

# SOLABS QM 10: Creating a Document

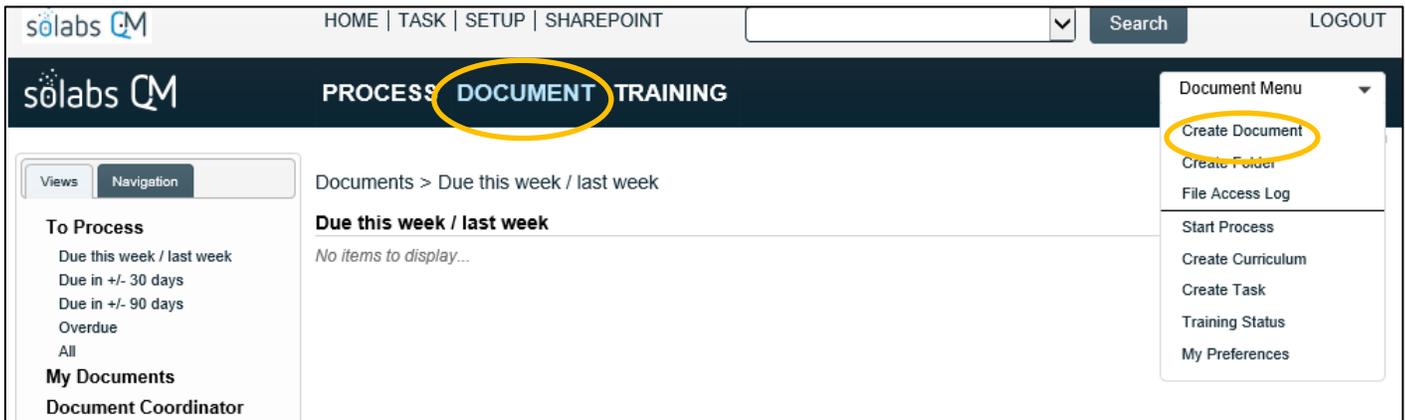
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## Introduction:

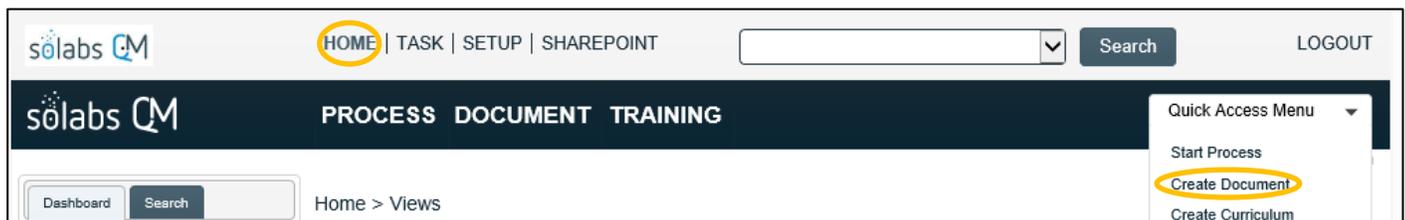
This document covers the process for creating a new document in SOLABS QM. To create a document in SOLABS QM, you will need at least **Modify** privileges.

## Creating a Document

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



**Create Document**, however, is such a commonly-used and universal function that it is also available from the **HOME** page.



The **Document File Create (Document > Main Page > Create)** screen is then displayed.

**NOTE:** The Drag & Drop section is new with SOLABS QM 10.5. Earlier versions will instead have only an option to Browse for the file.

If you prefer to Browse for the file you plan to upload, you can click on **OR SELECT FILE TO UPLOAD**

### 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.

The above example is for a new document. Therefore, 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 instead look like this:

## Uploading the Document

If you are using **SOLABS QM** version 10.5 or higher, you can either **Drag & drop** the file from your desktop or local network area or use the **OR SELECT FILE TO UPLOAD** option to browse and select it.

If you are using an earlier version of **SOLABS QM 10**, you will see a **Choose File** option to browse and select it.

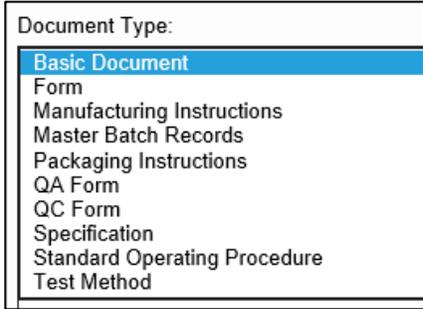
Clicking on the **Change Summary** option will allow you to browse for documents that you may want to attach as reference. For a new document that could be a summary of the purpose or evolution of the document. If you were revising an existing document, it could be a marked-up copy of an earlier version.

The **Clear** option allows you to erase the field and the uploaded document, allowing you to re-upload another file.

## Entering the Document Metadata

The following table provides information regarding the metadata fields associated with document **Standard Attributes** in **SOLABS QM**.

- Required fields will be identified with asterisks.
- Additional fields may have been created by your **System Administrator** for each **Document Type**. Those will be unique to your workplace so are not included in the table below.
- There is an option to **Auto-populate fields** with those 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. 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
<b>Document Type</b>	Use this field to identify the <b>Document Type</b> of the document. The choice made here will impact some of the other fields and options on the page.	<p>It is populated by a drop-down list that will default to the <b>Document Types</b> created by your <b>System Administrator</b> or <b>Document Administrator</b>.</p> 
<b>Name</b>	Use this field to enter the <b>Name</b> of the document.	You may already have naming conventions at your place of work that you obey as part of the workplace compliance standards.
<b>Description</b>	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.
<b>Version</b>	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 <b>Unique ID</b> , <b>Internal Version</b> and <b>Current Version</b> fields are read-only and are maintained by the system.
<b>Control Number</b>	Use this field to enter the document <b>Control Number</b> of the document. It will only be available to you if the <b>Document Type</b> was set up to use unique numbering; otherwise it will be greyed out.	You may already have document numbering conventions at your place of work that you obey as part of the workplace compliance standards. During <b>SETUP</b> of each <b>Document Type</b> , your <b>System Administrator</b> or <b>Document Administrator</b> will have established whether the <b>Control Number</b> will be auto-generated or not, unique or not and whether the previous number will be displayed for reference.

<p><b>Effective Date</b></p>	<p>Radio buttons are available to select one of the <b>Effective Date</b> options available for this <b>Document Type</b>.</p>	<p>You may have <b>Effective Date</b> conventions for each <b>Document Type</b> at your place of work. During <b>SETUP</b> of each <b>Document Type</b>, your <b>System Administrator</b> or <b>Document Administrator</b> will have established the <b>Effective Date</b> options, such as the date of final approval, a set number of days after final approval (perhaps for a training period), the option for a specific date to be chosen or the option to have it set through the <b>Document Control Process</b>.</p>
<p><b>Periodic Review Cycle</b> (called <b>Document Life Cycle</b> in versions earlier than 10.8).</p>	<p>The <b>Periodic Review</b> is the time (in months) after which a document should undergo a Periodic Review. The <b>Planned Review Task Duration</b> (in months) is the time ahead of life cycle at which that activity will start. If you select one or both of these options, you also need to enter the number of months.</p>	<p>During <b>SETUP</b> of each <b>Document Type</b>, your <b>System Administrator</b> or <b>Document Administrator</b> will have established whether there will be a <b>Periodic Review Cycle</b>. If it is not required, this field can be set as "N/A".</p>
<p><b>Location</b></p>	<p>The <b>Location</b> will default to that of the <b>Document Type</b> you chose at the top of the screen. It usually won't need to be changed but is editable.</p>	<p>To change the <b>Location</b>, click on "Available Folders" under the field. Search criteria will then be displayed to search for folders by <b>Treeview Level</b>.</p>
<p><b>Publishing Type</b></p>	<p>Radio buttons are available to select a <b>Publishing Type</b> for the document.</p>	<p>The options are <b>Publish in non-editable format (PDF)</b> or <b>Publish in editable format (original)</b>.</p>
<p><b>Reason for Change</b></p>	<p>Include any information that would be helpful later to those reviewing the document.</p>	<p>This is an optional field but is useful, especially if you are not using the <b>SOLABS QM Document Control Process</b> to more formally include change control information.</p>
<p><b>Document Ownership</b></p>	<p>The <b>Document Ownership</b> fields – <b>Originator (Author)</b>, <b>Document Owner</b> and <b>Document Coordinator</b> can be populated with appropriate Users/Roles. If you are the Author, choose yourself for that field.</p>	<p>These fields, and which of them are mandatory, are set up for each <b>Document Type</b> during <b>SETUP</b> by your <b>System Administrator</b> or <b>Document Administrator</b>.</p>

<p><b>Due Dates on Workflow</b></p>	<p>The <b>Due Dates on Workflow</b> should be checked if you plan to set due dates for review and/or approval cycles.</p>	<p>Check with your <b>Document Administrator</b> for questions on this option since it also requires setting time delays when establishing the Review and Approval Cycle workflows.</p>
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As previously mentioned, there may be additional **Standard Attribute** and **System Attribute** fields that you need to enter information for if they have been established for this **Document Type** by your **System Administrator** or **Document Administrator**.

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

## Attaching Related Items

While authoring a document, a Related Items section is available on the right-hand side that allows the linking of other documents within SOLABS QM 10 as a **Referred Document**, **Superseded Document** or **Reason for Change** (a Process). There are also menu options available to **Modify Description** of the related documents or to **Remove Links** to the related documents. The Modify Description and Remove Links options will also apply to other Related Items such as a related Document Control Process.

**Related Items**

- Referred Document
- Superseded Document
- Reason for Change
- Modify Description
- Remove Links

When choosing Referred Document or Superseded **Filter by** options will be displayed to allow you to search for the document that you'd like to link. The document must exist in SOLABS QM 10 and can be found by **Document Name and/or Control Number** or by **Location** in the Document Treeview.

**Related Items**

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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			
<b>Name:</b> Audit Checklist	<b>No.:</b> QA-0002	<b>Due:</b> <empty>	<b>Status:</b> Approved & Effective <span style="float: right;"><a href="#">Discard</a></span>
			<a href="#">Expand all</a> <a href="#">Discard all</a>

After attaching the document, click Submit and then Confirm. The document will now be included in the Related Items section as either a **References** or **Supersedes**.

References			
<b>Name:</b> Audit Checklist	<b>No.:</b> QA-0002	<b>Due:</b> <empty>	<b>Status:</b> Approved & Effective <span style="float: right;"><a href="#">Open</a>   <a href="#">View</a></span>
			<a href="#">Expand all</a>
Supersedes			
<b>Name:</b> Audit of Clinical Sites	<b>No.:</b> COP-004	<b>Due:</b> <empty>	<b>Status:</b> Approved & Effective <span style="float: right;"><a href="#">Open</a>   <a href="#">View</a></span>
			<a href="#">Expand all</a>

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.

Related Items	
Filter by:	<input checked="" type="radio"/> Unique ID
<input type="text"/>	
<input type="button" value="Filter"/>	
Available:	<empty>
Linked:	<empty>

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.

Reason for Change	
<b>Unique ID:</b> CAPA-000035 <b>Date Initiated:</b> 10-Oct-2018 <b>Status:</b> Completed <b>Current Process Task:</b> N/A	<a href="#">Discard</a>
<a href="#">Expand all</a> <a href="#">Discard all</a>	

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	
<b>Unique ID:</b> CAPA-000035 <b>Date Initiated:</b> 10-Oct-2018 <b>Status:</b> Completed <b>Current Process Task:</b> N/A	<a href="#">View</a>

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.

## Verifying your Document Status & Viewing the Audit Trail or Authoring History

Related Information
<a href="#">Audit Trail</a>
<a href="#">Authoring History</a>

After the **Document** is saved, click the **Related Information > Audit Trail** link on the right-hand side of the page. It will be empty at this point because the document is a brand new but will later capture the history of the reviews, approvals and effective date.

Document > Bulk Reception - Accountability > Audit Trail <i>No actions recorded</i>
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Click the **Related Information > Authoring History** link to see information on any incremental **Internal Versions** you may have created/saved before finally finishing and Submitting your work.

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.

Document > Folders > View

**Treeview**

- Root
  - Form
    - Engineering
    - Manufacturing
    - Packaging
      - PKG-FORM-001 / 1.0 (0.1) / Bulk Reception - Accountability - [Authoring]

**Actions**

View

**Privileges**

View

Highlight your version 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.

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**

Document &gt; Bulk Reception - Accountability &gt; Authoring History

**Bulk Reception - Accountability****Internal Version:** 0.1[Print](#)**Action Details:** Document Created**Document File****File:** <empty>**Change Summary:** <empty>**Standard Attributes****Document Type:** Form**Name:** Bulk Reception - Accountability**Description:** Packaging Form**Unique ID:** 1b637c8d-551b-48f9-a155-552c86307755**Internal Version:** 0.1**Version:** 1.0**Control Number:** PKG-FORM-001**Effective Date:** 100 days after final approval**Next Review Date:** <empty>**Document Life Cycle:** Life Cycle (in months) : 24 Planned Review Task Duration (in months) : 3**Location:** /Root/Form/Packaging**Publishing Type:** Publish in editable format (original)**Reason for Change:** <empty> Cosmetic Change**System Attributes****Department:** Packaging**Sub-Department:** Tablets**Document Ownership****Originator (Author):** dbarber (Delbert Barber)**Document Owner:** FCT\_Packaging Supervisor**Document Coordinator:** FCT\_Documentation Coordinator**Due Dates on Workflow** Use due dates set on document workflow tasks[Collapse all](#)[Print all](#)[View](#)