COMPLAINT MANAGEMENT

AssurX SOLUTIONS

The AssurX **Complaint Management Solution** provides the most efficient path from complaint intake to resolution. It is easy to deploy with the flexibility to adapt to unique business requirements.

COMPREHENSIVE, COMPLAINT MANAGEMENT FROM INTAKE TO CLOSURE

Complaint Management uses a point-and-click graphical user interface to ensure that all required intake information is collected and routed appropriately. Complaints are recorded within standardized form fields and follow precise routing actions for accurate data trending and analysis.

The AssurX platform drives the fastest path to resolution with decision-tree methodology that automates the entire process, from event intake through regulatory reporting and investigations.

Intake: A systematic intake process makes data easy to track and report from the moment a complaint is initiated.

The system facilitates the collection of all relevant, substantive and objective data required for investigation, analysis, and reporting. Once intake is completed, the complaint is routed to the review stage.

Review: Data collected at the review stage is analyzed to determine whether an issue is valid and/or reportable, or not a complaint. The flexibility of the solution allows you to configure the review stage to prioritize complaints based on your objectives.

When a review determines that the complaint is valid, the complaint is routed to an investigation. If the review determines that a complaint can be closed, the system will route for closure and save the record.

Investigation: Complaints enter the investigation phase based on severity thresholds based on established complaint type.

The investigation routes the complaint through a task and sub-task cycle based on workflow rules (e.g., initiate product return and tracking, submit report, initiate corrective action).

High-severity issues and adverse events can be escalated, and users can assign ad-hoc tasks, particularly in terms of sub-investigation tasks, ensuring the solution meets customer-specific needs.

Regulatory Reporting: Streamline submissions with AssurX Medical Device Reporting (eMDR) for FDA MedWatch 3500A adverse event submissions. All MedWatch data is automatically formatted, validated and submitted to the FDA. Acknowledgement files are attached to the MedWatch record as they are received. A dashboard provides instant acknowledgement status from the AssurX eMDR home page.

AssurX also supports electronic report generation for EU, Canada and Australia. Submit reports within all required time frames based on country and type of incident.

Additional reports can be generated from forms at any time, including Complaint Reports and Health Hazard Evaluations (HHEs).

BENEFITS OF ASSURX COMPLAINT MANAGEMENT

Visibility Throughout the Complaint Cycle

The status of each complaint in the system is visible based on user permissions. Users can have instant access to real-time status, analytics and performance metrics to see the current state of compliance health.

Dashboards can be created to highlight open complaints by cost center, location, division, business unit, or business-specific needs. Reporting provides management with concise trend reports (products, problems, reason codes, cost codes) by functional area.

Visibility drives accountability, minimizes the risk of complaint mismanagement and maximizes efficiency in complaint resolution.

Facilitate Compliance

AssurX complaint management provides built-in audit trails and electronic signatures. Each time a record is opened for edit, the system takes a snapshot of that record prior to any changes.

The ability to produce reports with a mouse click enables audit-readiness and compliance with FDA, ISO, GMP and other industry regulations.

QMS-Wide Process Integration

Complaint Management can integrate with any AssurX QMS solutions (CAPA, Change Management, Supplier Quality, Document Management), to provide an enterprise-wide, closed loop system for quality and compliance management.

KEY BUILT-IN FEATURES + FUNCTIONALITY

Business Performance Metrics + Visibility

+ Built-in configurable dashboards, reports and metrics. No additional third party tools required. Management dashboards monitor status and performance at the enterprise, division, functional area or department.
+ Reports based on real-time performance metrics for trending, cycle times and costing; drill-downs to trend elements for products and reasons.

Best Practice Workflows

+ Ready-to-use forms and best practice workflows are included. Add unlimited workflows, based on your company's need, using drag-and-drop, point-and-click technology.
+ Workflow version control and change management.
+ Workflow ownership by group, department, role, or employee.

Reportability Evaluation + Regulatory Reports

+ Decision-tree processing automates the evaluation of reporting requirements for adverse events.
+ Generate follow-up/supplemental reports based on changes to previously submitted reports.

Audit Trail + Electronic Signatures

+ Audit trail and electronic signature compliant with FDA 21 CFR Part 11, includes a secure, time-stamped archive
+ Audit trail on file attachment modifications.

Notifications, Escalations + Reminders

+ Dynamic approvals, escalation, rules and alerts as well as the ability to assign ad-hoc tasks and sub-tasks.
+ Automatically notify assignees when tasks become due or past due.
+ User-defined reminder & escalation rules.

Integration

+ Connect with other AssurX quality and compliance processes and other connected systems to launch additional actions.

PROCESS COMPLAINTS WITH *CONTROL* AND *CONFIDENCE*

+ Eliminate process gaps and delays inherent in manual an siloed systems
+ Full control of the entire process, from complaint processing, to triage, to closure
+ Full visibility into the current state of compliance
+ Built-in performance & monitoring metrics with real-time reports for trends and cycle times
+ Audit trails and electronic signature compliance with FDA 21 CFR Part 11 requirements
+ Automated rules enforcement for 21 CFR Part 803 for adverse event reporting
+ Task management with notifications, escalations, rules and reminders
+ Visibility drives full accountability throughout the process

SEE ASSURX IN ACTION.
Click to schedule a live demonstration.