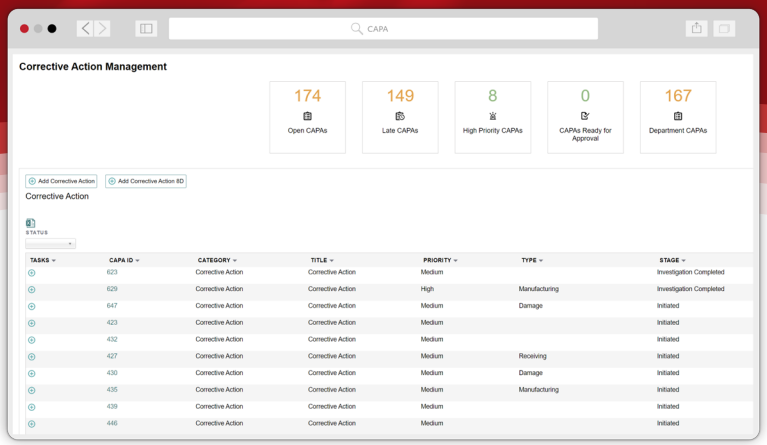
DATASHEET

Corrective and Preventive Actions (CAPA)

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.



Integration Efficiency

This centralized system 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.

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.

Automated Process

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

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.

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.