman says.

As part of implementation, Duke IT and AssurX collaboratively evaluated the available electronic°signature configurations. The team selected an option that did not require users to re°enter credentials for each approval, since the Single Sign-on (SSO) login already provides unique user authentication.

AssurX has also enabled the team to automate labor-intensive manual workflows. For instance, documents now activate automatically once approved based on a pre-set training period.

"We no longer need a calendar reminder to go in and manually mark documents effective. This automation removes a manual step that previously required dedicated staff time," she adds.

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"With AssurX, we can define clear stages within a customized workflow that automatically advances items to the next stage. It's always clear whether a task is with QA or the lab."

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She says that even with more documents, her team has been able to maintain their regular revision cycles. That visibility extends beyond documents to the tasks and actions associated with each workflow.

"With AssurX, we can define clear stages within a customized workflow that automatically advances to the next stage. So, it's always clear whether a task is with QA or the lab."

COMPLETING THE MIGRATION AND LOOKING AHEAD

Audit Management and Supplier Quality modules are currently being implemented and will complete QADVIP's full migration off the legacy system . Beyond that, the team is eager to explore more of AssurX's advanced analytics capabilities to gain even more visibility into their operations.

As for her experience with AssurX, Beerman points to the company's responsiveness to customer feedback and ongoing product improvements.

"AssurX communicates regularly with our team during implementation," she says. "Having a vendor that's committed to and focused on one software provides assurance that the vendor will likely continue to support and improve their software product."

While every organization will have different needs, Beerman says, those with complex requirements should carefully evaluate the flexibility of any QMS solution.

"For some companies, an out-of-the-box solution will work well," she says. "But for organizations that need a more flexible system, AssurX may provide support."

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.

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