## Solution Overview

OpenText Document Change Control for Extended ECM

A robust Document Change Control process lies at the heart of an organization's document management system. Every aspect of auditing and compliance verification is determined through the scrutiny of documented evidence. Document Change Control ensures controlled creation, revision, and obsoletion of controlled company documents.

OpenText™ Document Change Control for Extended ECM is a complete off-the-shelf best practice solution for managed document control in a workflow-driven environment that uses the document management and security features of OpenText™ Extended ECM.
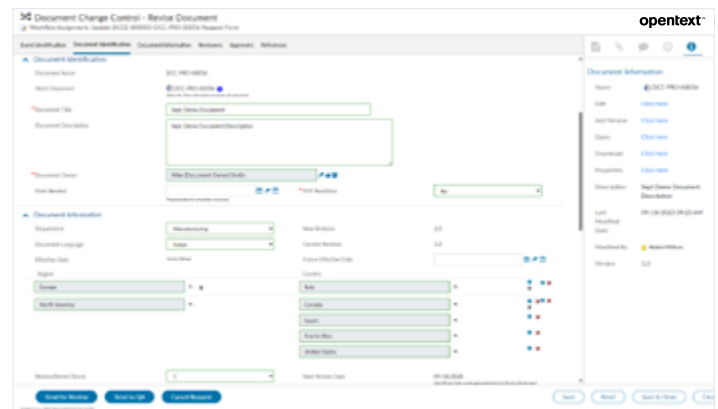
Features and benefits

→ **Single, centralized system:** Create, revise, obsolete, set, and remove holds on documents in a single centralized system

- Save time and money through automated document processes and reduce human errors

→ **Easy to deploy and use:** An add-on solution that is easily deployed on Extended ECM

- Reduce deployment time and effort, simplify training and roll-out and increase user adoption

→ **Real-time data and reporting:** Configure reports and dashboards to show real-time data

- Informed decision-making increases efficiency improves processes and drives revenue growth

→ **Notifications:** Ensure timely document revisions, reviews, and approvals and reduce non-compliance

- Optimize the process, increase efficiency

→ **Navigation:** Enhanced solution layout enables easy navigation to all records and associated history

- Optimize the user experience, increase efficiency

→ **Forms:** Create and update Forms with drag and drop configuration

- Save time, eliminate need for developer resources

Process

→ **Workflow enabled document change control process:** Pre-configured workflows provide predefined processes and a systematic way of managing all document change requests, reviews, and approvals. Standardize and automate your document creation and revision procedure. Processes available include create, revise, set hold, remove hold, and obsolete. Periodic review automates workflow initiation before the next review date.

- Ensures efficient and compliant operations and processes.

- Ensures compliance

→ **Supporting documents:** Easily add additional supporting documents to your document processes to ensure that all relevant data used to support the process and decisions is captured.

- Enables more informed decision-making through access to all related documents and data

→ **Role based processes:** All workflows are role based including the following roles:

- Document Owner — Create, revise, set, and remove holds and obsolete documents.

- Reviewer — Assigned documents to review. Can not update metadata but can edit document.

- Approver — Assigned documents to review. Cannot update metadata or edit document.

- Document Controller — Provides oversight to the process and is gatekeeper to ensure that documents meet company standards.

Roles can be renamed to suit your own terminology.

- Efficiently manage all processes and optimize resources.
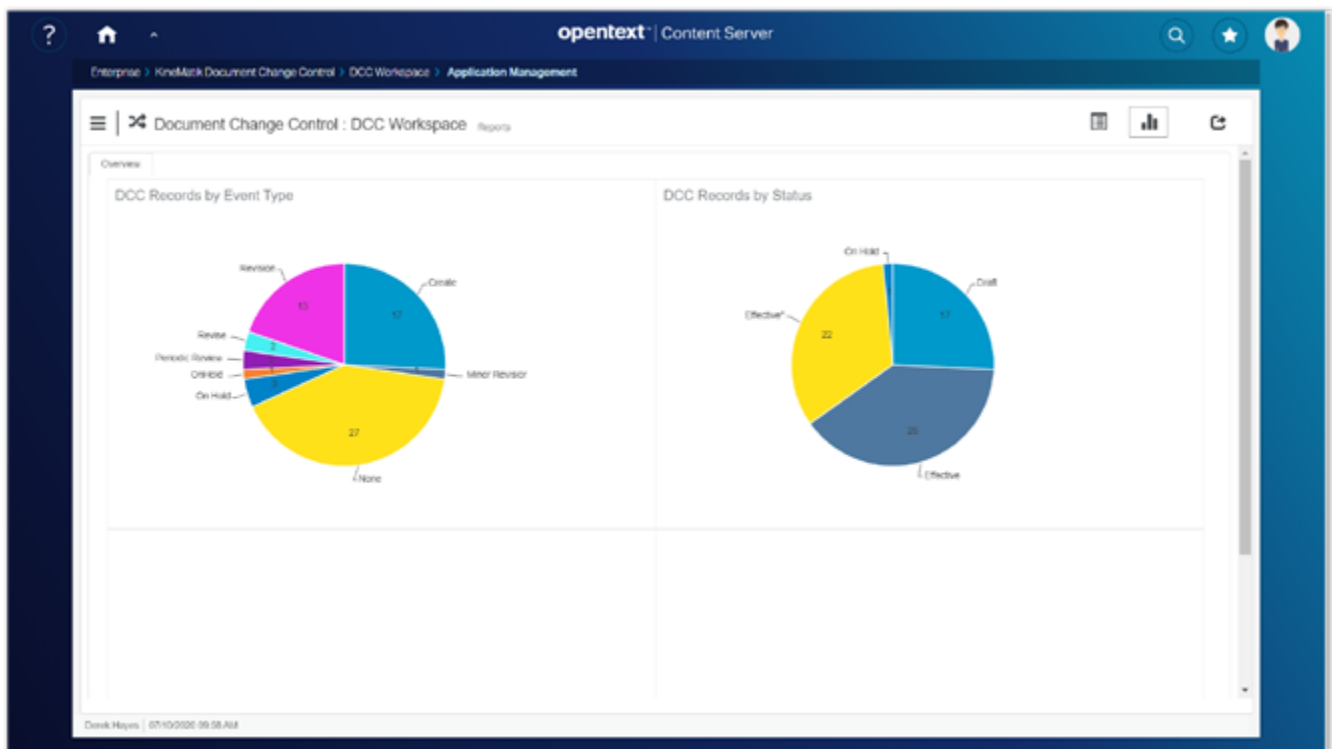
→ **Document Libraries:** Using a six library configuration allows for documents to be managed correctly often automatically, in the background.

- Source Library — Stores all versions of the original format of the document. The latest version of this document gets copied as part of any process, for example, Revise or Obsolete.

- Released Library — Contains only the latest released version of the document. The process controls whether this document is a PDF or retains its original format. Document consumers access the effective documents in this location.

- Retired — When a new effective document version is created via the revise process, superseded versions are moved to this location and the metadata updated to mark them as retired versions. PDFs have a watermark added to show that they are retired.

- On Hold — When a document is placed on hold, the effective document in the Released Library is temporarily moved to the On Hold library so that users cannot access it. The release Hold process reverses this process.

- Obsolete — When a document is no longer required, all documents (source, released, retired) are moved to the Obsolete Library. Records Management RSI can be used on these documents post obsoleting.

- Template — The Template Library allows for any company standardized templates to be made available for the creation of new documents.

- Increase efficiency and reduce errors

→ **Advanced Versioning:** Advanced versioning ensures consistency in the versioning of documents. Minor versioning is used during the workflows. The document is then promoted to a major version when the document is made effective. Confusion is avoided by ensuring that the Extended ECM document version and document version (sometimes called a revision) are maintained in sync.

- Reduce errors and increase efficiency, saving time and money

→ **Re-assignment:** If there is no document owner associated to the document metadata (e.g. the user account is deleted) the process intelligently assigns the first workflow step to the document controller who can reassign the document and associated workflow assignments to a new document owner. This eliminates workflow assignments not being assigned and provides greater control to the document controller in correcting essential missing metadata. Document administrators can now reassign reviewers and approvers during the active workflow.

- Increase efficiency and reduce human error
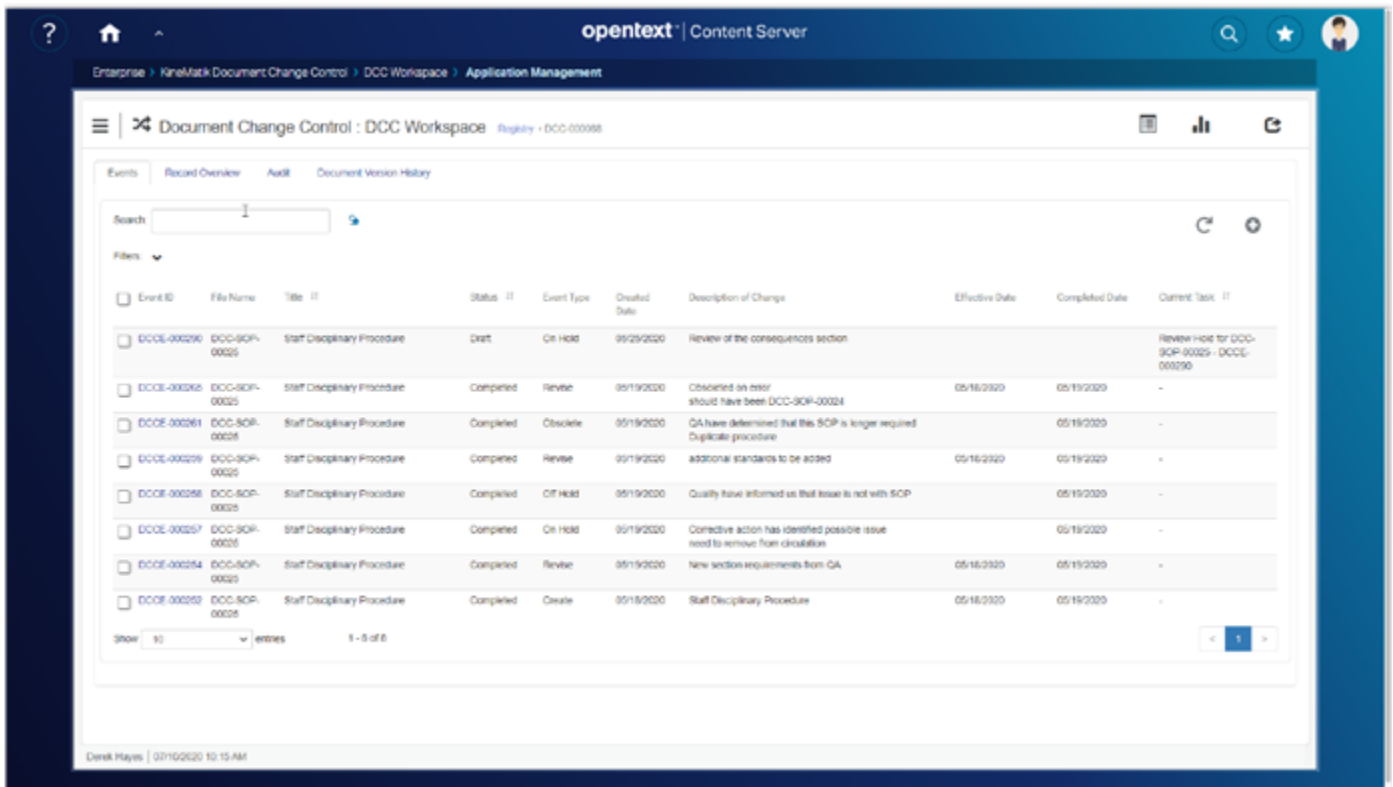
Auditing

→ **Audit tables:** Embedded reviewer and approver audit tables show every reviewer and approver disposition in the current process for each review and approval cycle. The same audit tables are available in the process overview, clearly showing historical process information.

- Regulation and ISO audits are faster to compile with full transparency

→ **Cover pages:** Documents that are converted to PDF can include a cover page that can be configured to include the description of change for every document version along with the approver data for that document version.

- Reduce effort and errors by automatically including document properties on the cover page

→ **Audit trail management and tracking:** Full audit trail of who requested and made changes, when

the changes occurred, and who reviewed and approved them is available. Electronic signatures, configurable to comply with regulations such as FDA 21CFR Part 11 requirements, can also be used if required.

Use the Document Version History widget to view and compare any two document versions across the entire document lifecycle.

- Improve governance by maintaining regulatory compliance

→ **Procedure compliance:** Demonstrate all document changes occur in a controlled manner and according to the organization's standard operating procedures and so adhere to regulatory compliance.

- Maintain internal policy and regulatory compliance

Administration

→ **Recover corrupted workflows:** Administrators can recover Document Records when workflows corrupt with a single action, which updates the record and event while also stopping any ongoing workflows.

- Reduce administrator burden to maintain system integrity

→ **Administrator dashboard:** An administrator dashboard provides a single location to access all the tools an administrator requires to configure and manage the solution.

- Increase efficiency and have better administrator control

→ **Upgrade simplification:** Solution updates do not require Extended ECM service restarts after first installation. This reduces risk and provides for more flexibility in applying updates.

- Reduce risk and simplify upgrades

Integration and enterprise system

→ **OpenText™ Blazon™:** Blazon allows for a document to automatically be converted to PDF within the workflow if required, along with the following advanced features:

- Automated validation for the support of a document mime-type ensures users cannot request PDF conversion of an unsupported mime-type.

- Cover pages are created dynamically and can include any document properties and metadata.

- Watermarking of retired or obsoleted documents.

- Adhere to regulations and certifications and protect approved document content

→ **OpenText™ Brava!™:** Brava! viewer can be enabled within the solution to provide additional value:

- Allow video annotations as part of a review process for video policies or procedures.

- Workflow assignments for specific roles can use Brava! to annotate documents instead of allowing them to edit the content.

- The Document Version History widget can be extended to use Brava! to compare any two versions of a document in the document lifecycle.

- Show annotations for any version of the document throughout the document lifecycle.

- Reduce software costs by using Brava! to view documents instead of a native solution

→ **OpenText™ Core Share and OpenText™ Extended ECM Mobile:** Use the native integration between Extended ECM and Core to share approved documents with your mobile workforce or an external audience.

- Improve collaboration with all internal and external parties

→ **Document Change Control and records management:** Records management is an important part of any organization, especially for regulated industries. Other certifications, for example ISO, also require control over your dispositions. The Document Change Control solution manages the record of a document and the associated releases of that policy. Records management policies can be applied to obsoleted documents to ensure that they are disposed of after their retention period.

- Reduce costs associated with records management

→ **Enterprise Systems:** The Document Change Control solution can be connected to enterprise systems such as SAP®, Oracle®, Microsoft® SharePoint® and more via OpenText Extended ECM. Connected or Business Workspaces can automatically be viewed in these solutions to render content in the familiar interface. This allows users to access content that they require through their line of business solution, for example, SharePoint, which becomes a portal to access all approved documents.

- Regulation and ISO audits are faster to compile with full transparency

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The OpenText Document Change Control for Extended ECM collection includes Audits, Change Control, Complaints, CAPA, Document Change Control, Document Training, and more. These solutions provide linked business processes with content management, allowing a real-time view of all business metrics and trends across an organization while maintaining data and document security.

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