

CASE STUDY

SIEMENS

Siemens Healthineers
Eliminates QMS Audit
Findings with AssurX



AssurX



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Director of Quality for North American Sales, Service, and Installation at Siemens Healthineers

OVERVIEW

In 2023, Siemens Healthineers embarked on an ambitious journey to digitize its quality management system (QMS). Where the company once struggled with manual handoffs and delays in their quality processes, today they have eliminated manual steps in their process. As a result, the AssurX QMS has helped Siemens achieve zero QMS findings on its FDA and ISO audits.

THE COMPANY

Siemens Healthineers is a leading global healthcare company with a unique portfolio of medical innovations in diagnostic and therapeutic imaging, molecular medicine, and precision therapy.

The organization’s North American (NAM) group focuses specifically on sales, service, and installation, and is subject to numerous FDA and Health Canada requirements as well as ISO standards . To ensure compliance, Siemens Healthineers has integrated quality and environmental, health, and safety management under one system that applies to its entire NAM zone.

MANUAL PROCESSES CREATE STANDARDIZATION ISSUES AND DELAYS

While the QMS Siemens Healthineers had built internally was compliant, the organization faced numerous challenges in areas such as internal audits, document management, risk management, and change management.

Processes were intensely manual, relying on Sharepoint lists, Word and Excel documents, and digital signatures via Adobe. All dialogue took place in email, with important information communicated among people rather than within a process.

“If someone goes on PTO, then your system goes on pause,” says Karen Singer, Director of Quality for North American Sales, Service, and Installation at Siemens Healthineers.

Singer notes that the reliance on manual systems left room for human error and process delays. Lack of standardization created issues with consistency in how they executed processes, for example after training individuals as backups for a process.

“Because the processes weren’t systematic, there would sometimes be differences when one person executed a process compared to someone else,” says Singer. “We saw that most clearly in our document management process.”

Standardization of similar processes also represented an opportunity for improvement. For instance, the company used three different change management processes for reviewing organizational updates, regulations and standards, and EHS change management.

“It’s all the same activity when something changes,” Singer says. “We need to look at it, disposition it, and determine if action needs to be taken. Because it’s the same steps across three different processes, we had a lot of duplication of these activities.”



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FINDING A SOLUTION TO STANDARDIZE CORE QUALITY PROCESSES

Like many companies, Siemens has spent years fine-tuning its processes to meet the organization’s needs and ensure compliance. Because of that, they wanted a flexible solution that could be customized to mirror those existing processes.

The company implemented a wide range of AssurX solutions to standardize core QMS processes, including:

- Internal audits
- CAPA and supplier corrective action request (SCAR)
- Document management
- Training and communication
- Planned deviations
- Risk management
- Change management
- Software validation

Most of the solutions were highly configured using internal IT resources, relying on AssurX support along the way. Whenever there were implementation issues, Singer says the AssurX team worked with her team to improve the process.

“It can be difficult to navigate all the different groups we’re working with,” she says. “The follow-up and attention to detail we got from AssurX was always above and beyond in providing support in our complex environment.”

STREAMLINING AND LINKING QMS PROCESSES

Where key management system support processes were once executed individually, today they are linked via process workflows with full traceability from start to finish. The result is that Siemens now has a digitized QMS that has helped them improve performance on their ISO audits and FDA inspections.

“We had zero findings from a QMS perspective,” says Singer, adding, “We’ve been complimented multiple times on our change management process, which is now very robust.”

When a change request comes in, the new process helps document and assess:

- Whether the change impacts the QMS
- If so, to what degree
- Any actions that need to be taken

From there, users can open up an action plan and track completion of tasks within the plan. The company has even developed metrics to monitor dispositioning and action plan completion, an area where Singer says Siemens has received the most positive feedback.



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Singer’s team uses PowerBI to pull metrics from AssurX into their quality dashboards, displaying data on internal audits, change management and risk in a user-friendly visual format. In the future, the system will also display metrics from other AssurX solutions such as CAPA, document management, and more.

Current AssurX process



Key Results

Document Management

- Centralized location for management system support processes
- Revision history and approvals stored in the document record
- Users can access documents, submit document change requests, and view recent activity such as new documents requiring review

Audit

- Audit plans, schedule, records and reports are available online
- Seamlessly links internal activities to the internal audit schedule and supporting sub-documents
- Automated notification of audit status
- Helps manage multiple regulations and standards
- Full traceability throughout each step of the process

Training

- LMS training links to controlled documents in the AssurX document library
- AssurX rule sends email to employees showing changed documents recently in effect
- Consistent and centralized communication of training tasks and resources

Risk Management

- Users can query historical records with cross-references to CAPAs
- Automated monthly notifications for updates on risk management activities
- Eliminates arbitrary due dates by requiring users to provide justification for estimated closure dates
- Automated notification to update risk status

Deviations

- Easy access view of all open deviations
- Ability to run queries on planned deviations
- Dashboard view enables efficient analysis and communication

Change Management

- Consolidation of multiple related processes
- Change requests link directly to impact assessment and any resulting change order
- Employees assigned subtasks automatically receive an email with a hyperlink to the subtask
- Tracks metrics for dispositioning and on-time completion of change requests



“Anything you can do to make the process user-friendly and less intimidating is key,”

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SEE ASSURX IN ACTION

As for what Singer recommends to other companies just starting the implementation process, she says it all comes down to building positive energy around digitization.

“Anything you can do to make the process user-friendly and less intimidating is key,” she says.

In terms of future plans, Singer’s team is currently working to improve their QMS by eliminating remaining manual steps and linking more processes to deliver end-to-end automation.

For those considering working with AssurX, Singer says it’s the support that makes AssurX different from other software vendors.

“The AssurX team is always listening and responding,” says Singer, adding that AssurX is quick to respond to requests. “It’s the people who really make it happen. We feel supported, like we’re not out there by ourselves.”

