CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

AssurX SOLUTIONS

The AssurX CAPA solution creates a clear path to resolution and prevention through root cause analysis of nonconformances and system or process failures. Identify and document root causes, implement controls to reduce or eliminate the risk of recurrence, and minimize the likelihood of negative financial impact.

ELIMINATE PROCESS SILOS

Having multiple, disconnected systems and segregated networks is impractical for today's competitive landscape where access to information needs to be instantaneous and trusted.

AssurX eliminates manual processes and siloed data with a centralized system that makes data and documents shareable and cross-referenceable between authorized users and groups. Unified data becomes a valuable corporate asset for tracking, metrics for trending, KPIs and actionable intelligence for decisions.

AUTOMATE THE CAPA PROCESS

AssurX enables enterprises of any size and complexity to clearly define and continually refine the CAPA process.

All CAPAs follow a defined course of action with reminders and escalations for an unbreakable chain of accountability by:

- Logically and routing tasks down the most appropriate path for actions, escalations and exceptions
- Gathering important data and documentation at each step of the process to address the *who, what, where, when, why*, and *how* required for thorough investigations
- Providing 21 CFR Part 11 compliant electronic signatures and audit trails
- Integrating with all AssurX quality solutions as well as enterprise business systems

ENTERPRISE-WIDE CAPA

CAPAs initiated from any source or system are automatically associated with related issues and CAPAs, creating an enterprise level approach to solving quality problems. The system assigns the investigation to an owner based on conditions such as product, issue type, or personnel roles.

- Integrated 5 Why (5Y) and 8 Discipline (8D) problem solving models and reports for consistent guidance and documentation of root cause.
- CAPAs can be initiated from any issue source including complaint, nonconformances, deviations, product returns, corrective action requests, safety incidents, supplier issues, etc.
- Automatically link CAPAs to one or more existing or new issues, or initiate independent of a logged issue. CAPAs can be associated based on any data parameter (e.g, product, process, issue type, cause code, etc.). Trend reports and graphs are hyperlinked directly from the related CAPA records to provide instant trend analysis.
- Manually or automatically assign CAPAs to an investigator. Automatic assignments can be based on any known condition such as product, initiator's department, role, location, risk, or other condition.
- Automatically set due dates based on business rules or CAPA criticality.
- Notify affected personnel of new assignments automatically via email with data copied directly from the record and a hyperlink to the initiated record.

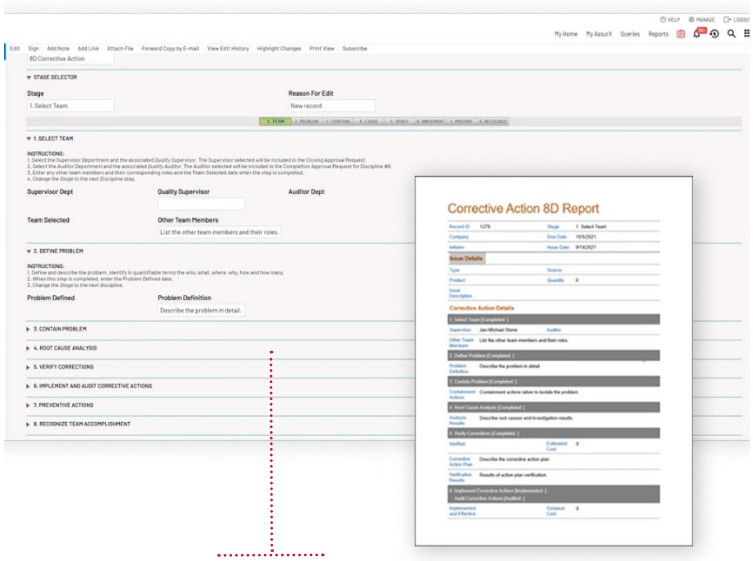
INTEGRATE WITH OTHER ASSURX SOLUTIONS

A forms-based architecture makes it possible to configure, automate, and connect any quality process within the AssurX platform. Dashboards, status reports, alerts, notifications, and escalations keep you in control of quality and compliance health. Build a collaborative,harmonized quality system.

- **Risk Management:** Assign risk impact for appropriate CAPA escalation and determining the type of investigation required. Establish linkages to appropriate documentation (FMEAs, controls, processes, etc.).
- **Document Management:** Maintain updated, versioned documents for SOPs, employee training and any other file types within a controlled solution. Route documents for review and electronic signatures.
- **Training Management:** Automation ensures employees are sufficiently trained on new procedures and re-trained as necessary. Maintain electronic training records to demonstrate compliance.
- **Supplier Quality Management:** Extend the CAPA process to your supply chain. Update documentation, re-train, and audit your suppliers entirely within the AssurX platform.
- **Audit Management:** Plan, schedule, and conduct an audit of any kind. Launch CAPAs for audit findings that require investigation.
- **Change Management:** Launch a change request when a CAPA identifies a new or elevated risk, or deficiencies in the existing change control process.

BUILT FOR COMPLIANCE

All CAPA activities and information are systematically recorded to meet requirements for FDA and other regulations for validation, audit trail, electronic signatures, retention and traceability. Once added to a specific record, signatures cannot be modified, copied, transferred, or deleted. AssurX automatically maintains a secure, time-stamped archive (audit trail) of all changes made to any electronic record.



Utilize 5Y or 8D methodologies that provide adequate knowledge to effectively perform and document root cause analysis from investigation to containment and resolution.

ASSURX CAPA BENEFITS AT-A-GLANCE:

- Reduce costs associated with siloed and manual CAPA processes.
- Capture detailed data regarding issues in real time.
- Utilize data for trending, tracking, and actionable intelligence.
- Collect analytics and link related issues across your operations for continuous quality improvement.
- Identify and minimize risk to products, components, services and customers.
- Manage simple to complex workflows using best practices.
- Centralize documentation and data in auditable format.
- Maintain a proactive compliance posture.
- Identify and remediate existing gaps in current processes and procedures.

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