

Customer Knowledge Transfer

Document Management v6.0 and v6.1

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Document Management

Improve document processing with enhanced workflow functionality



Templates



Simplify the workflow with templates stored as documents so each template document has its own controls in place to ensure only current templates are used



SharePoint collaboration



Collaborate using native file format with SharePoint collaboration, which offers options to retain custom features



Authoring task



Optional policy supports document author in the workflow with task notifications



Minor versioning



Track minor changes without requiring retraining and approvals, while retaining document controls



Prerequisites



Set requirements for essential training that must be completed prior to the current certification



Archiving Documents



Set archival parameters for documents to be removed from global searches and find menus for efficiency gains

Templates



Document Management

Templates

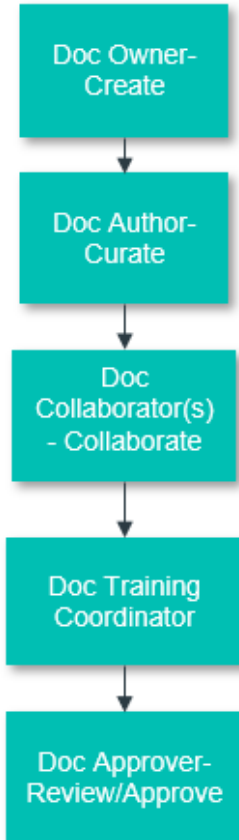
Expedite your development and review process and efficiently prepare and store your standardized, compliant templates using Document Management:

- ✓ Build your Templates using Document Management workflows
- ✓ Option to upload existing Templates with only necessary workflows
- ✓ Keep your Templates in a controlled environment with revision control
- ✓ Obtain approvals for Templates
- ✓ Prevent staff from uploading files from their desktop
- ✓ Set a policy to require Templates are used when creating the document

Document Management

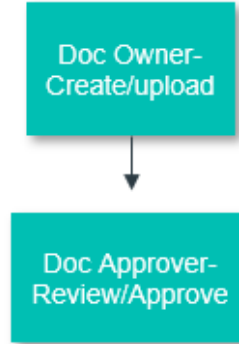
Templates

QMS Documents



Vs.

Template Documents



- ✓ Template Numbering Scheme
- ✓ Template team members
- ✓ Only major versions
- ✓ No watermarks

Templates can be stored as controlled documents with their own numbering scheme, specific team alignment, and versioning control for a more structured oversight of templates

Document & Training Management 6.0

Templates- Administrator

Document Administrator creates the Document Type that will contain the template(s)

An out-of-box Document Type is available with the following parameters predefined and ready to use:

- ✓ Document Type Name: **Template Document**
- ✓ A new field called **Document Type is only used to build templates**: Ensures the correct filters are in place when creating & searching for template documents and defaults the following features:
 - PDF Preference is set to **Not Required**
 - Only **Approve Document** is enabled in the policy
 - An out-of-box numbering scheme is available for document templates with the following format: TEMPLATE-{0}-NUM

Once the Document Type record is created, the option to change the setting **Document Type is only used to build templates** is no longer available.

For existing records and the customer upgraded to Doc 6.0, this field **Document Type is only used to build Templates** will be set to No.

Create Document Type

Type *
Template Document

Description *
Document Type is used to add Templates

Document Type is only used to build templates
 Document Type is used for pharmaceutical regulatory submission

Numbering Scheme *
Template Document Numbering

Administrator Role *
ADMINISTRATOR

Team *
Document - Team

PDF Preference
 System Generated Manual Upload Not Required

Versioning Option
 Major only Major and Minor Versioning Control

Policy
 Enable Author
 Collaborate Document
 Define Requirements for User Training
 Approve Document
 Get Feedback during Periodic Review

Tip: This Document Type will contain only templates, therefore a unique team and numbering scheme along with an abbreviated workflow is recommended when setting up your own Document Types to be used for Templates

Document & Training Management 6.0

Templates- Administrator

Document Administrator adds the template as controlled documents

From the create menu, select **Template Document**: this new form will filter and only display the Document Types that enabled the field Document Type is only used to build Templates.

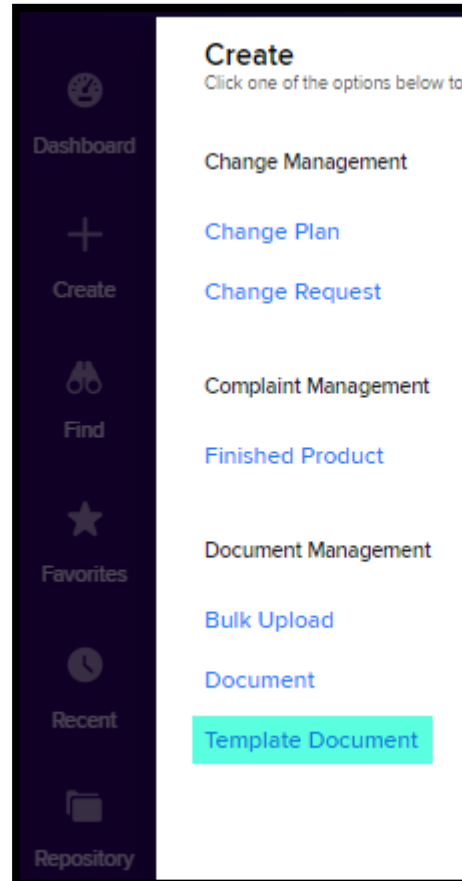
The create form will require the same data elements as a standard document record with a few new fields:

A new checkbox **Template available on all Document Types**, and when checked will ensure the new template document being created is accessible and can be used from any of the Document Types.

When left unchecked, you may zoom to select which Document Type the template will be accessible from.

At the next step to prepare the document profile, follow the steps and policy as set forth for this Template Document Type in order to move it to CURRENT status.

A new right (SDC_CREATE_TEMPLATE) is added to the Document Administrator Rights Group to ensure the new Create Template is accessible on the menu for administrators.



Create Document

This form is used to create Template Document

Type *
Template Document

Title *
Standard Operating Procedure Template

Description
Template to be used when creating SOP documents

Site
LakeView Lakeview Center

Department
PROD Product Manager

Template available on all Document Types

Applicable Document Type *
CT12 Machine

Primary File
SOP Template.docx [Browse](#)

Tip: At this stage, this document record is the template and the document type selected should be the unique team, numbering scheme and workflow that will apply only to the template. This is not the controlled QMS document yet and therefore will not require the full workflow process.

Document & Training Management 6.0

Templates- Document Owner

Document Owner Using Templates

Once the templates are defined, a simple function allows for the document owner to select the correct template based on the Document Type used.

When creating a document record the template(s) aligned to the Document Type are available to select at the Create Document and Check In steps of the workflow.

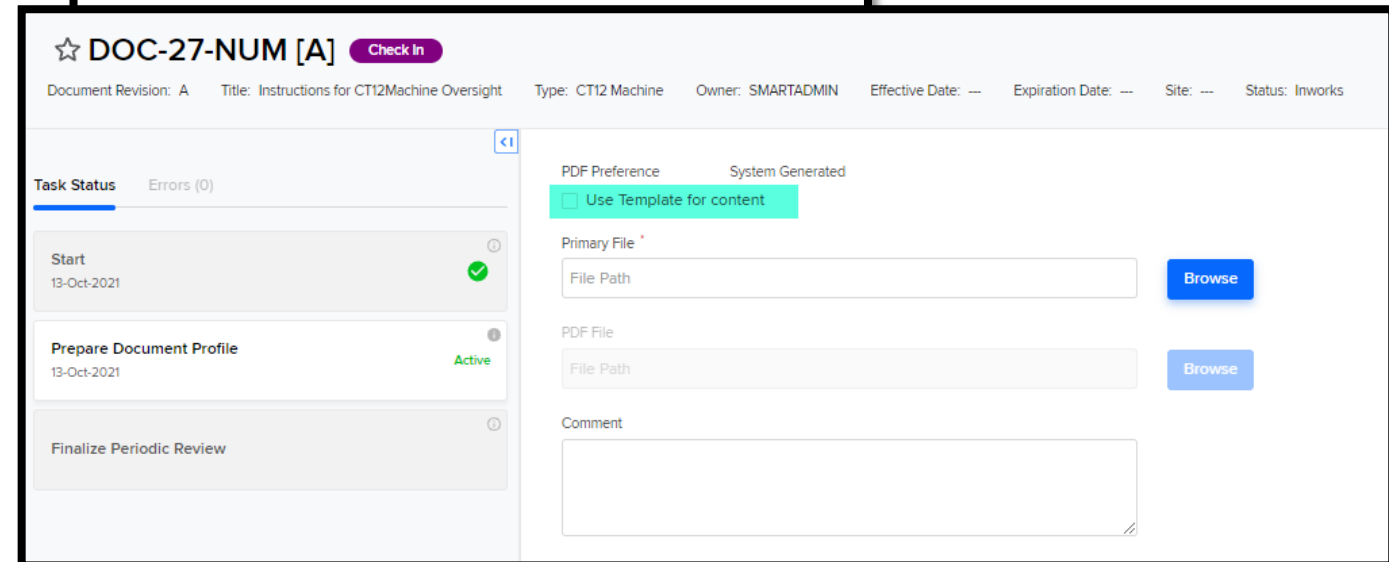
- ✓ Only CURRENT & PRERELEASE template documents are displayed in the zoom list of Template Documents
- ✓ Click the Template number link to view the template before continuing
- ✓ If the policy **Allowed to edit content outside the system** is unchecked at the Document Type level, the option to “Browse” and upload a file is hidden and the document owner may only use the available template(s)
- ✓ Once the template is selected, this will transfer to the primary file



Create Document

Type *

Work Instructions



☆ DOC-27-NUM [A] Check In

Document Revision: A Title: Instructions for CT12Machine Oversight Type: CT12 Machine Owner: SMARTADMIN Effective Date: --- Expiration Date: --- Site: --- Status: Inworks

Task Status Errors (0)

Start 13-Oct-2021 ✓

Prepare Document Profile 13-Oct-2021 Active

Finalize Periodic Review

PDF Preference System Generated

Use Template for content

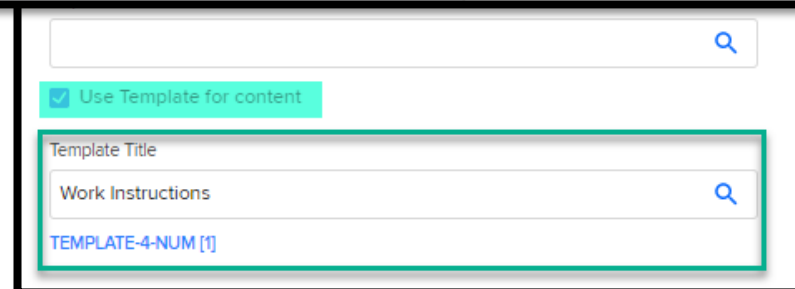
Primary File *

File Path Browse

PDF File

File Path Browse

Comment



Use Template for content

Template Title

Work Instructions

TEMPLATE-4-NUM [1]

Authoring



Document Management

Authoring

Document curation may be assigned to a Document Author

- ✓ Additional policy to include authors in your workflow
- ✓ Assign authors tasks independent of the document owner
- ✓ Authors receive task notifications and due dates
- ✓ When an author task is enabled, the content isn't required until the author takes ownership of their task, freeing up the Document Owner to focus on the overall management of the workflow

★ Clinical Edit Document Type

Applicable Security: Manage PDF Preference: Not Required Numbering Scheme: Regulatory Document Team: Pharma Doc Team

Policy and Due Dates (# of business days)

- Allowed to edit content outside of the system
- Enable Author

Authoring Due (days) *

5

- Collaborate Document

Collaboration Due (days) *

10

The background features a light blue network pattern of interconnected nodes and lines. Scattered throughout are various blue line-art icons: a balance scale, a magnifying glass over a bar chart, a group of people, a gear with a clock face, a clipboard with a pie chart, a caduceus, a heart held by two hands, a cube with three smaller cubes on top, and a circular flow diagram with arrows.

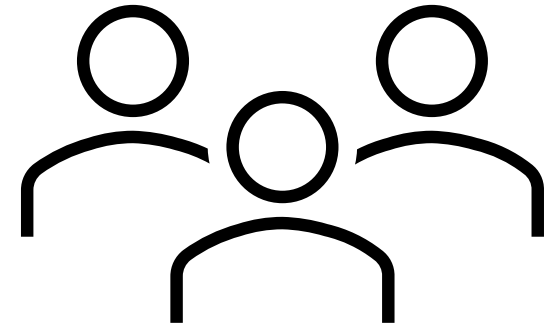
SharePoint Collaboration

Document Management

SharePoint Collaboration

Enhance your document author process with SharePoint Collaboration:

- ✓ Allows for desktop Microsoft file features
- ✓ Retain formatting of the document, such as security and locked formatting
- ✓ Ability to utilize full scope of the review and track changes features with accept and reject by section
- ✓ Available for on premise customers



Document Management

SharePoint Collaboration

SmartSolve has integrated with SharePoint offering customers the option to edit and collaborate on documents records using the desktop version of document.

When using SharePoint Online or on-premise to edit and collaborate on a document, the file retains many of the custom views and parameters defined in the native format. Here are a few requirements that must be met in order to utilize SharePoint in your Document Management workflow:

- SharePoint Online will require customers to procure an Office 365 subscription license with Microsoft. In order use full office desktop experience customer must have a plan that has SharePoint Online. Refer to <https://www.microsoft.com/en-us/microsoft-365/sharepoint/compare-sharepoint-plans>
- Modern authentication is supported & required when connecting with SharePoint online
- The business must have a secured SharePoint folder for the documents (Document Library) as they are edited and collaborated.
- The business must have a designated owner (full control permission) to the SharePoint Document Library and the SharePoint site.
 - The designated owner should have Full Control up to the parent level of the Document Library.
 - The designated owner of the SharePoint folder must grant Limited Access (to the SharePoint folder) for the document task owners (owner, author, collaborator).
- For each of the document task owners that will have capability to edit/collaborate on the documents, their email address used for access to the SharePoint location must be added to their user profile in SmartSolve under 'Email'.

Document Management

SharePoint Collaboration

Document Setup

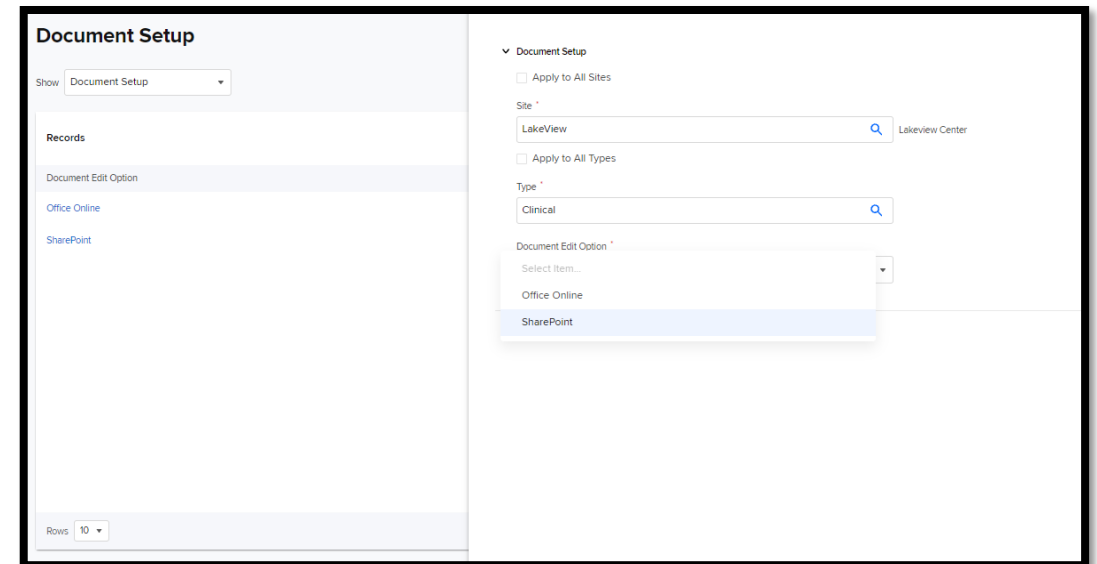
Add SharePoint Edit Options in Document Management:

The default edit/collaborate setting is Microsoft Office Online. Follow the below steps to define when SharePoint shall be used to edit/collaborate documents. In order to manage the below settings, the administrator must have the following Rights Group assigned: Document Administrator

From the Admin menu> select Document Setup under the Document Management category

1. Click “Add Record” button
2. Define the site(s) and Document Type(s) that shall use SharePoint to edit and
3. Define the ‘Document Edit Option”
4. Submit

Site has been added to the Document Create form to allow for unique edit type based on site option



The screenshot displays the 'Document Setup' configuration page. On the left, a 'Records' table lists 'Office Online' and 'SharePoint' as document edit options. On the right, the configuration details for 'Document Setup' are shown, including checkboxes for 'Apply to All Sites' and 'Apply to All Types', a 'Site' dropdown set to 'LakeView', and a 'Type' dropdown set to 'Clinical'. A 'Document Edit Option' dropdown menu is open, showing 'Office Online' and 'SharePoint' as selectable options. The 'SharePoint' option is currently selected and highlighted.

Document Management

SharePoint Collaboration

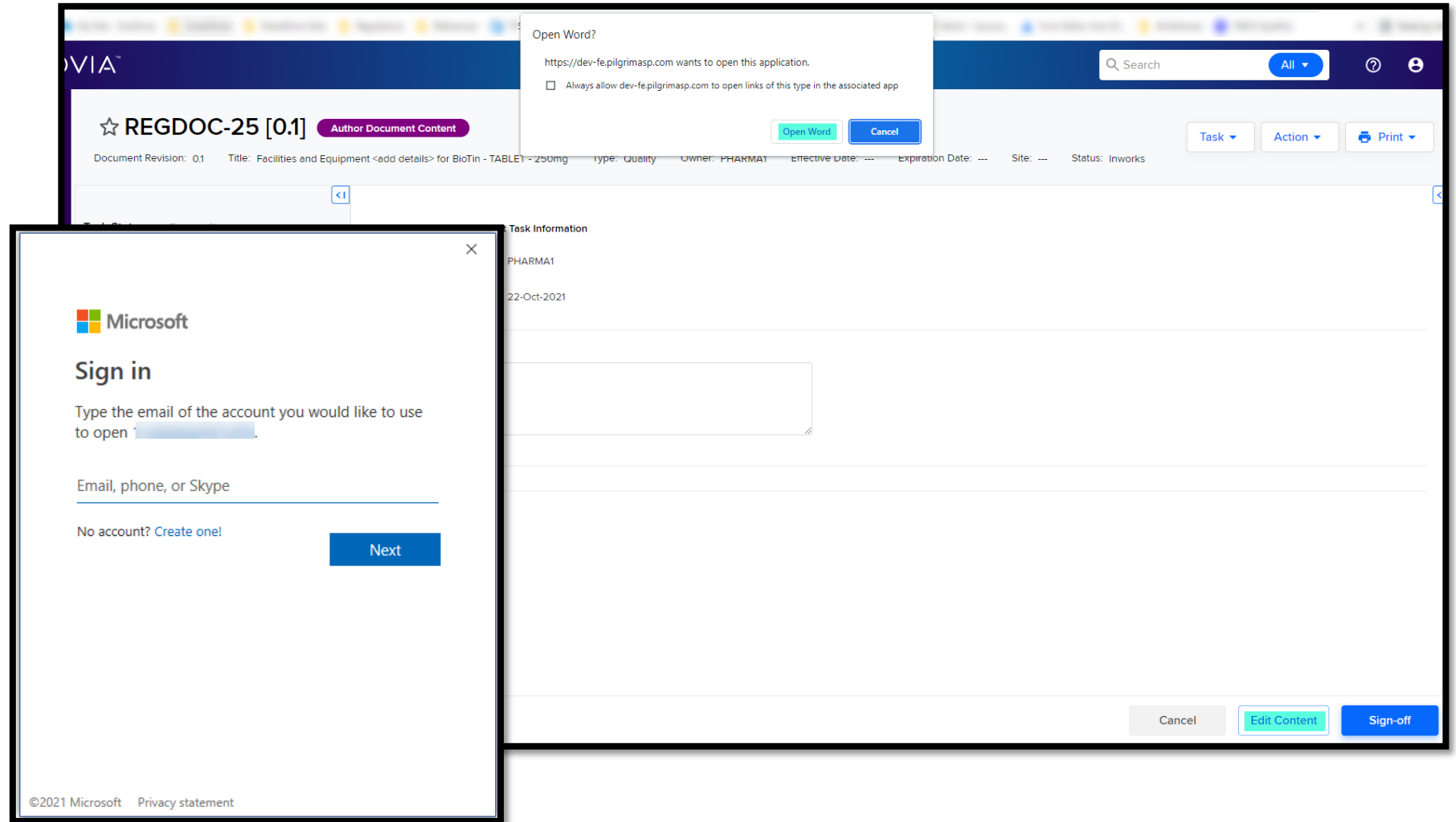
Edit Content

When SharePoint is enabled for the Site/Document Type selected, the edit button changes to “Edit Content” and a pop-up window appears to confirm the type of file you’re opening.

When logging in for the 1st time, you’ll receive a pop-up message to sign in using your email setup to access the SharePoint site.

After entering your email address, the file will open in your desktop view and is editable at this point.

You may close out of the file once complete as the file is automatically saved as you work.



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Prerequisites

Document Management

Prerequisites

Drive conditional requirements using Prerequisites

- ✓ Ensure certain documents or courses are completed prior to starting a specific training
- ✓ Helps establish knowledge of a subject before user may access the requirement

The screenshot shows the 'DOC-34-NUM [1]' document management interface. The document is titled 'C3 Policy Overview' and is of type 'C3 Device Components'. The 'Certification' tab is active, showing a table of prerequisites. The prerequisites table is highlighted with a green border.

| Requirement Number | Revision | Title | Status |
|----------------------------|----------|----------------------|-------------|
| DOC-18-NUM | A | Quality Plan | Current |
| CUR-1-NUM | A | Device HL56 | Current |
| DOC-9-NUM | A | Product Requirements | Current |
| DOC-33-SOP | A | M3 Device SOP | Prereleased |

The screenshot shows the 'PRE10CT [A]: PRE10CT Overview' interface. A warning message at the top states: 'Cannot sign-off on training requirement. User is not certified on one or more prerequisite requirements : 54414'. Below the warning is a table of prerequisites.

| Requirement Number | Revision | Title | Status | Certified |
|--------------------|----------|-------------------|---------|-----------|
| 523.66 | A | CT523 | CURRENT | No |
| DOC-22-NUM | A | 10.10CT Mechanics | CURRENT | No |
| Course 17 | A | CT10.10 | CURRENT | No |
| SCORM5.2 | A | SCORM5.2 | CURRENT | No |

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Minor Versioning

Document Management

Minor Versioning

Track small, non-approval required changes using minor versioning

- ✓ Retain versioning control when making spelling or grammatical changes
- ✓ Option to skip training when updating a minor version
- ✓ Versioning control - allows for minor versions during draft creation of the document and will automatically increase to major version upon approval

The screenshot shows a configuration form for a document type. The fields are as follows:

- Type ***: Clinical
- Description ***: Document Type contains clinical documents
- Numbering Scheme ***: Regulatory Document
- Force Auto Numbering**
- Administrator Role ***: ADMINISTRATOR
- Team ***: Pharma Doc Team
- PDF Preference**: System Generated, Manual Upload, Not Required
- Versioning Option**: Major only, Major and Minor, Versioning Control
- Release Information** (expanded):
 - Grace Period to Release (days)**: 0
 - Retention Time (years)**: (empty field)

Document Management

Minor Versioning

Major & Minor versioning

- ✓ Once set at the Document Type level, then the option is available at each revision to select the type of version (Major or Minor)
- ✓ The Document workflow will retain the default settings based on the Document, and allow the document owner to skip training if minor version

DOC-33-SOP [A] Revise Document

Document Revision: A Title: M3 Device SOP Type: M3 Device Mechanics Owner: KMCTAVISH Effective Date: 19-Oct-2021 Expiration Date: ---

Site: --- Status: Prereleased

Task Status Errors (0)

- Start 18-Oct-2021 ✓
- Prepare Document Profile 18-Oct-2021 ✓
- Author Document Content 18-Oct-2021 ✓
- Define Training Requirements 19-Oct-2021 ✓
- Finalize Periodic Review

Minor Versioning *
 Yes No

New Revision *
B

Reason *

Update Document Information
Manage Properties
Manage Certification
Manage Certification Role
Manage Attachments
Manage Document References
Schedule Periodic Review
Revise Document
Copy Document

Cancel Sign-off

DOC-33-SOP [A] Revise Document

Document Revision: A Title: M3 Device SOP Type: M3 Device Mechanics Owner: KMCTAVISH Effective Date: 19-Oct-2021 Expiration Date: ---

Site: --- Status: Prereleased

Task Status Errors (0)

- Start 18-Oct-2021 ✓
- Prepare Document Profile 18-Oct-2021 ✓
- Author Document Content 18-Oct-2021 ✓
- Define Training Requirements 19-Oct-2021 ✓
- Finalize Periodic Review

Minor Versioning *
 Yes No

Reason *
Making update to company logq

Cancel Sign-off

Document Management

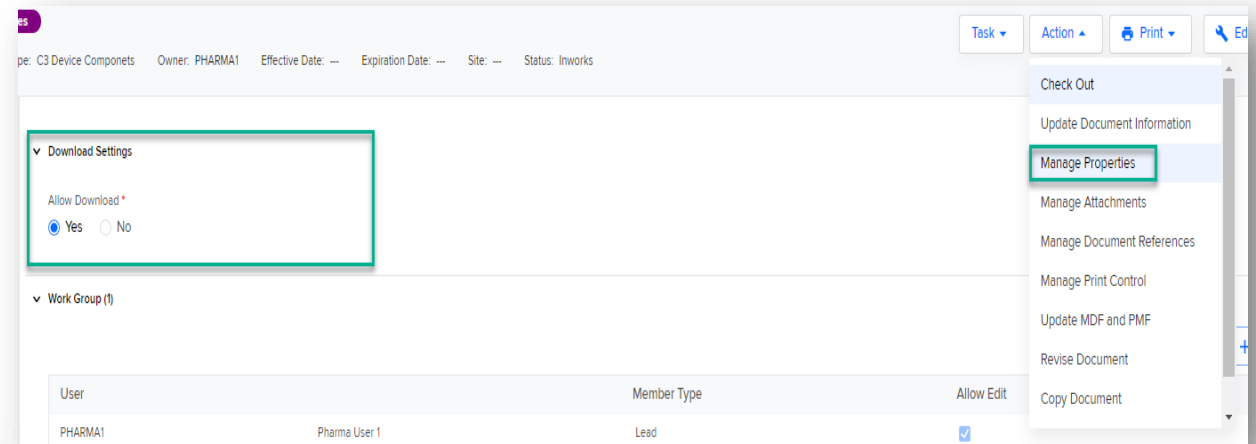
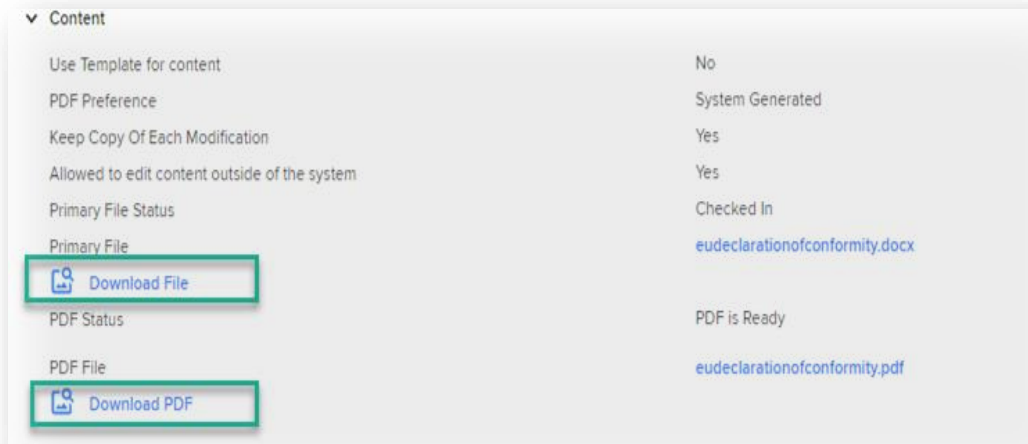
Disable Download

Removing the download feature from the Document record helps retain document control when a Document is Viewed

To provide additional controls over document records, the option to download documents within SmartSolve is contained to the Document File Viewer for everyone except the assigned document team members, and only while the document is INWORKS.

The "Download File" hyperlinks are removed for all users except the Document Team Members, and then only when the document is INWORKS, else download is only found from within the File Viewer:

Document is INWORKS vs. all other document status



From the Manage Properties Action Menu, Download settings provides Document Owners and Supervisors the option to restrict download of the document from SmartSolve.

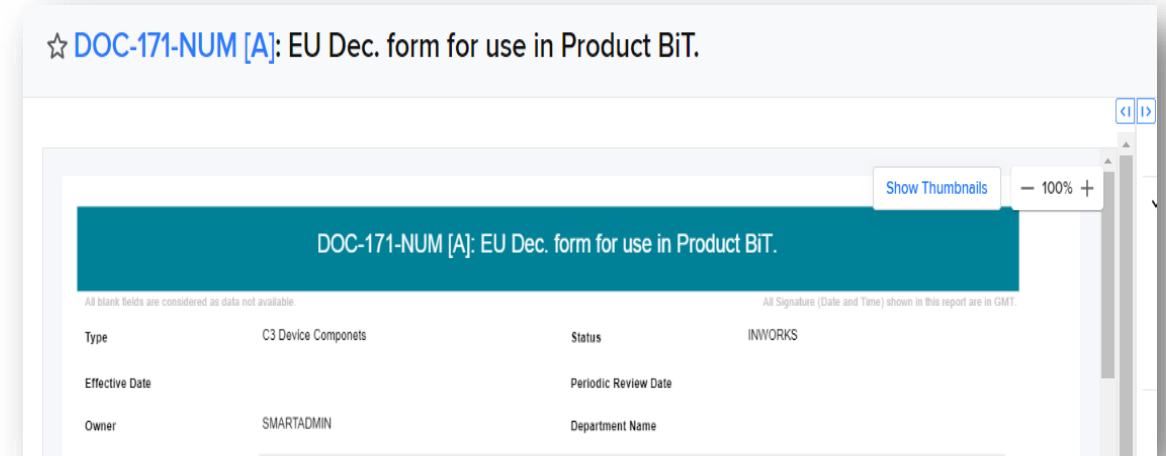
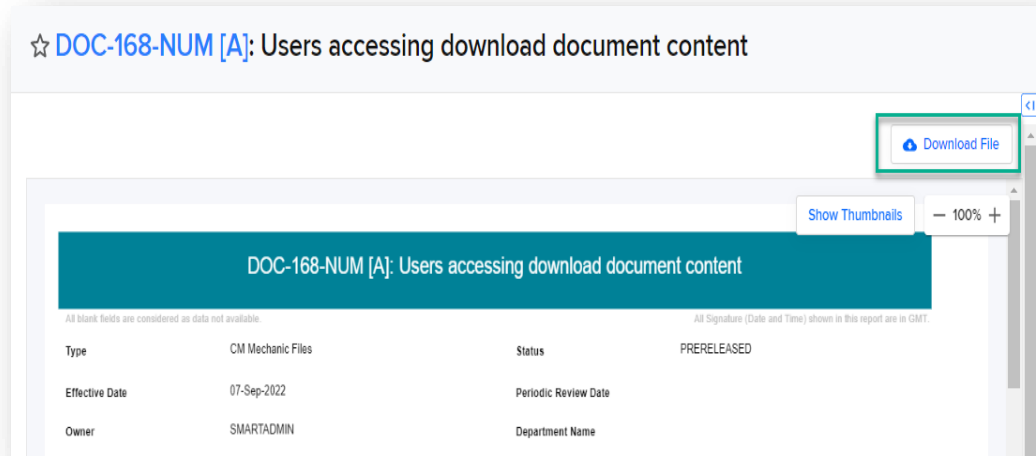
Allow Download = Yes is the default setting

Document Management

Disable Download

When Allow Download= No, then the option to download the document from the File Viewer is removed.

***This includes read & sign-off view**



For the Document team, the option to download the document will remain by using the hyperlinks to download the document while it is INWORKS state. The hyperlinks are found in the Prepare Document Profile task and Detail page. Also found in the Finalize Document task when Author task is not enabled.

NOTE: The download options found in document compare, packet downloader, and DEU utility are not included in the download restrictions and must be managed at the business level

The background features a light blue network of interconnected nodes and lines. Scattered throughout are various icons: a balance scale, a magnifying glass over a bar chart, a group of people, a gear with a clock face, a clipboard with a pie chart, a caduceus, a heart held by two hands, a cube with three smaller cubes on top, and a circular flow diagram with an arrow.

Archive Document Records

Document Management

Archiving Transactional Document Management Records

Archiving Document records provides the ability to remove the transactional record from the menus such as Find or Saved Search to reduce volume of records users shift through when searching and viewing data.

Archiving a record will prevent users from being able to view the record in SmartSolve, however the record is retained in the database and may be accessible based on user rights in an upcoming release. Archiving a record does not delete the record and the record will still be discoverable with the correct permissions (including content and attachments).

Once a record is archived, it will no longer appear in Save Searches, including dashboard views, Repositories, and Find menus. If a user types in the record number directly into the search it will appear, however once user clicks on the record link a blank record will display without any identifying information.

- ✓ Reports will not produce data or results on archived records
- ✓ References will display archived records, however when user clicks on the hyperlink to the record it will display a blank record without any identifying information.

Document Management

Archiving Transactional Document Management Records

A new Archive setup table is available in the Admin menu (see Platform SmartSolve 2022 R3 for additional Archive & Purge administrative setup details). Administrator must have the Role= Archive and Purge Administrator in order to view & manage the archive setting.

To access the archive parameters and manage the settings, navigate to the Admin menu> System Wide section= Archive and Purge.

Select Archive Policy to view and manage the solution archive parameters

The screenshot displays the IQVIA Admin console interface. The top navigation bar includes the IQVIA logo, a search bar, and user profile options. The left sidebar contains navigation icons for Dashboard, Create, Find, Favorites, Recent, Repository, and Calendar. The main content area is titled "Archive and Purge" and has an "Edit Mode" toggle. Below the title, there are tabs for "Notifications" and "Archive Policy". A "+ Add" button is located in the top right corner of the table area. The table has three columns: "Solution", "Product", and "Retention period in years". It contains three rows of data:

| Solution | Product | Retention period in years | |
|----------|---------|---------------------------|----|
| Document | | 10 | 🗑️ |
| Document | BIOT | 7 | 🗑️ |
| Document | COQVIA | 7 | 🗑️ |

At the bottom of the table, there is a "Rows" dropdown set to 5, a pagination indicator "Items 1-3 of 3", and a "Page 1 of 1" navigation. A footer note states: "Only records in Closed or Void or Expired state may be archived. Product selected refers to the primary product on the record. Archive policy with a blank product field means the retention period will apply to all products."

Document Management

Additional features available effective Document Management v6.1.10

- Deactivate Document Type
- Training History Report for Actors
- Bulk Upload of Documents
- Pharmaceutical Regulatory Documents
 - Versioning during the document build
 - Product attributes supporting eCTD metadata
 - Manageable PDF capabilities to help facilitate efficient submission reviews
 - Signature Page at the end of the Document

Thank you! Please contact us for more information



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