Document Change Control

for Quality & Regulatory Compliance

Quality and Compliance Solutions

ColumbiaSoft™

Document Control Software for Microsoft Windows

Improve efficiency and enforce consistency

Introducing document change control by ColumbiaSoft.

Bring products to market faster, reduce financial risk stemming from lost or incorrect information, and improve compliance with regulations and standards.

Manage the complete document lifecycle:

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

Supports both Electronic & Digital Signatures

FDA 21CFR Part 11 Compliant

ISO 13485 Compliant

Upload your existing documents and get started quickly.

Document Change Control by ColumbiaSoft strictly controls:

- Revision Level
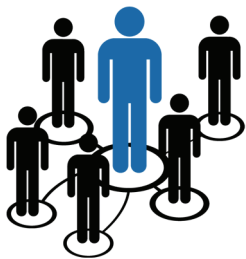- Revision Author
- Effective Date
- Change Control Number

Built on ColumbiaSoft's DL document control platform, the Document Change Control module is designed to improve the effectiveness of quality and compliance programs.

Document Change Control

The Document Change Control repository (DCC) provides an out of the box structured methodology that automates the traditional manual document change control procedure.

Empowering Process Owners

The system is designed so that Process Owners have end-to-end responsibility for their documents. Process owners design the process, and process teams carry it out, overseeing their own work and making all the day-to-day operating decisions required to keep things moving smoothly.

The complete lifecycle of documents: template management, document change request, creation/edit, review, approval, training, distribution, archive and obsolescence… everything is managed in the system. You can upload your existing documents to get started quickly. Full text search allows you to find documents in seconds.

Role based workflows enforce best practices and consistency. Workflow participants are automatically notified of their assignments via email. Workflow reminders and escalations keep workflows on schedule.

Security and access privileges are controlled by user roles and user groups dependent upon the associated process. New or revised documents are automatically published and prior versions are archived.

DL version control maintains versions of documents throughout their lifecycle. The Document Log tracks when a document was accessed, who accessed it, and what action was taken. Reporting provides a comprehensive set of reports to track the status of documents and monitor trends.

> " A recent FDA audit clearly demonstrated the value of Document Locator by reducing the time it took us to retrieve requested records in half."
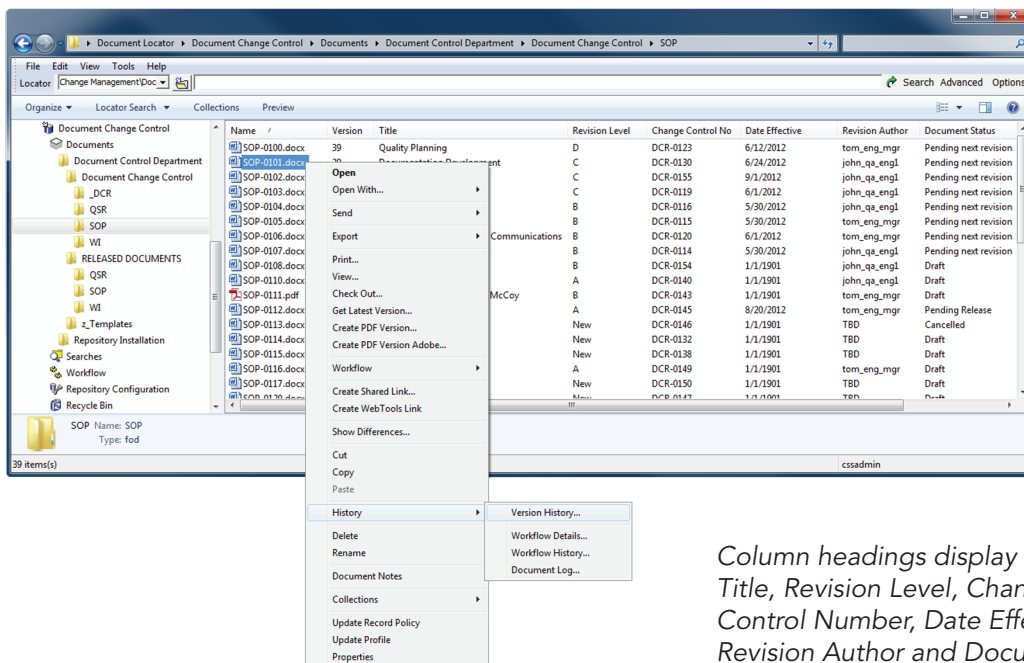>
> *The Anspach Effort, Inc.*

The system supports both electronic signatures and digital signatures, in compliance with ISO standards and 21 CFR Part 11. System validation is facilitated by a comprehensive set of validation scripts.

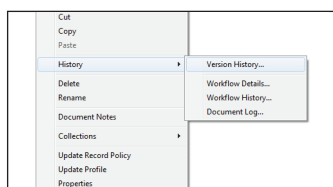# The document change control process

Step	Description
Change Request	The change request process is used to document the request for change, the reason for the change and the impact of the change. The process is also used to assign user roles: Revision Author, Review & Approve, and Training.
Create/edit	The create/edit process is initiated when the assigned Revision Author receives a workflow notice that they have been assigned to either create a new document or edit an existing document.
Review	Once the assigned task has been completed, the Revision Author checks in the document and starts the Review workflow which allows the assigned reviewers to collaborate on the edits to a document until all reviewers are in agreement.
Approve	The approve workflow is used to approve the document. DL supports both electronic signature and digital signature technologies that comply with 21CFR Part 11.
Training	When training is required, the system provides two methods. Employee review or Supervisor training. Both methods provide an audit trail of training provided.
Publishing	The final step in the process publishes a copy of the signed PDF version of the document in the Released Documents folder. If there is a prior version it is automatically replaced with the most current approved version.
Archive	Records management archives the document per predefined schedules.

Full-integration within the Microsoft architecture makes document change control easy

Document Change Control is fully integrated into Microsoft Windows which makes it easy and intuitive to use. Simply right click on a document to access a menu of document control commands.

Column headings display the Title, Revision Level, Change Control Number, Date Effective, Revision Author and Document Status for the SOP's in this folder.
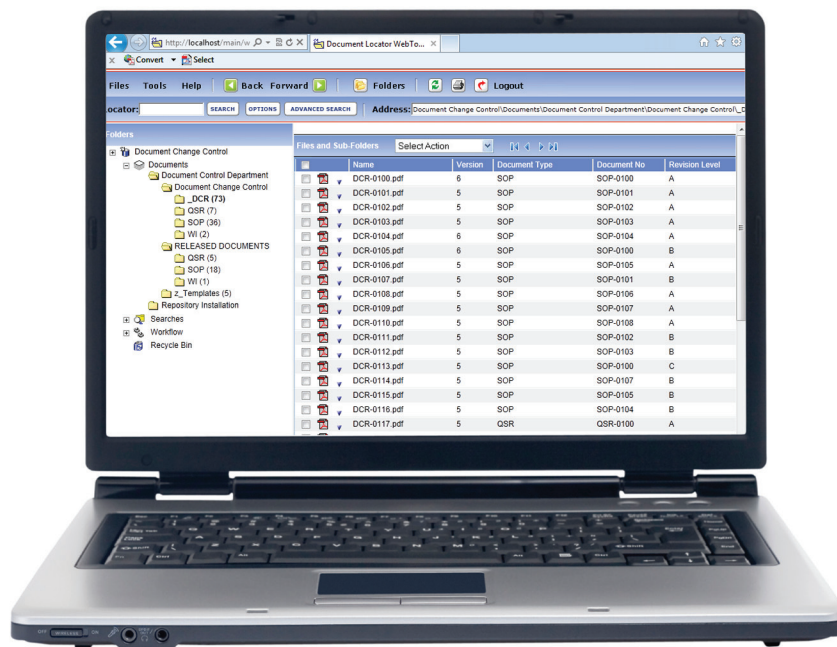

In this example the History menu is selected which then shows sub-menus for workflow and log histories.

Document change control reaches beyond the office walls

People working outside the office who are authorized for access can retrieve documents and participate in workflows over the Internet. The self-hosted Web access provides users with an interface that closely resembles the desktop experience.

A new mobile interface (2012 release) extends the reach of files in the document control system worldwide on mobile devices and tablets.

Insightful business intelligence for smart decision-making

Reporting is critical for managers to make timely decisions. A comprehensive set of reports for monitoring system configuration, usage, throughput, and trend analysis are included. Reports are numbered, categorized and named for easy access. Plus, you can add your own custom reports.

Reports track the status of documents being changed in the system.
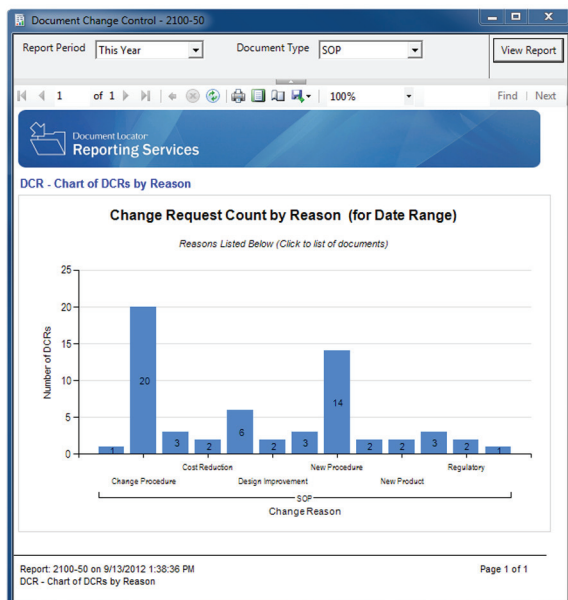

Chart reports allow you to analyze trends in the system. Users can drill down to see the detail.

ColumbiaSoft quality and compliance solutions

- CAPA
- Non-conformance
- Corrective Action
- Employee Training
- ECO
- Certification Packages

- Document Transmittals
- Accounts Payable Processing
- Human Resources
- Contract Management
- Project Management
- First Article Packages

SEE HOW IT WORKS

ColumbiaSoft™

ColumbiaSoft is a leading provider of enterprise document control solutions.

Since 1998, we've been helping businesses and government agencies with intelligent solutions to meet regulatory compliance and improve quality. Our solutions are fully-integrated with Microsoft and other leading software technologies, making it easy for people to use.

We are headquartered in the United States, and provide all development, support, and services from the U.S.

Contact us to learn more.

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