SOLABS QM10: Creating a Document

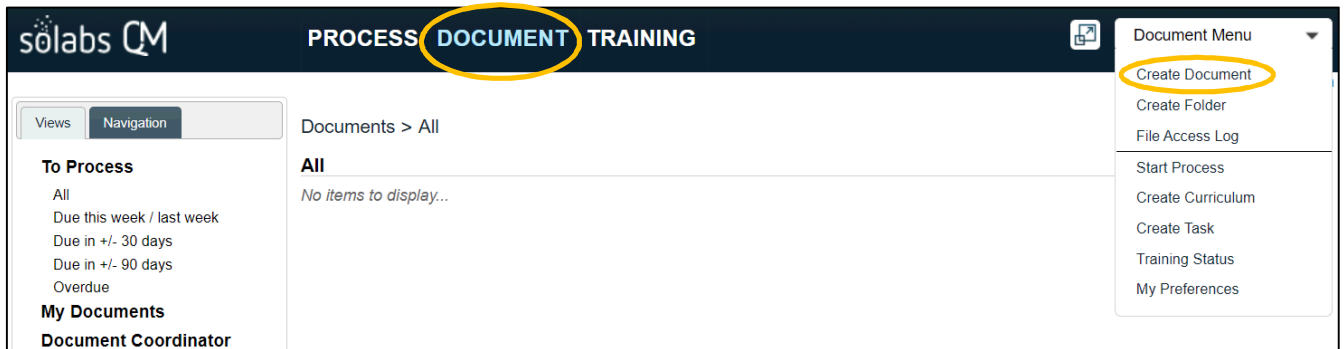## Introduction:

This document covers the process for creating a new document in SOLABS QM10. To create a document in **SOLABS QM10**, you will need at least **Modify** privileges on the folder where it will be located.

Creating a Document

After logging into **SOLABS QM10**, click on **DOCUMENT** and choose the **Create Document** option from the **Document Menu**.

Create Document, however, is such a commonly-used and universal function that it is also available from the **HOME** page Quick Access Menu.
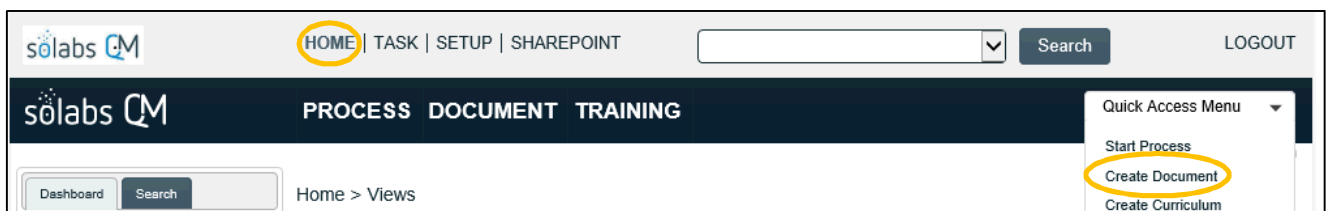
The **Document File Create** (**Document > Main Page > Create**) screen is then displayed, open to the **Authoring** tab.

Document Status Tabs – Visual Indication of Status

Document life cycle status tabs are visible at the top of a **Document** screen. The light grey tab indicates the status of the version you are currently viewing or working on. A dark grey tab indicates another status of the same document.

When you are creating a new document the **Authoring** tab is light grey and none of the other tabs are dark grey. If we were authoring a new revision to an existing document, the life cycle status tabs would look like the one above.

Document File section:

Use the **Drag & drop file here** section to drag and drop your new document file from your desktop. Many file types are allowed as documents in QM10 – Word, Excel, PowerPoint, etc.

If you prefer to Browse for the file you plan to upload, you can click on

The checkbox for **There is no file for this document** is new with Release 10.9. If you have a need to capture, approve and store metadata without having an actual file attached, check this box so that you will be able to Submit and Confirm the Authoring page without an error.
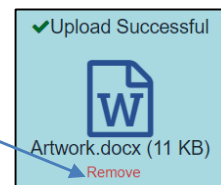
Uploading the Document

If you plan to upload a file, use the **Drag & drop file here** to import the file from your desktop or local network area or use the **OR SELECT FILE TO UPLOAD** option to browse and select it. Do <u>not</u> check the box for There is no file for this document. If you select that box, the whole section for document upload will be hidden.
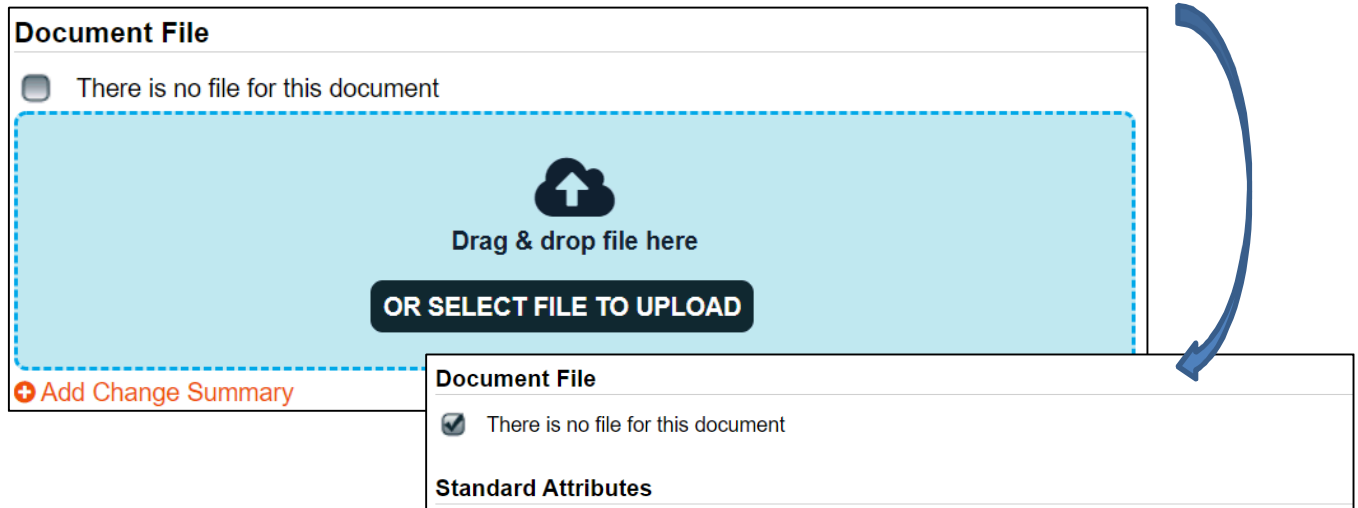
Clicking on the **Change Summary** option will allow you to browse for documents that you may want to attach as reference. For a new document that could be a summary of the purpose or evolution of the document.   If you were revising an existing document, it could be a marked-up copy of an earlier version. These will be visible to people opening the document to view or to train on it so keep that in mind. There is also a Reason for Change field that can be used to summarize the changes.

After uploading a document, the **Remove** option allows you to erase the field and the uploaded document, allowing you to re-upload another file.

Entering the Document Metadata

Standard Attributes

The following table provides information regarding the metadata fields associated with document **Standard Attributes** in **SOLABS QM10**. Mandatory fields are identified by asterisk. These fields will be displayed on the SOLABS Cover Pages if those are set to be used for the Document Type.

- There is an option to **Auto-populate fields from** an existing document that you know to be similar to your new one.   To use this, click **Open** and use the drop-down list to select a document.   It will include the last 10 documents processed. Use this option carefully so you don't include any incorrect information in your new document.   Use it BEFORE uploading your document since it will wipe out that selection and you'll have to upload it again.
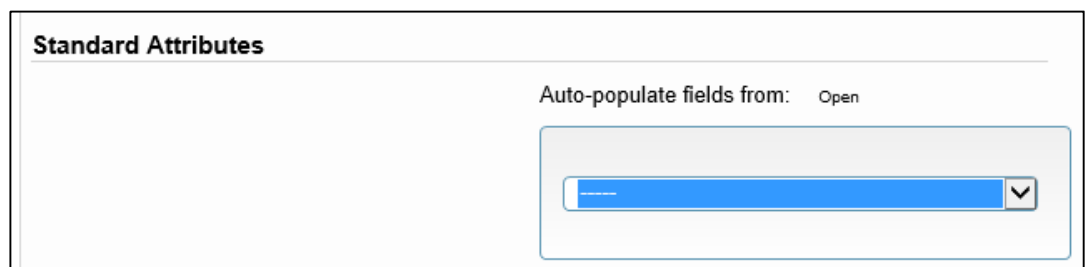
Field	Requirement	Notes
Document Type	Use this field to identify the **Document Type** of the document. The choice made here will impact some of the other fields and options on the page. If nothing is selected, it will default to "Basic Document" which is a default Document Type that comes with the software.	It is populated by a single-item selection list that will default to the **Document Types** created by your **Document Administrator.** Document Type: Basic Document Form Manufacturing Instructions Master Batch Records Packaging Instructions QA Form QC Form Specification Standard Operating Procedure Test Method
Name	Use this 256-character text field to enter the **Name** of the document.	You may already have naming conventions at your place of work that you use as part of the workplace compliance standards.
Description	Use this field to provide a general description of the document.	This field is not mandatory but can be helpful to provide context for those viewing the document.
Version	This field will default to 1.0 for a new document. If you are migrating documents from a legacy system, and want to maintain the historical revision numbers, you may decide to change this.	The **Unique ID, Internal Version** and **Current Version** fields are read-only and are maintained by the system.
Control Number	Use this field to enter the document **Control Number** of the document. It will only be available to you if the **Document Type** was set up to use unique numbering; otherwise, it will be greyed out and a number will be assigned automatically after Submitting this page.	You may already have document numbering conventions at your place of work that you use as part of the workplace compliance standards. During **SETUP** of each **Document Type**, your **Document Administrator** will have established whether the **Control Number** will be auto generated or unique and whether the previous number will be displayed for reference.

Effective Date	Radio buttons are available to select one of the **Effective Date** options available for this **Document Type.** If an Effective Date Delay is set for the Document Type, that radio button will be selected by default. If this new document was initiated using the Document Control Process, that radio button will be selected by default.	You may have **Effective Date** conventions for each **Document Type** at your place of work. During **SETUP** of each **Document Type**, your **Document Administrator** will have established the **Effective Date** options, such as the date of final approval or an Effective Date Delay (a set number of days after final approval - perhaps for a training period). There are also options to choose a specific date or to have it set through the **Document Control Process**.
Periodic Review Cycle	The **Periodic Review** is the time (in months) after which a document should undergo a Periodic Review. The **Planned Review Task Duration** (in months) is the time ahead of that life cycle at which the review activity should start. If you select one or both of these options, you also need to enter the number of months.	During **SETUP** of each **Document Type**, your **Document Administrator** will have established whether there will be a **Periodic Review Cycle.** If it is not required, this field can be set as "N/A". Starting with Release 10.9, email Notifications will be triggered at the start of the Planned Review Task Duration setting and will go to the users set as Author, Document Owner and Document Coordinator, if those fields are populated.
Location	The **Location** will default to that of the **Document Type** you chose at the top of the screen. It usually won't need to be changed but is editable.	To change the **Location**, click on "Available Folders" under the field. Search criteria will then be displayed to search for folders by **Treeview Level** and/or **Folder Name Contains.**
	TIP: If you highlight the related folder in the Document Treeview before clicking on **Create Document**, the document will be placed in that folder location, even if the Document Type has no default location or a different default location.	
Publishing Type	Radio buttons are available to select a **Publishing Type** for the document.	The options are **Publish in non-editable format (PDF)** or **Publish in editable format (original).** The default setting is **Publish in non-editable format.**
	NOTE: If importing PDF Fillable Forms, be sure to use the **Publish in editable format** option.	

Reason for Change	Include any information that would be helpful later to those reviewing the document.	This is an optional field but is useful, especially if you are not using the **SOLABS QM10 Document Control Process** to initiate the change. This field will be displayed on the Document Cover Page if those are set as part of the related PDF Rendering Template.
Cosmetic Change	This check box would not apply to a new document.	This can be used on future revisions if the changes are minor, and you don't want training to be retriggered. Refer to the Knowledge Base article titled **Use of the Cosmetic Change Option When Revising Documents.**

System Attributes

Additional **System Attribute** fields may have been created by your **Document Administrator** for each **Document Type**. Those will be unique to your workplace so are not included in the table above. They will be displayed in the **System Attributes** section of the Authoring page.

The possible field types are Numeric, Date, Text Field, Text Area, Single-Item Selection or Multiple-Item Selection.   Mandatory fields will be identified by asterisk. Text Fields and Text Areas can also be populated by Quick Text. Quick Text are lists of values created and maintained by your Document Administrator.

Document Ownership

Document Ownership	The **Document Ownership** fields – **Originator (Author), Document Owner** and **Document Coordinator** can be populated with appropriate Users/Roles. If you are the Author, choose yourself for that field.	These fields, and which of them are mandatory, are set for each **Document Type** during **SETUP** by your **Document Administrator**. If they are not set as required for the Document Type, they will be grayed out. If they are set as required but are not set as Mandatory, they can be left blank.

Due Dates on Workflow

Due Dates on Workflow	The **Use due dates on document workflow tasks** box should be checked if you plan to set due dates for review and/or approval cycles.	Check with your **Document Administrator** for questions on this option since it also requires setting time delays when establishing the Review and Approval Cycle workflows.

Click **Submit,** check your work, and then click **Confirm.** The document is now saved in **SOLABS QM10** and will be ready for the **Document Coordinator** to initiate **Review/Approval Cycles**.

Related Items

After you Submit and Confirm the Authoring page settings, a **Related Items** menu is available on the right-hand side that allows the linking of other documents or processes within SOLABS QM10 as a **Referred Document**, **Superseded Document** or **Reason for Change** (a Process). There are also menu options available to **Modify Description** of the related items or to **Remove Links** to the related items.

Related Items
Referred Document
Superseded Document
Reason for Change
Modify Description
Remove Links

Referred Document and Superseded Document

Use the **Referred Document** option to link a related document as a reference. This is helpful for situations such as forms that are related to an SOP or vice versa. Users will see the Referred Document in the Related Items section of the document you are creating. If the Referred Document were to be updated in QM10 at a later date, all active links to other documents will be updated as well.

Use the **Superseded Document** option when renumbering a document or when creating a new document that will combine the content of multiple existing documents. It eliminates the need to separately retire the previous document(s). When your new document becomes Effective, the document(s) you linked as Superseded Documents will automatically go to a "Superseded" status. They will be visible and accessible only to SOLABS Document Administrators using the Hidden Folders in the Document Treeview, similar to documents that are at a "Retired" status.

When choosing the **Referred Document** or the **Superseded Document** menu option, a **Filter by** option will be displayed to allow you to search for the document that you'd like to link. The document must exist in SOLABS QM10 and can be found by **Document Name and/or Control Number** or by **Location** in the Document Treeview.

Related Items

Filter by:

- ● Document Name and/or Control Number

  [   ]

- ○ Location

[Filter]

Available:
<empty>
Linked:
<empty>

After searching for and selecting the document, it will be linked as a **Related Document**. There will be an option to Discard the document if the wrong one was attached.

References:

Related Documents

Name: Audit Checklist **No.:** QA-0002 **Due:** <empty> **Status:** Approved & Effective   **Discard**

                                                                        Expand all   Discard all

After linking the document(s) that you would like as a Reference or that you would like Superseded by the document being created, click Submit and then Confirm. The document(s) will now be included in the Related Items section under either **References** or **Supersedes**.

Refer to the Knowledge Base article titled **SOLABS QM10: Using the Superseded Document Option** for a video tutorial on that topic.

Reason for Change

When choosing **Reason for Change** the **Filter by** options will allow you to search for the **Unique ID** of the process you would like to link.

After searching for and selecting the process, it will be linked as a **Reason for Change.** There will be an option to Discard the document if the wrong one was attached.

After attaching the process, click Submit and then Confirm. The process will now be included in the **Related Items** section as a **Reason for Change**.

Related Items
Reason for Change
Unique ID: CAPA-000035 **Date Initiated:** 10-Oct-2018 **Status:** Completed **Current Process Task:** *N/A*   View

For either linked documents or processes, the **Modify Description** option allows you to modify the description of the attached document or process.   All Related Items will be listed with a **Modify** option.

For either linked documents or processes, the **Remove Links** option allows you to modify the description of the attached document or process.   All Related Items will be listed with a **Remove** option.

Related Information

Related Information
Audit Trail
Authoring History

The right-hand **Related Information** menu options include **Audit Trail** and **Authoring History**.

The **Audit Trail** will be empty at this point because the document is brand new, but it will later include the history of the reviews, approvals, and effective date.

Document > Bulk Reception - Accountability > Audit Trail
No actions recorded

The **Authoring History** will include information on any incremental **Internal Versions** you may have created and saved before finally finishing and Submitting your work.

The **Audit Trail** and the **Authoring History** displays include an **Expand all/Collapse all** toggle option.   Clicking on **Expand all** will display all the metadata associated with each of the listed versions.

When multiple versions are listed, you can view the metadata for just one version by simply clicking on the listing.

There are also options to **Print all** and to **Print** individual document information.   Choosing these options opens a Print to PDF dialog box, allowing you to save the printout to an external location.

Document > Bulk Reception - Accountability > Authoring History

Bulk Reception - Accountability

Internal Version: 0.1   Print
Action Details: Document Created

Expand all   Print all   View

Checking Document Status

Document Treeview

From within the **DOCUMENT Section** click the **Navigation** tab on the left-hand menu and then choose **Show All**. The **Treeview** hierarchical document folder structure will be displayed. Go to the folder location for your document and you should see it listed with **[Authoring]** after it.

Highlight the listing and then either double-click the title or choose **Actions > View** to open the **Document File > View** screen. From there you can view the **Audit Trail** or **Authoring History** under **Related Information,** as described above. You can also make any additional changes that may be required before initiating the Review/Approval Cycles.

Document Section Views

After clicking on DOCUMENT from the main menu at the top of the screen, you will see various Views.

The **My Documents** menu options include an option for **I am the author or owner.** Use this option to check on the document status.

The **Document Coordinator** menu options are available to users with the **SOLABS Document Administrator** role assignment. The option for **In process – all** will display all documents in an active workflow – Authoring, Pending Review, Pending Approval or Pending Retire.

My Documents

Top 30 (last 90 days)
Read (last 30 days)
Effective (last 90 days)
I acted on (last 90 days)
I am the author or owner
I am the author or owner - by next review date

Document Coordinator

In process - my
In authoring - my
In review - my
In approval - my
To retire - my
In retire - my
Due for review - my
In process - all
To retire - all
In retire - all
Approved, not effective - all
Awaiting retire date - all
Superseded and retired - all
Due for review - all
Back from review
Rejected during approval