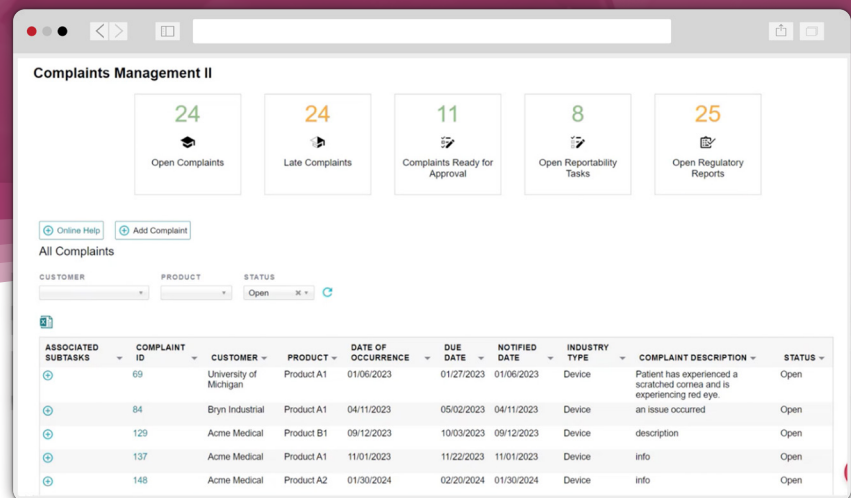


## DATASHEET

# Complaint Handling Solution

### COMPREHENSIVE, COMPLAINT MANAGEMENT FROM INTAKE TO TRIAGE TO CLOSURE

The AssurX Complaint Handling Solution software provides full visibility into the current state of compliance and drives the fastest path to resolution with decision-tree methodology that automates the entire complaint process, from event intake through regulatory reporting and investigations.



## Visibility Throughout the Complaint Cycle

Manage accountability, minimize risk and maximize efficiency in complaint resolution. Users 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.

## 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. Generate reports with a mouse click for audit-readiness and compliance with FDA, ISO, GMP and other industry regulations.

## 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 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).

### Key Features & Functionality

#### Business Performance Metrics

- Simplify reporting and tracking of workplace incidents using highly configurable forms.
- Design a process unique to your organization's requirements with no customer coding necessary.
- Compatible with all future core service packs and upgrades.

#### Best Practice Workflows

- Conduct a process-driven, step-by-step root cause analysis.
- Turn trend analysis data into actionable information to identify the potential for future events and drive informed decisions.
- Capture structured data to classify EHS incidents properly.

#### Reportability Evaluation & Regulatory Reports

- Identify trends that may be indicative of a potential or recurring hazard.
- Support cross-functional approvals for complete visibility.
- Continuous quality improvement using quality data.

#### Audit Trail & Electronic Signatures

- Configurable, best practice workflows capture all related information.
- Maintain and demonstrate audit-ready compliance by attaching document records including SOPs and initiating training tasks as needed.
- Open API allows integration with enterprise applications including ERP, MES, CRM, and other systems.