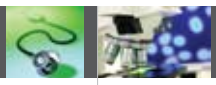
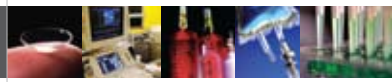

Complaints Management and Regulatory Reporting

For over a decade, AssurX systems have been used in heavily regulated environments including medical device manufacturing, life sciences, utilities and financial services. Our medical device industry solutions address the unique issues faced by FDA-regulated businesses whose quality and compliance is not simply a goal, but a bottom-line requirement.

The Industry Solution From AssurX

AssurX's Complaints Management & Regulatory Reporting system provides a best practices process for managing the entire event lifecycle from event intake through investigation, root cause analysis and reporting to regulatory agencies.

This comprehensive system is designed to help medical device companies streamline their processes. By using the decision-tree methodology, the software automates from the intake of events through regulatory reporting and provides ease of use at all levels of the organization. With built-in audit trail and electronic signature functionality stringent enough to meet the FDA's rigorous requirements, AssurX creates an iron-clad closed loop system—so you can rest assured that all issues are being properly handled and reported.

Key Features—Built-in, right out of the box

Business Performance Metrics: Monitoring / Management Visibility

- Management dashboards to easily monitor status and performance at any level; the entire enterprise, division, functional area, or department
- Reports based on real-time performance metrics for trends, cycle times and costing
- Drill down into all reports to view the source data and navigate to individual records
- Management reports on trend elements (products, problems, reason codes, cost codes) by department, function, division, corporation
- Activity cycle time (response, resolution, planning, implementation times) reports that trend by month, quarter, year

Best Practice Workflows

- End-to-end workflow for processing all events intake, reportable & non-reportable
- Additional unlimited best practices workflows may be added
- Point-and-click modification of template workflows by process owner
- Workflow version control and change management
- Workflow ownership by group, department, role, employee (one or more)

AssurX Delivers:

- Control of the entire complaints lifecycle
- Built-in performance & monitoring metrics with real-time reports for trends, cycle times and costing
- Form 3500A, FDA approved
- Audit trails & electronic signatures compliant with FDA 21 CFR Part 11
- Generate Medwatch, supplemental and international regulatory reports
- Task Management with notifications, escalations, rules and reminders

AssurX®

"After assessing several quality software packages, AssurX is the most flexible & intuitive solution on the market. It is also the most user friendly from both the end user and administrative perspective. AssurX is 5 - 10 years ahead of their competitors."

David Vario
Associate Director
Regulatory Affairs
Genzyme Corporation

Integration with other Processes

- Integrate to other quality processes (audits, CAPAs, issue tracking, change management)
- Cross query any selected process by any field element (product, problem type, reason etc.)
- Enterprise reports broken out by function, department, division or on whole enterprise across integrated processes

Audit Trail, Electronic Signatures

- Audit trail and electronic signature compliant to the FDA's 21 CFR Part 11, includes a secure, time-stamped archive
- Audit trail on file attachment modifications
- Query on audit trail
- View edit changes on the form in the audit trail showing the before/after field values
- View changes on entire record, not just the fields
- Electronic signatures cannot be modified, copied, transferred or deleted
- Accommodate signatures comments
- Manage proxy signatures allowing user to designate backup approvers

Reportablity Evaluation & Regulatory Reports

- Decision-tree processing automates the evaluation of reporting requirements for the US FDA, Canada, Europe, and Australia
- Automatically manage report due dates and notify assignees when tasks become due or past due
- Generate MedWatch 3500A and other vigilance reports in PDF format
- Generate follow-up/supplemental reports based on changes to previously submitted reports

Task Lists, Notification, Escalation, Reminders

- Easily manage workload through a list of assigned tasks and approval requests on your home page
- Department tasks and approval request listed on supervisor's home page
- Reminder and escalation rules are all user-defined
- Users are automatically notified of task assignments, reassignments, pending and late tasks based on rules
- Process owners may also be notified of task milestones and approval accomplishments based upon user-defined criteria

About AssurX, Inc.

AssurX, Inc., provides highly regulated organizations with enterprise quality management and compliance solutions. With a choice of OnDemand services or OnPremise (licensed) software delivery options, AssurX offers a flexible, comprehensive all-in-one solution that automates quality and regulatory compliance related processes so issues can be properly managed. It helps collect, organize, analyze and share information to better manage and improve quality and compliance performance everywhere in your enterprise. FDA-regulated companies around the world, including Alcon Labs, Siemens Medical Systems, Genzyme, Bausch & Lomb, and Guidant Corporation use AssurX.

AssurX, Inc.
18525 Sutter Boulevard
Suite 150
Morgan HIll, CA 95037
Tel 888.927.7879
Fax 408.776.1267
www.assurx.com

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