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 Windowsintegrated document control system.

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1 Document Change Control ^ Name	Version Title		Revision Level	Change Control No	Date Effective	Revision Author	Document Status
SOP-0	100.docx 39 Quality Planning		D	DCR-0123	6/12/2012	tom_eng_mgr	Pending next revision
Document Control Department SOP-0	101.docx 20 Decomposition Dec	-lent	с	DCR-0130	6/24/2012	john_qa_eng1	Pending next revision
Document Change Control	102.docx Open		с	DCR-0155	9/1/2012	john_qa_eng1	Pending next revision
DCR SOP-0		•	с	DCR-0119	6/1/2012	john_qa_eng1	Pending next revision
QSR SOP-0			в	DCR-0116	5/30/2012	john_qa_eng1	Pending next revision
SOP-0	105.docx		в	DCR-0115	5/30/2012	tom_eng_mgr	Pending next revision
with SOP-0		 Communications 	в	DCR-0120	6/1/2012	tom_eng_mgr	Pending next revision
SOP-0			в	DCR-0114	5/30/2012	john_qa_eng1	Pending next revision
SOP-0	108.docx		В	DCR-0154	1/1/1901	john_qa_eng1	Draft
QSR SOP-0			A	DCR-0140	1/1/1901	john_qa_eng1	Draft
SOP E SOP-0		McCoy	в	DCR-0143	1/1/1901	tom_eng_mgr	Draft
👪 WI 📾 SOP-0			A	DCR-0145	8/20/2012	tom_eng_mgr	Pending Release
z_Templates SOP-0			New	DCR-0146	1/1/1901	TBD	Cancelled
Repository Installation SOP-0			New	DCR-0132	1/1/1901	TBD	Draft
SOP-0	115.docx		New	DCR-0138	1/1/1901	TBD	Draft
Workflow SOP-0		•	A	DCR-0149	1/1/1901	tom_eng_mgr	Draft
Reportion Configuration			New	DCR-0150	1/1/1901	TBD	Draft
Recycle Bin	120. door		Mean	DCR 0147	1.4.4001	TPD	Desti
SOP Name: SOP Type: fod	Show Differences Cut Copy	csadmin					
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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

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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
- Training
- Creation / edit
- Review
- Approve

- 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.

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		information use the document profi	1						
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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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