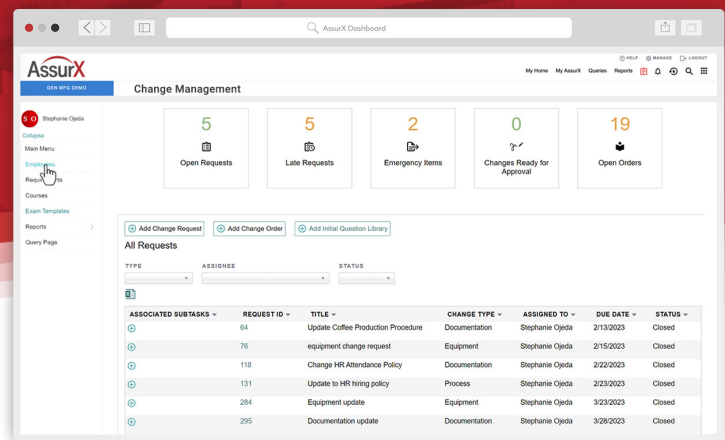


DATASHEET

Change Control

Automated, Flexible, Enterprise-Wide Control

AssurX Change Management software promotes a robust and sustainable change and improvement cadence, designed to enable cross-functional engagement and provide visibility of tasks, assessments and timelines. The solution orchestrates, tracks and documents changes across all functional areas of an organization. The configurable processes integrate seamlessly with the entire suite of solutions to provide a single, all-in-one solution for managing quality and compliance enterprise wide.



Collaboration And Continuous Improvement

- Centralize activities for collaboration, review and approvals from designated subject matter experts (SMEs). Monitor the progress of each change to ensure proper planning, prioritization and communication for deliverables and effective implementation and rollout.

Configurability

- Manage any type of change across all functional areas of your business process. AssurX's low code configuration model creates unlimited workflows and field level modifications with point-and-click tools.

Automatic Escalation

- Automated escalation rules, notifications and email alerts keep the change process moving through active communication. Transparently monitor progress and prevent issues and tasks from falling through the cracks.

Enterprise System Integration

- Designed to easily integrate with external business systems like ERP, PLM, CRM, LIMS and other enterprise applications. Change requests triggered from any source can be immediately captured and put into action.

Benefits Of Automating Change Management

- Increases accountability through tasks, process approvals, and automated audit trails
- All change controls are initiated, tracked and managed to ensure compliance requirements and product specifications are met
- Integrate with relevant QMS processes including complaint management, nonconformance and deviation management, CAPA and supplier management for a robust, efficient system
- Demonstrate compliance with regulatory requirements and standards including FDA, ISO, GxP, NERC and other industry regulations with a closed-loop change control
- Workflows enable collaboration for tracking regulatory filing and approvals and quality management processes that must be performed in alignment with the change request
- Connect to documents, configuration files, nonconformance reports, supplier records, design controls or any other interdependent digital records for greater visibility

Key Features

- Fully configurable; unlimited workflows
- Time-stamped audit trails for change history
- 21 CFR Part 11-compliant electronic signatures
- Configurable dashboards for quick insight into the state of all open change tasks
- Escalations rules for critical tasks
- Seamless integration with other AssurX quality solutions, business, and regulatory systems

About AssurX

With decades of expertise built into our quality management and regulatory compliance software platform, AssurX helps companies maintain quality and compliance, streamline workflows, control risk and better manage any enterprise. Our incredibly configurable software and deep understanding of users' needs produces a unique system that easily adapts as your business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant. To learn more about how AssurX can help with your quality and regulatory compliance management needs, please connect with us online.