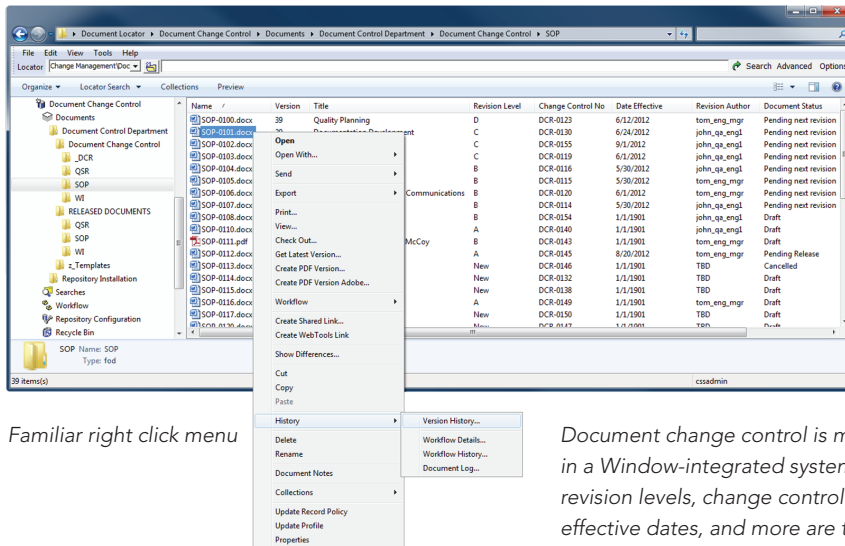


Quality and Compliance Solutions

Document Change Control

Out-of-the-box, structured methodology that automates what are otherwise manual document change control procedures.

Manage the complete lifecycle of documents, from change request, to creation/edit, to review, approvals, training, distribution, and archiving in a Windows-integrated document control system.



Familiar right click menu

Document change control is managed in a Window-integrated system where revision levels, change control numbers, effective dates, and more are tracked and displayed in the folder view.

Windows integration makes it easy

Replace time-consuming and error-prone procedures that rely on paper and spreadsheets with a system for Document Change Control that is built into Microsoft Windows and uses Word-based templates.

- Standard Windows folder operations
- Microsoft Office integration, including Outlook



The Document Change Control module is built on ColumbiaSoft's DL document control platform.

“

A recent FDA audit clearly demonstrated the value of Document Locator by reducing the time it took us to retrieve requested records in half.”

The Anspach Effort, Inc.

Bring products to market faster, reduce financial risk stemming from lost or incorrect information, and maintain regulatory compliance.

The Document Change Control module by ColumbiaSoft offers quality managers and document control professionals an easy and efficient way to manage changes to procedures in compliance with FDA and ISO requirements.

(800) 298-1172
www.ColumbiaSoft.com

A complete system for document change control

Upload existing documents to get started quickly. Fully-configured, customizable procedures automate the complete change control process.

- Change Request
- Creation / edit
- Review
- Approve
- Training
- Publishing
- Archive

Workflow

- Role-based workflows enforce best practices and consistency.
- Notifications are received via email.
- Reminders and escalations keep everything on schedule.

Security

- Access privileges are controlled by user roles and user groups.
- Common user roles and user groups are preconfigured and customizable.
- Document logging tracks access history and actions taken.

Version Control

- New or revised documents are automatically published and prior versions are saved.
- Keeps a complete audit trail of how documents changed over time.

Search

- Full text searching makes it easy to find documents in seconds.
- Save custom searches, and share saved searches with others.

Reporting

- Includes comprehensive reports to track the status of documents and monitor trends.
- Analyze data, charts, and graphs for insight into the efficiency of processes and to validate regulated activities.

Electronic Signatures

- Electronic signatures and digital signatures are supported in compliance with FDA 21 CFR Part 11.

SOP FORM				Page 1 of 2		
<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Instructions: Review and complete the following information </div>						
(1) Title	Tongpro					
(2) SOP Number	SOP-00000000	(3) Document Status	N/A			
(4) Revision Number	None	(5) Revision Number	None			
(6) Change Control No.	None	(7) Effective Date	12-20-2011			
<div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> APPROVED APPROVED </div>						
By: Approved By:	TPO	Approved Title:	TPO			
(8) Approved Date:	Unapproved	(9) Approved Date:	Unapproved			
(10) Approved Signature:	Unapproved	(11) Approved Signature:	Unapproved			
<div style="border: 1px solid black; padding: 5px;"> Signature Block </div>						
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> X John QA Eng 1 <small>Signature of John QA Eng 1 Date: 12/20/2011 Title: QA Eng 1</small> </div>		<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> X Ann Doc Control Mgr <small>Signature of Ann Doc Control Mgr Date: 12/20/2011 Title: QA Eng 1</small> </div>				
QA Eng <small>Signature of John QA Eng 1</small>		Document Control Manager <small>Signature of Ann Doc Control Mgr</small>				
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> X Tom Eng Mgr <small>Signature of Tom Eng Mgr Date: 12/20/2011 Title: QA Eng 1</small> </div>		<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> X Susan QA-Mgr <small>Signature of Susan QA-Mgr Date: 12/20/2011 Title: QA Eng 1</small> </div>				
Document Manager <small>Signature of Tom Eng Mgr</small>		QA Manager <small>Signature of Susan QA-Mgr</small>				
<div style="border: 1px solid black; padding: 5px;"> Revision Table </div>						
Rev	Effective Date	Description of Change	Reason for Change	Revision Author	Required Training	Change Number

Cover sheet – continue to next page for SOP form

Word-based templates and Microsoft Office integration make document change control procedures easy to perform right inside familiar, everyday applications.

Quality System Regulations (QSRs), Standard Operating Procedures (SOPs), Work Instructions, Employee Training, everything is managed in the document control system.



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