CARDIOVASCULAR DEVICE MANUFACTURER

Moving from Paper Processes to an Automated Enterprise Quality and Compliance System

AssurX

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Class III medical device manufacturers design and manufacture life-sustaining technologies. Their quality and compliance management systems must meet rigorous standards to insure that their products will not fail and result in patient illness or death. A cardiovascular device manufacturer of ventricular assist devices (VADs) for patients with advanced heart failure was facing quality challenges related to growth and siloed processes that, if not streamlined, could ultimately be an issue of life or death.

WHY ASSURX WAS SELECTED FOR QUALITY AND COMPLIANCE MANAGEMENT:

+ Simple, Flexible Configurability
+ Intuitive Workflows
+ Built for the Medical Device Industry
+ 21 CFR Part 11 Compliant
+ Seamless Integration with CRM Application
+ Automated FDA Reporting

Problems with a Manual Quality System

In a relatively short period of time, the ventricular assist device manufacturer company had tripled in size from 300 to over 1,000 employees. In addition, it needed to process quality and compliance information between four locations in the United States and two locations in Europe.

The company's former quality management system consisted of a combination of disparate electronic and paper-based records that involved physical distribution from one person to the next. Resources required to maintain the current system could not keep up with growth or allow time for analysis of reported problems resulting in delays across the quality chain. In addition, validation of the system was laborious and protracted.

The Solution: Automate and Integrate an Enterprise QMS

The company needed to automate quality and compliance processes in order to consistently track issues from detection through corrective action and trend analysis. The AssurX quality and compliance management platform offered the company a configurable, integrated system that met the medical device manufacturer's key requirements:

+ Full range of integrated solutions for end-to-end visibility and management
  • Corrective and Preventive Actions (CAPA)
  • External CAPA (eCAR)
  • Non-Conformance Reporting (NCR)
  • Receiving & Inspection
  • Complaint Management
  • Electronic Medical Device Reporting (eMDR)
+ Met requirements for FDA Class III medical devices (high risk devices)
+ High configurability with workflows designed for the medical device industry
+ Met 21 CFR Part 11 requirements for audit trails
+ Electronic signatures for all quality and compliance records

Corrective and Preventive Action (CAPA) + External Corrective Action Reports (eCARs)

The medical device manufacturer weighed the importance and interconnections that each process would have and determined an order of implementation. Since a universal process like CAPA is the FDA's most expected platform for maintaining GMP compliance and meeting 21 CFR Part 11 and ISO standards, the company elected to deliver that process first.

Prior to implementing AssurX, the company's entire CAPA process involved the manual assignment of tasks and all paper-based reporting. With AssurX, tasks are automatically assigned to their respective groups or owners, and each task must be completed according to the workflow before it can move forward. Dashboards and charts provide real time visibility into open CAPAs and alerts are sent according to severity and risk when tasks are behind due dates.

The automated CAPA process integrates all quality and compliance information, and provides detailed reporting and a single source of truth.

External Corrective Action Reports (eCARs) are the company's system for tracking CAPAs assigned to external vendors with some minor modifications. All eCARs connect to their respective master CAPA records.

Non-Conformance Reporting (NCR)

Previously, a full-time non-conformance reporting coordinator was needed to keep track of the status of NCRs. Each week, the management review board would hold a time consuming in-person meeting to review NCRs. There was no assignment or ownership of parts and the location of parts and related materials was often unknown.

With workflows built for the requirements of the medical device industry, AssurX automated the NCR process by generating a record whenever a product, process or procedure does not comply with standards. The workflow enables the company to assign, track, and resolve the disposition with full visibility.

The automated complaint management process connects ownership and responsibility for each step of NCR when an issue is identified. For example, part owners are now defined in the ERP system, disposition tasks are assigned by rules, and material locations are visible in real time. The record is routed for sign-offs as it moves through each step of the process.

Receiving & Inspection (R&I)

Today, receiving and inspection records are generated automatically from the ERP system through integration with the AssurX platform. Communications between inspectors and engineers is now automated, eliminating any exchange of emails.

A configurable dashboard displays all work pending assignment and provides real time updates with records as they are created or altered. Management can see all in-progress work assignments, which results in equal distribution of work among employees and a high degree of accountability.

The AssurX platform has enabled the medical device manufacturer to improve the speed of investigations by integrating directly with Salesforce to automatically create records for complaints without data re-entry.

"The AssurX platform is so configurable that it is supporting more systems than our original scope!"

Senior Analyst
Medical Device Manufacturer

AssurX enables the company to prioritize critical inspections and draw insights from analysis of completion times. Now, all stakeholders can view which employee was working on a certain process and how long it took them to complete the process.

Inspection times are now available in real time and metrics are used to insure KPIs are being met. Non-conformance reports (NCRs) are now launched instantly from the inspection record.

Complaints & Investigations

Prior to AssurX implementation, the medical device manufacturer's complaint management solution had limited external application integration. Complaints captured in Salesforce® investigation reports were re-entered manually into a paper report. Manual routing of folders for signature approvals followed multiple paths for investigations and MedWatch reports. The investigations process was stalling.

AssurX eliminated paper and manual routing. Today, all complaints and adverse events are opened in AssurX and are seamlessly routed through workflows all the way to closure.

A direct interface with Salesforce creates new complaint records in AssurX (See Figure 1). Complaints go through reportability assessment; investigations; product return tracking; sub-investigation (when a product is returned); additional sub-task creation (if applicable) and risk assessment—all within the AssurX platform.

MedWatch vigilance reports for adverse event reporting can be automatically generated from an investigation and submitted to the FDA with a few clicks.

Figure 1: *Customer Complaint & Investigation Workflow Utilizing Salesforce Interface*
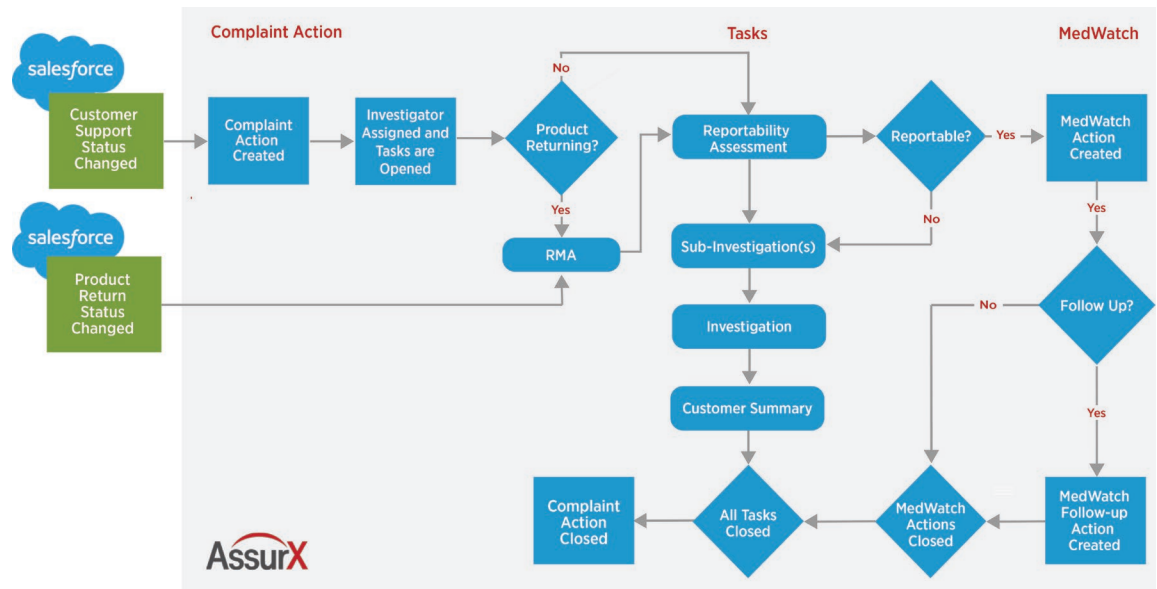
Automated eMDR creation and submission is done with two simple hyperlink clicks. All data is exchanged electronically through the AssurX record with complete traceability.

"Our AssurX eMDR system works great! With just two clicks, MedWatch reports are submitted and all acknowledgments from the FDA are received in real time. Consistently."

Senior Analyst
Medical Device Manufacturer

Electronic Medical Device Reporting (eMDR)

Class III medical devices support or sustain human life and pose the greatest risk of death if they fail. The VAD device manufacturer knew they needed to implement electronic control of eMDR and MedWatch submissions for greater reporting accuracy and productivity.

AssurX allows the company to click two hyperlinks—the first to generate the eMDR and the second to submit the eMDR to the FDA. All data is exchanged electronically from the AssurX record with real-time status.

Summary

AssurX enabled the cardiovascular device manufacturer to design an enterprise-wide quality control system that better facilitates compliance. All manual processes were automated within the system—significantly improving the speed and accuracy of incident resolution.

Key benefits:

+ Electronic signatures replaced all manual signature processes.
+ The flexibility of AssurX supports unlimited growth and integrations.
+ All quality metrics are available for analysis via a customizable dashboard.
+ Well-defined risk assessment process better identifies root cause issues.
+ Audit trails provide history of all transactions from start to completion.
+ Industry best practice workflows drive quality management, improving time to resolution.

Replacing manual processes with an automated solution has **eliminated over 2,400 manual hours per year** in NCR management. The management team no longer needs to sit in meetings to get updates and prioritize issues. Instead, escalation is driven through workflows and they can view the company's quality state of health on dashboards anywhere and at any time.

Additional processes can be added as required due to the flexibility of the AssurX system. AssurX's configurable quality management system supports multiple integrations and processes to form a closed-loop quality and compliance management solution.