

CHANGE MANAGEMENT

AUTOMATED, FLEXIBLE, ENTERPRISE-WIDE CONTROL

AssurX's Change Management is a centralized flexible system used to orchestrate, track and document changes across all functional areas of a business. It creates a consistent, closed-loop method to process any change type (business process, product design, documentation, materials, line repair, etc.), even for regulated industries. Proposed changes initiated from any department are evaluated; change plans are mapped out with feedback from designated personnel; tasks, reviews and approvals assigned and tracked; and then approved changes are released and implemented across operations—all in a best practices workflow.

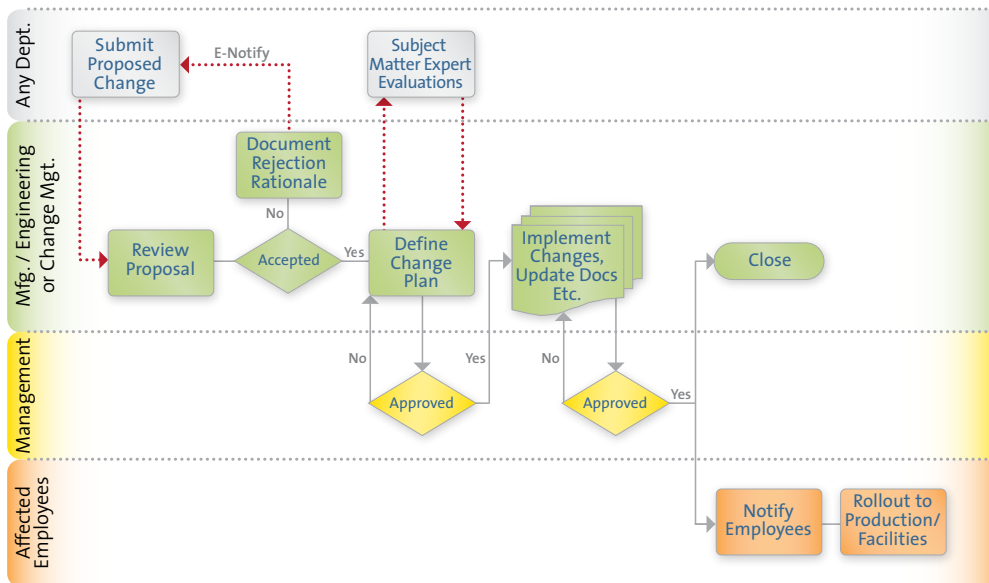
Complete Change Management

Particularly in regulated industries, paper-based or ad-hoc approaches to change control are inefficient, prone to error, and don't provide the global visibility to effectively manage the process. Changes need to be implemented in a controlled manner following a framework that accommodates adjustments of any type. A comprehensive automated system is needed to manage business changes and maintain regulatory compliance across operations.

WITH ASSURX CHANGE MANAGEMENT:

- **Initiate, plan and track any type of change** from proposal through implementation in a consistent, automated process across the enterprise
- **Keep coordinated control over changes implemented across multiple** business groups, entities, plants or countries
- **Reduce redundant change processing efforts**, facilitate project collaboration and continuous improvement
- **Instantly access real-time data capture and metrics**—so you KNOW all tasks, plans, reviews and approvals are being properly handled
- **Centralize/Streamline/Speed change request processing** by automatically linking related processes, issues, actions and information
- **Meet regulatory requirements for closed-loop change control** with time-stamped audit trails and electronic records/signatures (21 CFR Part 11 compliant)

Change Management spans the organization



GET COMPLETE CONTROL OF CHANGE WITH:

REDUCED CYCLE TIME, REDUNDANCY & COST

GREATER VISIBILITY & IMPROVED TASK MANAGEMENT

RUN AND CONTROL PARALLEL CHANGES, ACROSS FACILITIES

SEGREGATE CHANGES BASED ON REGULATORY REQUIREMENTS

INTEGRATION WITH DOC CONTROL, TRAINING, CAPA & OTHER SYSTEMS SUCH AS ERP, LIMS, ETC.

EXTENSIVE, BUILT-IN METRICS, REPORTING

Manage Across Operations:

The system receives any type of proposed change and efficiently manages evaluation, planning, implementation and documenting across every part of your operation—all in a closed-loop workflow.

Graphical Performance Metrics/Management Dashboards:
Configurable dashboards, metrics and ad-hoc query functionality provide real time monitoring, trending and analysis.

Key, Built-in Features

A POWERFUL TOOL FOR COLLABORATION AND CONTINUOUS IMPROVEMENT

The system combines centralized control with collaboration, review and approvals from designated Subject Matter Experts. Feedback on the effectiveness of proposed change plans is automatically requested and tracked to ensure each change is properly planned and will deliver the expected results, *before* it's rolled out across operations.

EASY INTEGRATION WITH OTHER SYSTEMS

AssurX integrates easily with external business systems like ERP, PLM, CRM, LIMS and MES solutions—so change requests triggered from any source can be immediately captured and acted upon.

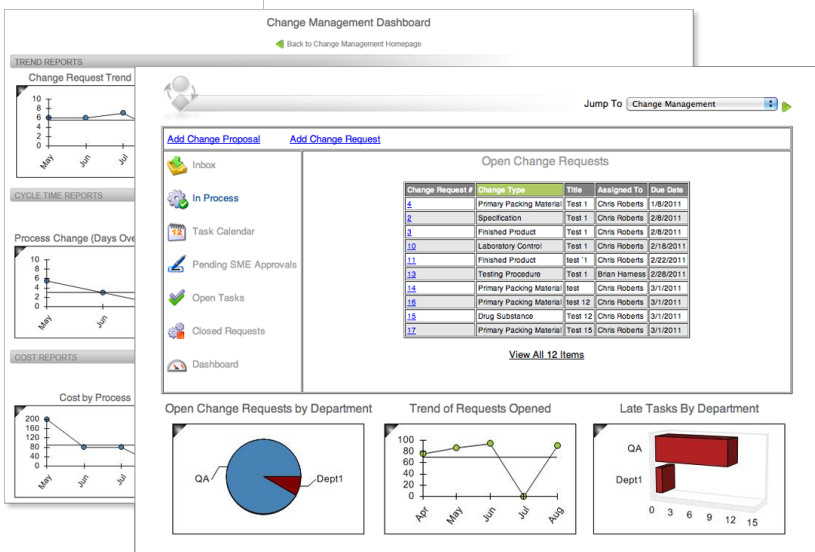
WITH ASSURX TECHNOLOGY, ONE SIMPLE SYSTEM FITS ALL

A true zero-client architecture (CATSWeb) means it runs on all browsers and operating systems with no need to install, upgrade, validate or manage client computers. AssurX's configurable processes integrate seamlessly with each other providing a single, all-in-one solution for managing quality and compliance enterprise-wide.

FAST AND EASY DEPLOYMENT

The turnkey process is provided with setup and user guides, validation scripts, template forms, workflows, dashboards, and everything else needed for quick deployment.

- Simple point-and-click configuration of workflows, fields, forms, rules, lists, signatures, etc. No programming required.
- 100% Web-based—no client side software/validation
- Minimal training needed for users due to a clean, intuitive interface.
- OnDemand (Software-as-a-Service) option gets you up and running in days with no hardware or software to install, and allows the system to be brought "in-house" at anytime.



Instantly see the status of change requests, plans and tasks in an easy-to-parse format.

AUTO-ESCALATION, NOTIFICATION, REMINDERS
 Built-in automatic escalation and e-mail alerts keep the process moving by preventing issues and tasks from falling through the cracks.

100% COMPLIANCE

For FDA regulated companies, AssurX is fully compliant with 21 CFR Part 11 and Part 820, GMP, ISO and more. The software is validated and comes with IQ/OQ validation templates.

HIGHLY CONFIGURABLE

AssurX manages any type of change across all functional areas. Unlimited workflows can be added, and modifications to existing template workflows can be easily made with point-and-click tools.

About AssurX

AssurX, Inc. provides global companies with enterprise quality management and regulatory compliance solutions. AssurX's flexible, all-in-one system automates quality and compliance processes so issues can be centrally managed. It helps collect, organize, analyze and share information to better manage and improve quality and compliance performance everywhere in your enterprise.

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