AutoSave

Device Program Change Approval & Audit Trails

Enterprise tools for automation source management & 21 CFR 11 Compliance

AUTOSAVE ALWAYS PROVIDES...

AutoSave's feature-rich change management and internal security features have long been beneficial to sites as they endeavor to meet the regulatory requirements of the FDA. AutoSave capabilities such as the following have aided in their 21 CFR 11 compliance efforts:

- Secured and limited program or feature access
- Electronic signatures, timestamps of changes
- Computer generated, permanent audit trails: who, what, when, where, & why of changes
- Record and file retention in secured server
- Automatic notification of changes
- Scheduled change discovery
- Library management with real-time archiving
- Broadest range of supported architectures, devices, and editor software applications

ADD-ON MODULE'S APPROVAL AND AUDIT TRAIL FEATURES...

ELECTRONIC APPROVALS

- Configure approval groups of users
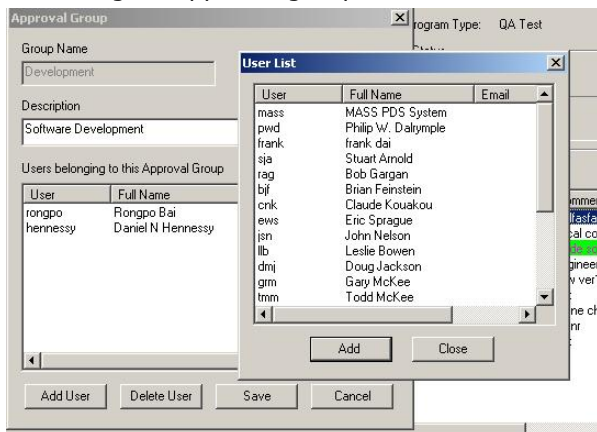
- Establish lists of required approval groups for specific programs
- Automatically e-mail approvers when changes ready for the process

- Electronic entry of each approval requiring comments and optional authorization number
- Electronic entry of approval <u>rejection</u> with comments during any status results in immediate demotion of the revision's status
- Automated maintenance of approval status and full history

ENHANCED LOGGING OF ALL EVENTS

- Augment AutoSave's already substantial tracking/audit trails to include logging of virtually all events including admin functions, providing both before and after images; ability to add manual log entries for clarification

MULTIPLE REVIEW STATUSES

- Signify program versions that are in different statuses: Request for Approval, Test, Validate, Implement
- Allows *only* a program's 'Implemented' version be downloaded to a production processor

VERIFY & CONFIRM PROCESSES

- Access to key functions requires user to re-enter password, thereby verifying individual is the logged in user
- Critical functions require verification process, then electronic confirmation by an approver to prove individual is the logged in user

SECURITY FEATURES

- Control expiring passwords and prior password re-use
- Capture e-mail addresses for AutoSave users for approval notifications

MDT software
the change management company
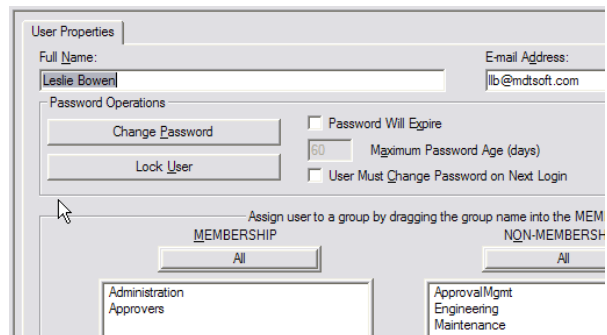
- Default classes for approvals, approval administration
- Unique privileges for the various approval process steps
- Customize required approval processes by program or area
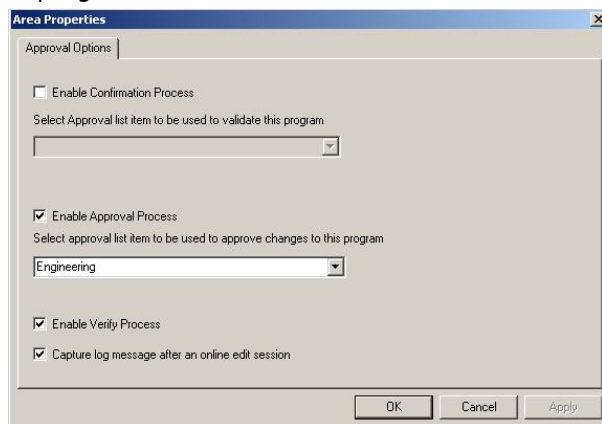
FUNCTIONS & FEATURES
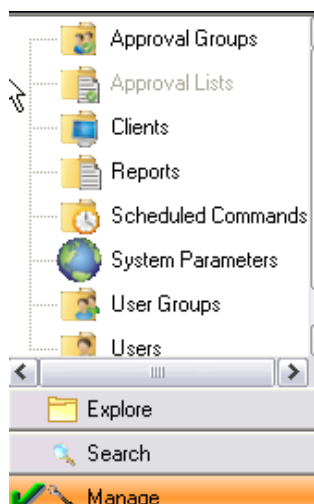
- Device Approvals & Audit Trails add-on module's feature set is licensed separately and can be enabled with any AutoSave module for a particular device/editor application
- Configure approval groups and lists of groups applicable to entire directory or customize at program level
- E-mail notification of approval process events
- License automatically includes the AutoSave Reports Module to provide access to historical logged data

LIFECYCLE OF A CHANGE

1. Create new version; automatic status of 'Edit'
2. Off-line edits performed, saved, completed
3. Request approval to download; automatic status to 'Request for Approval'
4. Status change triggers e-mails to all potential approvers in configured groups
5. Approvers determine whether or not to approve
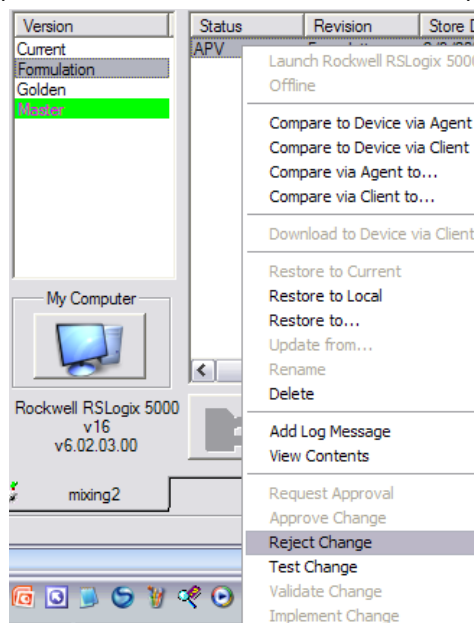
If approve...
- Approver accesses **Add Approval** menu
- Verify & confirm processes performed
- Add Approval dialog completed
- Approval record stored; e-mail sent
- Approval process repeated by each group
- Partial approvals tracked, color coded

If Reject...
- Approver accesses Reject menu
- Verify & confirm processes performed
- Add Reject dialog completed
- Reject record stored, e-mail sent
- Automatic status change = Edit
- Change life cycle starts over

6. All approvals added; automatic status change to **Approved Pending Validation**
7. APV version downloaded to quarantined processor, status to **Test** (verify/confirm)
8. Validation testing, documentation, sign-offs performed
9. Manual change status to **Validated**
10. Manual change status to **Implemented**, put into production; previous Implemented version automatically demoted to Previously Approved

MDT software
the change management company