

SOLABS QM10: Introduction to the DOCUMENT Section

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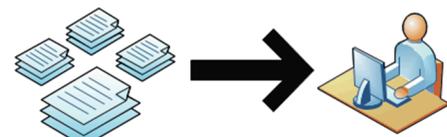
Introduction

This guide is intended for those Users who will be creating, revising, reviewing or approving documents in **SOLABS QM10**. It also describes some of the maintenance typically done by SOLABS System Administrators or SOLABS Document Administrators, such as creating Folders and setting Privileges for documents and folders. A separate document titled **SOLABS QM10: Guide to the DOCUMENT Section for General Users** covers some of this same information but is intended for Users who will not be participating in the above activities. Another separate document titled **SOLABS QM10: Guide for SOLABS Document Administrators** goes into additional detail for those who have the SOLABS Document Administrator role assignment.

The DOCUMENT Section

A Document in SOLABS QM10 is comprised of the software file itself (such as a Microsoft Word file) and the related Metadata:

- Standard Attributes
- System Attributes
- Document Ownership
- Document Workflows
- Related Items



You can think of the **DOCUMENT section** in **SOLABS** as a giant library: Documents are catalogued, checked in, etc., and live in a controlled environment, recorded in great detail in the **Audit Trail**

A primary Role in **SOLABS QM** is the **Document Coordinator**, which may be one or more people. In the field of compliance/regulatory and in the life sciences, controlled documents are central

The **Document File** section includes the files that are visible and accessible from the **Document > View** page. Starting with Release 10.9, if there is intentionally no file being included, this section will be hidden.

The first file is the document being created or revised.

- During **Authoring** and **Review Cycle** stages, it will be an editable file.
- During **Approval Cycle** and when it becomes **Approved & Effective**, it will usually be rendered to a PDF.

A second file associated with a document revision is a **Change Summary** that helps highlight revisions being made to an existing Document.

Document File



Approved Supplier List.docx(18 KB)

Open

Get Unmarked PDF

Get Editable File Format

Change Summary:



Compare-2.7-2.0_04a7ae0c-a80f-4877-aa27-b2bd077e6540.pdf (39 KB)

Open

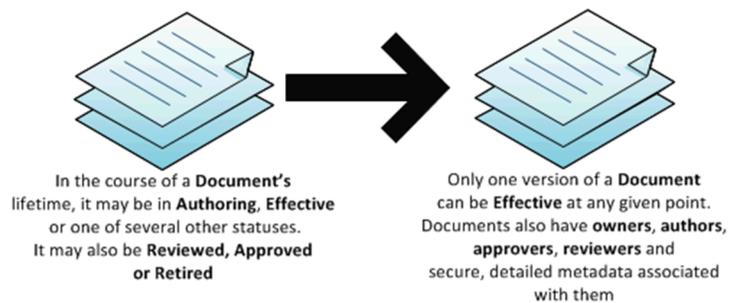
| <p>The Standard Attributes section includes the information such as Document Type, Name, Version, Control Number, Effective Date, Location, etc. Default values can be established by creating a Document Type as part of SETUP > Administration but can be edited at the individual Document level.</p> | <p>Standard Attributes</p> <hr/> <p>Document Type: Form</p> <p>Name: Approved Supplier List</p> <p>Description: <empty></p> <p>Unique ID: 04a7ae0c-a80f-4877-aa27-b2bd077e6540 Internal Version: 3.0</p> <p>Version: 3.0</p> <p>Control Number: QA-0001</p> <p>Effective Date: 27-Aug-2020 UTC-04:00 Next Review Date: N/A</p> <p>Periodic Review Cycle:</p> <p><input type="checkbox"/> Periodic Review (in months): N/A</p> <p><input type="checkbox"/> Initiate Notifications ahead of Review Date (months) : N/A</p> <p>Location: /Root/Form/QA</p> <p>Publishing Type: Publish in non-editable format (PDF)</p> <p>Reason for Change: Add new suppliers</p> <p><input type="checkbox"/> Cosmetic Change</p> | | | | | | | | | | | | | | | |
|---|---|----------|-----------------------------|----------------------|-----------------|-----------------|----------|---|-----|-----------------------------|---------------------|----------|---|-----|----------------------|----------------------|
| <p>The System Attributes section includes additional information that is unique to the Document Type such as Applicable Department for an SOP, Product Dosage/Strength for a Batch Record, etc. Default values can be established by creating a Document Type as part of SETUP > Administration but can be edited at the Document level.</p> | <p>System Attributes</p> <hr/> <p>Additional Information: <empty></p> <p>Approved Supplier: Yes</p> <p>Supplier Name: Company A</p> | | | | | | | | | | | | | | | |
| <p>The Document Ownership section includes the Author, Document Owner and Document Coordinator for the document, if set as required for the particular Document Type.</p> | <p>Document Ownership</p> <hr/> <p>Originator (Author): bgreen (Bonnie Green)</p> <p>Document Owner: FCT_Manager Quality Control</p> <p>Document Coordinator: FCT_Documentation Coordinator</p> | | | | | | | | | | | | | | | |
| <p>The Document Workflows section includes information on the Review and Approval Cycles of the document. If the workflows are in progress, they will be listed as Pending Review or Pending Approval Cycle.</p> | <p>Approval Cycle</p> <table border="1"> <thead> <tr> <th>Status</th> <th>Order</th> <th>Due Date</th> <th>Approver (Role)</th> <th>Approver (User)</th> </tr> </thead> <tbody> <tr> <td>Approved</td> <td>1</td> <td>N/A</td> <td>FCT_Manager Quality Control</td> <td>TG (Theresa Garcia)</td> </tr> <tr> <td>Approved</td> <td>1</td> <td>N/A</td> <td>FCT_Director Quality</td> <td>DR (Delores Rennold)</td> </tr> </tbody> </table> | Status | Order | Due Date | Approver (Role) | Approver (User) | Approved | 1 | N/A | FCT_Manager Quality Control | TG (Theresa Garcia) | Approved | 1 | N/A | FCT_Director Quality | DR (Delores Rennold) |
| Status | Order | Due Date | Approver (Role) | Approver (User) | | | | | | | | | | | | |
| Approved | 1 | N/A | FCT_Manager Quality Control | TG (Theresa Garcia) | | | | | | | | | | | | |
| Approved | 1 | N/A | FCT_Director Quality | DR (Delores Rennold) | | | | | | | | | | | | |

| | |
|--|---|
| <p>The Related Items section includes other existing SOLABS QM10 documents, Training Activities or Processes that are associated with or linked as reference information to the document.</p> | <p>Related Items</p> <hr/> <p>References</p> <p>Name: Validation Program No.: VAL-001 Due: <empty> Status: Approved & Effective Open View</p> <p style="text-align: right;">Expand all</p> <hr/> <p>Training Activities for this Document</p> <p>Name: SOP ENG-001, Equipment Calibra[...] Due: Completion: 100.0 % Status: Active View</p> <p style="text-align: right;">Expand all</p> |
|--|---|

Document Life Cycle Stages – Status

Documents go through a life cycle, from creation, possibly through multiple revisions and finally retirement. As documents move through the life cycle, they have different statuses at different times.

- Authoring
- Pending Review
- Pending Approval
- Approved, Not Effective
- Approved & Effective
- Pending Retire
- Retired



One way you can tell the status of a document is to check the **Status** metadata displayed with Document Views and Search results. For example, the View for **Document > In process – all** brings up documents in various stages of their life cycle, and therefore various statuses.

| Documents > In process - all | | | | |
|--|--------------------------|---------------------|---------------------------------|--|
| In process - all | | | | |
| Name: Equipment Calibration Program | No.: ENG-001 | Due: <empty> | Status: Pending Approval | |
| Name: Device Manufacture - 2017 | No.: IA000001 | Due: <empty> | Status: Pending Approval | |
| Name: In-Process Controls for Check [...] | No.: MFG-002 | Due: <empty> | Status: Authoring | |
| Name: FDA Annual Report 2017 - 5% De[...] | No.: FDA-AR000002 | Due: <empty> | Status: Authoring | |
| Name: Clinical Protocols and Checkli[...] | No.: COP-001 | Due: <empty> | Status: Pending Review | |

The SOLABS System Administrator or SOLABS Document Administrator can set permissions on document folders to control user access at all stages of the life cycle. For example, Train ID Users – those using SOLABS QM10 just to complete Training Activities – will have the **Read Only** privilege and will be limited to viewing documents that are at the **Approved & Effective** status or the **Approved, Not Effective** status for documents assigned to them for training. Users with **Review/Approve** privileges can see all in-process documents and act on document Review and Approval tasks. Users with **Modify** privileges can create and revise documents so will be able to see documents that are in the **Authoring** status. These privileges can be granted for just certain folders or for all folders, depending on the needs of the organization and can be set by Function Role or Security Role.

Clicking on the **View** option to the right of a document listing will display the **Document > View** page for that document.

Document Status Tabs – Visual Indication of Status

At the top of the **Document > View** page there is a row of status tabs. The highlighted lighter gray tab indicates the current status of the document. A document can have more than one active version if it is an existing document that is being revised. In that case the other status will be highlighted in a darker gray.



Document Status Meanings

| | |
|---|--|
| Authoring | This Document is being actively created or revised. It is editable only by Author/Owner or the assigned Document Coordinator . |
| Pending Review | This Document is currently in a Review Cycle and is Awaiting Review from the assigned Reviewers . |
| Pending Approval | This Document is currently in an Approval Cycle and is Awaiting Approval from the assigned Approvers . |
| Pending Retire | This Document is currently in a Retire Cycle and is Awaiting Retire status from the assigned Approvers of the retirement. |
| Approved, Not Effective | This Document has completed the Approval Cycle but has not yet been made Effective . NOTE: Documents at this status may become Effective when a related event triggers that status change. For example, if there is a Training Activity associated with the document, the Document Type may allow an Effective Date Delay for a training period. When the established training period is complete, the document will become Effective. It may also be awaiting a pre-determined Effective Date that was set using a Document Control Process . |
| Approved & Effective | This Document has completed the Approval Cycle and has also been made Effective . Depending on the Document settings, that can happen immediately upon the last Approval, after an Effective Date delay or at a pre-set date. |
| Retired | This document has been Retired from further use. The content can be retrieved by SOLABS Document Administrators via the Audit Trail, in case it ever needs to be referred to, or used in another document. |
| <ul style="list-style-type: none"> • The Review Cycle is optional and the Approval Cycle (with at least one approver) is mandatory. • If a multiple Reviewers are reviewing a document in parallel and one of them has comments, the document will go back to the Authoring status after all Reviewers have completed their review. • If one of multiple Approvers chooses to Reject the document, it will go back to the Authoring status immediately and be removed from pending tasks for any other approvers. | |

Views Tab in the Left Side Menu of the DOCUMENT Home Page

These **Views** are a handy way to keep track of documents that you are involved with in different ways. You may also track your work obligations and prioritize your work on documents using these Views.

| | | |
|--|---|--|
| To Process | | <div style="border: 1px solid #ccc; padding: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid #ccc;"> Views Navigation </div> <p>To Process</p> <ul style="list-style-type: none"> All Due this week / last week Due in +/- 30 days Due in +/- 90 days Overdue <p>My Documents</p> <ul style="list-style-type: none"> 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 <p>Document Coordinator</p> <ul style="list-style-type: none"> 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 </div> |
| All: All documents currently requiring action on the part of the User. This is the default view starting with Release 10.9. | | |
| Due this week/last week: Documents due to act on this week or in the previous week. This is the default view in Releases 10.8 and earlier. | | |
| Due in +/-30 days: Documents due to act on in the next 30 days or in the previous 30 days. | | |
| Due in +/-90 days: Documents due to act on in the next 90 days or the previous 90 days. | | |
| Overdue: Documents tasks that are overdue on the part of the User. | | |
| My Documents | | |
| Top 30 (last 90 days): The 30 documents accessed most frequently by this User in the last 90 days. | | |
| Read (last 30 days): All documents this User has read in the last 30 days. | | |
| Effective (last 90 days): Documents made Effective in the last 90 days. | | |
| I acted on (last 90 days): Documents this User has acted on in the last 90 days. | | |
| I am the author or owner: Documents for which this User is the author or owner. | | |
| I am the author or owner - by next review date: Documents for which this User is the author or owner, displayed in order by the date of their next Periodic Review. | | |
| Document Coordinator | | |
| In process – my: | Views available for the Document Coordinator to quickly access their own documents at various statuses. | |
| In authoring - my | | |
| In review - my | | |
| In approval - my | | |
| To retire – my | | |
| In retire - my | | |
| Due for review – my (Periodic Review) | | |
| In process - all | | Views available for the Document Coordinator to quickly access all documents at various statuses. |
| To retire - all | | |
| In retire - all | | |
| Approved, not effective - all | | |
| Awaiting retire date - all | | |
| Superseded and retired - all | | |
| Due for review – all (Periodic Review) | | |

| | |
|--|--|
| Back from review: Documents that are back at Authoring because one or more Reviewers had comments. | |
| Rejected during approval: Documents that are back at Authoring because one or more Approvers rejected the document. | |

Document Listing Tables

- Results from a Document View or Search selections bring up a **Document Listing Table**.
- Each Listing can be expanded to see more detail by clicking on the listing itself.
- The entire list can be **Expanded** and **Collapsed** using the option in the lower right corner.
- To the right of each listing is an **Open** link (which will open the document) and a **View** link (which will display the Document > View screen with document metadata information).

Documents > I am the author or owner

| I am the author or owner | | | | |
|--|------------------------|---------------------|-------------------------------------|---|
| Name: Supplier Management | No.: QAC-003 | Due: <empty> | Status: Pending Review | Edit View |
| Name: Supplier Management Document Type: Standard Operating Procedure Control Number: QAC-003 Effective Date: <empty> Document Coordinator: FCT_Documentation Coordinator Originator (Author): kallen (Kelly Allen) Document Owner: FCT_Manager QA Compliance | | | | |
| Name: Receiving | No.: MFG-SC-002 | Due: <empty> | Status: Approved & Effective | Open View |
| Name: Production Planning Process - [...] | No.: MFG-SC-001 | Due: <empty> | Status: Approved & Effective | Open View |
| Name: Production Planning Process - [...] | No.: MFG-SC-003 | Due: <empty> | Status: Approved & Effective | Open View |
| | | | | Expand all 1 |

Searching for/Locating a Document

When Users are required to take action on a document (such as Review or Approval) they will receive an **Email Notification** that includes a link to the document. If the user needs to simply view a document, there are several ways to search for it, in addition to all of the View options described on pages 5 and 6.

Method 1: The HOME or 'To Do' Screen

- If the document requires action by the User, or by someone in the User's Function Role, the document will be listed on the User's **HOME** "To Do" Page in the **DOCUMENTS** section.
- In the example below, a document is **Pending Review**, and the **Review** option is available to the user, to the right of the document listing.

| DOCUMENTS | | | | |
|--|---------------------|---------------------|-------------------------------|--|
| All | | | | |
| Name: Clinical Protocols and Checkli[...] | No.: COP-001 | Due: <empty> | Status: Pending Review | Edit View Review |
| | | | | Expand all 1 |

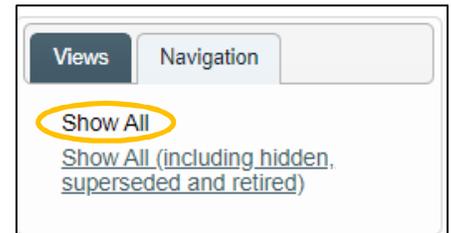
Method 2: Navigation > Show All > Treeview

- From the top navigation bar displaying **PROCESS | DOCUMENT | TRAINING**, select **DOCUMENT**.

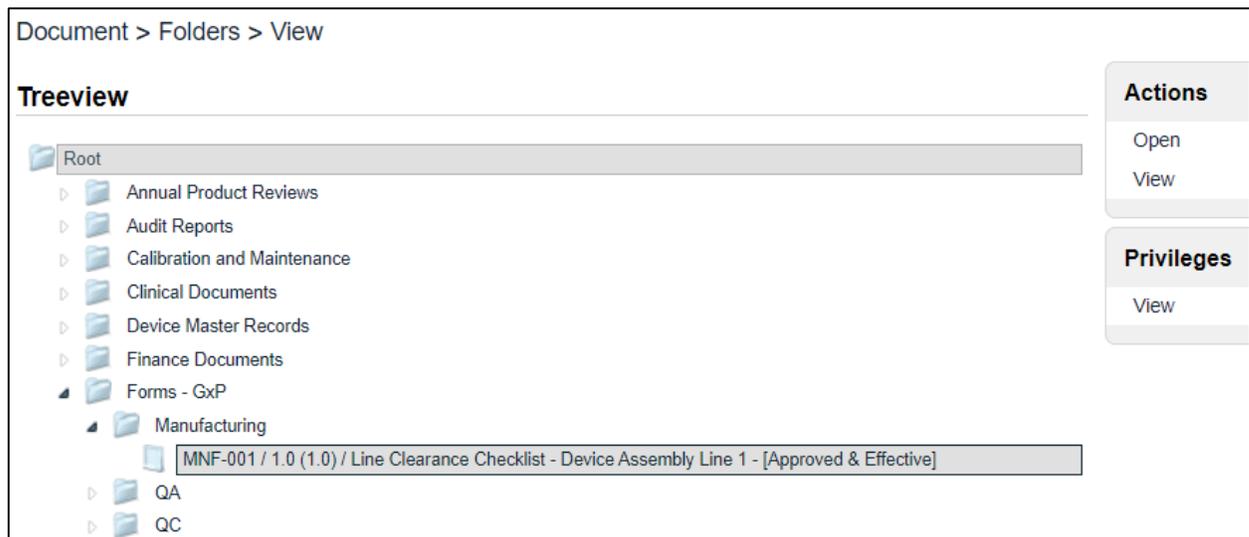


- From the Left Side Menu, click the **Navigation** tab and then choose **Show All**.

The option **Show All (including hidden, superseded and retired)** is available only to SOLABS Document Administrators since they have the appropriate privileges, to also see Hidden documents and folders such as those used to store Related Documents for Training Activities or Processes and documents that are superseded or retired.

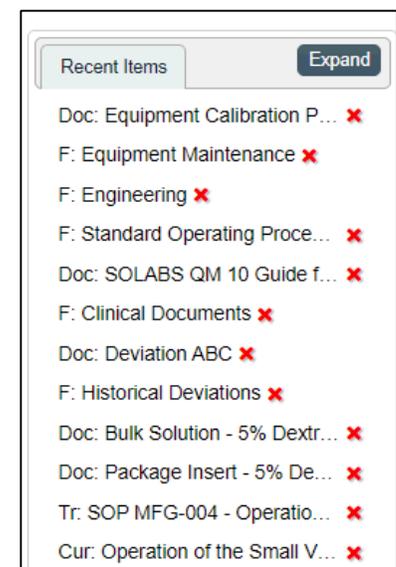


Navigate through the folders as required to locate the document you need to view. The document is shown in the hierarchical **Treeview**. To open the document/file, select it in the **Treeview** and then click **Open** (to open the document) or **View** (to view document metadata) from the right-hand **Actions** menu.



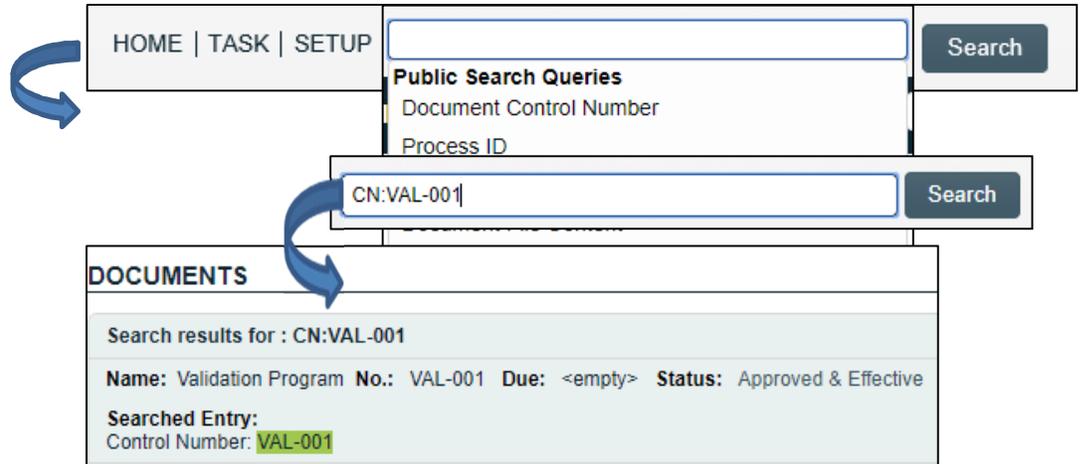
Method 3: Left Hand Menu Views

The **Views** described on pages 5 and 6 are a handy way to keep track of documents that you are involved with in different ways. You may also track your work obligations and prioritize your work on documents using these Views. The **Recent Items** list provides another way to view things you have worked on recently. If you see a document on that list, just click on the listing to open it again. It will then be at the top of the list afterwards.



Method 4: Targeted Searching

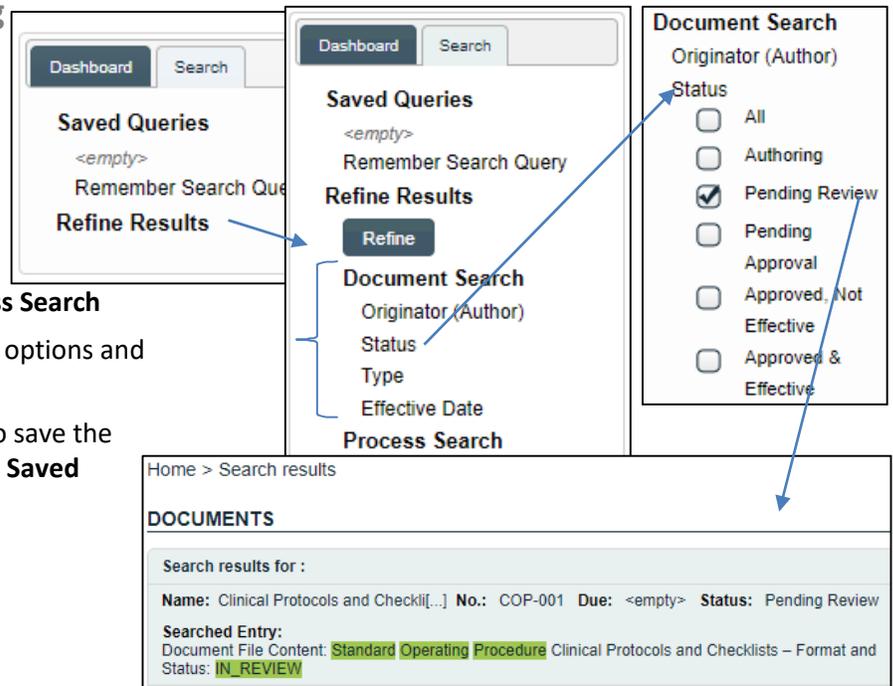
The Search field at the top of the screen can be used for targeted Searches for Documents or Processes. Additional, more advanced Search capability is also available if needed, and is described in a separate Knowledge Base document titled **SOLABS QM10: Enhanced Search Features**.



Method 5: Refined Searching

The Refine Results Search is also available and is helpful for searches that are done frequently, especially since these Refined Searches can be Saved.

- Click on **Refine Results**
- Choose **Document Search** or **Process Search**
- Make a selection from the available options and click the **Refine** button.
- Use the **Remember Search Query** to save the search. It will then be added under **Saved Queries**.

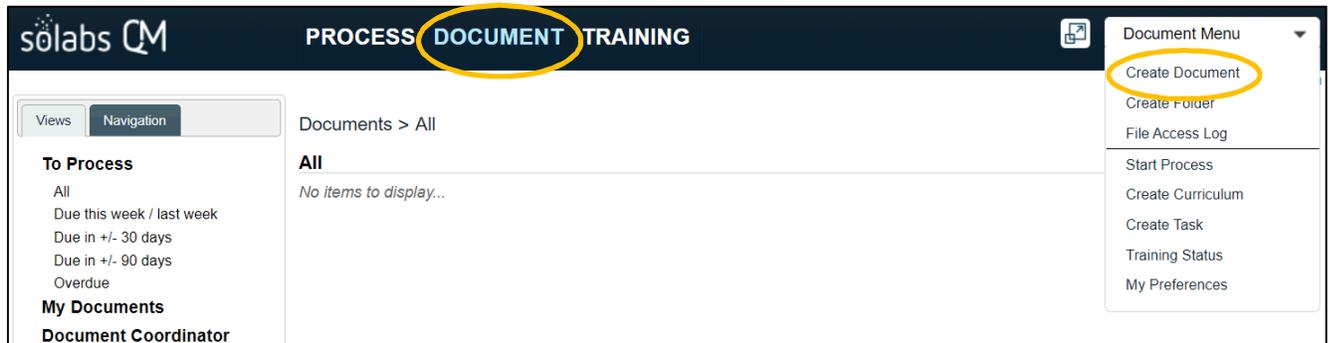


Viewing a Document

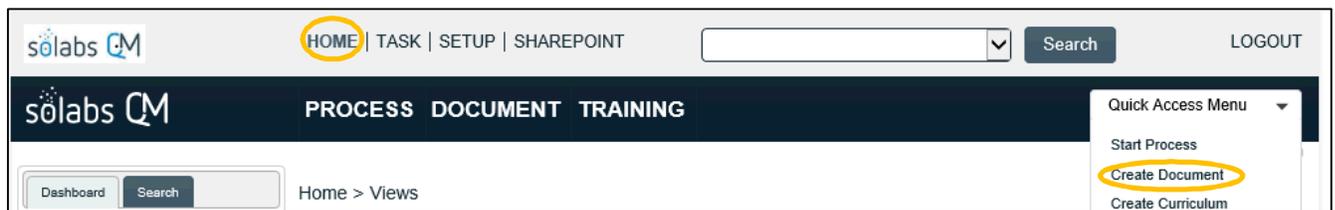
After using any of the above methods to locate a document it will be listed in a Document Listing Table, as described on Page 6 -7 of this document.

Creating a Document

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



Create Document 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, open to the **Authoring** tab.

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 **OR SELECT FILE TO UPLOAD**

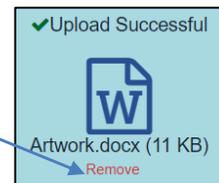
The checkbox **There is no file for this document** is new with Release 10.9. If you have a need to capture, approve and store metadata without having an actual file attached, check this box so that you will be able to Submit and Confirm the Authoring page without an error.

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 not 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 | <p>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.</p> <p>If nothing is selected, it will default to “Basic Document” which is a default Document Type that comes with the software.</p> | <p>It is populated by a single-item selection list that will default to the Document Types created by your Document Administrator.</p> <div data-bbox="812 352 1209 640" style="border: 1px solid black; padding: 5px;"> <p>Document Type:</p> <ul style="list-style-type: none"> <li style="background-color: #e0f0ff; margin-bottom: 2px;">Basic Document Form Manufacturing Instructions Master Batch Records Packaging Instructions QA Form QC Form Specification Standard Operating Procedure Test Method </div> |
| 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 | <p>Radio buttons are available to select one of the Effective Date options available for this Document Type.</p> <p>If an Effective Date Delay is set for the Document Type, that radio button will be selected by default.</p> <p>If this new document was initiated using the Document Control Process, that radio button will be selected by default.</p> | 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**.

Attaching 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 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 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 a **Superseded Document**, the **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 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 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**Name:** Audit Checklist **No.:** QA-0002 **Due:** <empty> **Status:** Approved & Effective **Open | View**

Expand all

Supersedes**Name:** Audit of Clinical Sites **No.:** COP-004 **Due:** <empty> **Status:** Approved & Effective **Open | View**

Expand all

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

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:

Unique ID

[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

Unique ID: CAPA-000035 **Date Initiated:** 10-Oct-2018 **Status:** Completed [Discard](#)

Current Process Task: N/A

[Expand all](#) [Discard all](#)

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 [View](#)

Current Process Task: N/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.

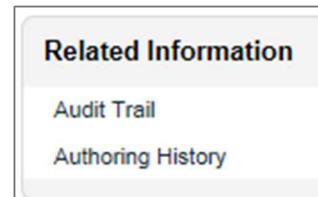
For either linked documents or processes, the **Remove Links** option allows you to modify the description of the attached document or process. All Related Items will be listed with a **Remove** option.

After uploading the document, completing all of the metadata fields and adding any Related Items, click the **Submit** button, verify the information, and then click the **Confirm** button.

The document is now ready to assign a review and/or approval **Workflow** and start the **Review Cycle** or the **Approval Cycle**.

Related Information

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.



Modifying a Document

A User with at least **Modify privileges** on a document can make a revision to that document through the Modify option.

Search for the document to be modified, using the Document Treeview, left hand Views, targeted Searching or Refined Searching, as described earlier in this document.

Once you have located your document, double-click the listing or click on the **View** option to open the **Document > View** screen. The document must be in **Approved & Effective** status in order for you to initiate another version.

Pending Review Pending Approval Pending Retire Approved, Not Effective Approved & Effective Retired

Document > View Approved Supplier List

Visibility: Visible

Document File

Approved Supplier List.docx (18 KB)

 Open  Get Unmarked PDF  Get Editable File Format

Change Summary:

Compare-2.7-2.0_04a7ae0c-a80f-4877-aa27-b2bd077e6540.pdf (39 KB)

 Open

Standard Attributes

Document Type: Form

Name: Approved Supplier List

Description: <empty>

Unique ID: 04a7ae0c-a80f-4877-aa27-b2bd077e6540 **Internal Version:** 3.0

Version: 3.0

Control Number: QA-0001

Effective Date: 27-Aug-2020 UTC-04:00 **Next Review Date:** N/A

Periodic Review Cycle:

Periodic Review (in months): N/A

Initiate Notifications ahead of Review Date (months): N/A

Location: /Root/Form/QA

Publishing Type: Publish in non-editable format (PDF)

Document Actions

- View
- Modify
- Modify Metadata Only
- Change Location
- Metadata to PDF
- Clear PDF
- Hide Document
- Get Link
- Email Link

Document Workflow

- Retire

Related Items

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

Related Information

- Audit Trail

Privileges

- View

Click **Get Editable File Format** to get an editable copy of the current version. When asked if you'd like to **Open** or **Save** your document, click **Open**, and then **Save As** to your desktop or a network location intended for this purpose. You are now able to make changes to the **Document**, generating your new version.

Document Actions

- View
- Modify
- Modify Metadata Only
- Change Location
- Metadata to PDF
- Clear PDF
- Get Link
- Email Link

On the **Document View** page in **SOLABS QM10**, click the **Modify** option on the right-hand **Document Actions** menu.

The **Document File Modify (Document > Main Page > Modify)** screen appears.

The **Authoring** Status Tab at the top of the page is **pale grey** to indicate this latest status.

Starting with Release 10.9, the **Document File** section includes a checkbox for **There is no file for this document**. If you do not plan to link a file (you are processing this “document” to capture metadata only), that box must be checked. The **Document File** section will then become hidden from view.

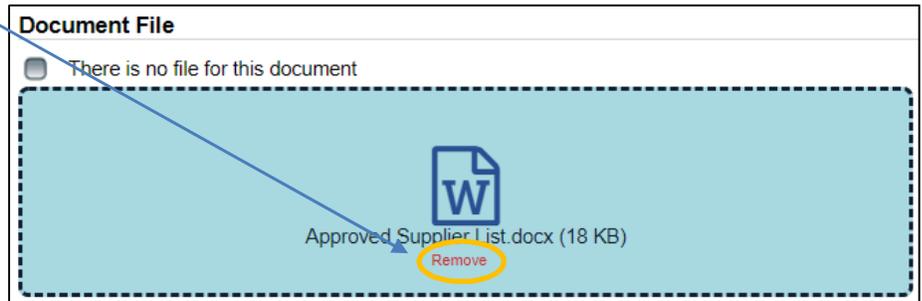
When that box is not checked, you will not be able to Submit and Confirm the Authoring page unless there is a document attached.

The screenshot shows the 'Document File Modify' screen. At the top, there are tabs for 'Authoring', 'Pending Review', 'Pending Approval', 'Pending Retire', 'Approved, Not Effective', 'Approved & Effective', and 'Retired'. The 'Approved & Effective' tab is selected. Below the tabs, the breadcrumb 'Document > Main Page > Modify' is visible. The 'Visibility' is set to 'Visible'. The 'Document File' section has a checkbox labeled 'There is no file for this document' which is unchecked. Below this, a file named 'Approved Supplier List.docx (18 KB)' is shown with a 'Remove' link. There is an 'Add Change Summary' button. The 'Standard Attributes' section includes a 'Document Type' dropdown set to 'Form', a '* Name' field with 'Approved Supplier List', a 'Description' field, and several other fields: 'Unique ID' (04a7ae0c-a80f-4877-aa27-b2bd077e6540), 'Internal Version' (3.1), 'Version' (3.0), 'Current Version' (3.0), 'Control Number' (QA-001), 'Effective Date' (radio button selected for 'Date of final approval'), and 'Next Review Date'.

The screenshot shows the 'Document File Modify' screen with a validation error. A dark red banner at the top contains the message: 'Valid information must be entered in all required fields.' Below this, the 'Document File' section has the checkbox 'There is no file for this document' checked. A red dashed box highlights the area where a file should be uploaded, containing a cloud upload icon, the text 'Drag & drop file here', and a button that says 'OR SELECT FILE TO UPLOAD'. The 'Visibility' is set to 'Visible'.

Replacing the Current Document with your New Version

Click the **Remove** option under the title to remove the file associated with the existing version. You can then drag/drop your updated file from the location you saved it to earlier.

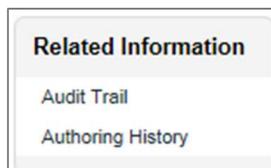


Entering the Document Metadata

The metadata fields will default to the information entered for the previous version but can be edited as necessary for the new version. **You will need to edit the Version field manually to the next version** but the greyed out **Internal Version** and **Current Version** fields are recognizing the versioning of the document.

After all required information is entered, click **Submit**, check your work, and then click **Confirm**. The document is now saved as the next version and will be ready for the **Author** or the **Document Coordinator** to initiate **Review/Approval Cycles**.

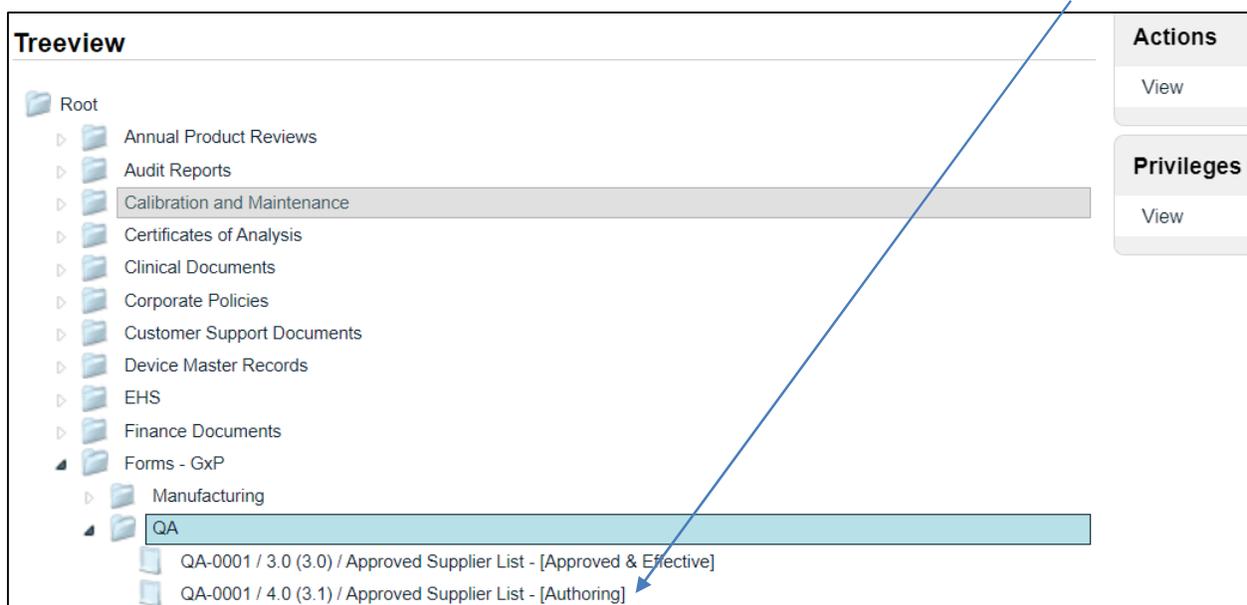
Verifying your Document Status & Viewing the Audit Trail or Authoring History



After the new version of your **Document** is saved, click the **Related Information > Audit Trail** link on the right-hand side of the page. The information for the past and the current, effective versions will be displayed but there is nothing in the trail for your new version because it is a brand new. That will be in the **Authoring History**.

Click the **Related Information > Authoring History** link to see information on any incremental **Internal Versions** you may have created/saved before finishing and Submitting your work.

To access your document at any time from within the **DOCUMENT Section** click the **Navigation tab** on the left-hand menu and then choose **Show All**. The **Treewiew** hierarchical document folder structure will be displayed. Go to the folder location for your document and you should see the new version with **(Authoring)** after it.



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.

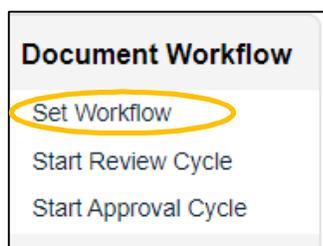
The Audit Trail will not show the Authoring version because it is in progress.

| | |
|---|-------|
| Document > Approved Supplier List > Audit Trail | |
| Approved Supplier List | |
| Internal Version: 3.0 | Print |
| Action Details: Document Approved & Effective | |
| Date: 29-Jul-2020 10:26:37 UTC-04:00 | |
| Username (Full Name): gdixson (Gretchen Dixson) | |
| Reason for Change: N/A | |

| | |
|---|-------|
| Document > Approved Supplier List > Authoring History | |
| Approved Supplier List | |
| Internal Version: 3.2 | Print |
| Action Details: Document Modified | |
| Internal Version: 3.1 | Print |
| Action Details: Document Modified | |
| Expand all Print all View | |

Set Workflow

To define, verify or edit the Document Workflow settings for the Review Cycle and the Approval Cycle, you need **Modify** privileges on the document, and it must be in the **Authoring** stage.



In the right-hand **Document Workflow** menu, click **Set Workflow** to review the current workflow settings for the document. This brings up the **Workflow Details** screen.

The **Available Templates** field is a single-select drop-down list populated with the active **Document Workflow Templates**. Refer to **SOLABS QM10: Document Administration** for information on Document Workflow Templates.

In this example, we see the **QC Documents** workflow template is selected for this document, but another **Available Template** can be selected for this revision if appropriate. If another Available Template were selected, the list of **Reviewers** and **Approvers** would change to the defaults for that template.

These default lists can easily be edited.

- To remove one of the default Users, click the **Remove** option to the right of their name.
- To add another User, use the **Workflow Parameters** section to choose the **Cycle Type** you need to add a User for, then choose the **Cycle Assignee**.

Options for **Cycle Assignees** are **Custom Selection** (by Role or User), **Originator (Author)** or **Document Owner**.

Workflow Details

Available Templates: QC Documents (Default)

Workflow Parameters

* Cycle Type: [Dropdown menu showing Review, Approval]

Cycle Assignee:

- Custom selection
- Originator (Author)
- Document Owner

* Role: [Dropdown menu]

* User: [Dropdown menu]

Order: [Dropdown menu: 1] Insert Delay to review/approve: [N/A] day(s)

+ADD

Review Cycle (Parallel only)

Reference Date [Calendar icon]

| Order | Reviewer (Role) | Reviewer (User) | Delay (days) | |
|-------|--------------------------------|--------------------------|--------------|--------|
| 1 | FCT_Supervisor Quality Control | bgreen (Bonnie Green) | N/A | Remove |
| 1 | FCT_Manager Quality Control | tgarcia (Theresa Garcia) | N/A | Remove |

Approval Cycle (Serial/Parallel)

Reference Date [Calendar icon]

| Order | Approver (Role) | Approver (User) | Delay (days) | |
|-------|-----------------------------|----------------------------|--------------|--------|
| 1 | FCT_Director Quality | drennold (Delores Rennold) | N/A | Remove |
| 1 | FCT_Manager Quality Control | tgarcia (Theresa Garcia) | N/A | Remove |

For each **Cycle Assignee**, click the **+ADD** button to add that User to the appropriate list. For a Cycle Type of Review, the **Order** field will be grayed out because Review Cycles are assigned in parallel. For a Cycle Type of Approval, the Order field can be used to set up a serial Approval Cycle where those at Order “1” receive the document first and those at Order “2” or later, don’t receive it until the Approvers at Order “1” have approved.

Setting Due Dates for Review Cycles and Approval Cycles

- **Delay to review/approve** – allows the option to set the number of days in which you’d like the User to complete the task – establishes a **Due Date** for the task.
- **Reference Date** – if setting a **Delay to review/approve**, this date will be the start date for that calculation. If left blank, the **Due Date** will be calculated from the day the Review Cycle or Approval Cycle is started.
- **NOTE:** When setting a **Delay to review/approve**, whether or not a Reference Date is set, the Due Dates on Workflow box must be selected on the Document Create/Modify screen.

Delay to review/approve: [N/A] day(s)

Reference Date [Calendar icon]

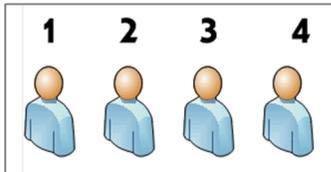
Due Dates on Workflow

Use due dates set on document workflow tasks

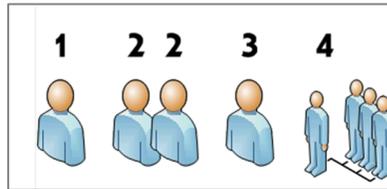
As mentioned above, a **Review Cycle** is optional. When utilized, it is a parallel review cycle which means all **Reviewers** receive the document to review at the same time. User completion of a **Review Cycle** is covered later in this document.

The **Approval Cycle** is mandatory and must have at least one User defined as an **Approver**. That one person can be the Originator (Author) if appropriate. **Approval Cycles** can be set in parallel (all **Approvers** receive the document to approve at the same time), in series (each **Approver** receives it one at a time, after the previous **Approver** completes their approval of the document) or a combination of the two. User completion of an **Approval Cycle** is covered later in this document.

Series Approval Cycle:



Comination of series and parallel:

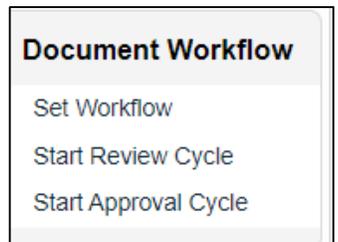


When all settings are complete for the desired **Review Cycle** and **Approval Cycle**, click on **Submit** and then **Confirm** to save the changes. The document is then ready to **Start Review Cycle** (optional) or **Start Approval Cycle** (mandatory, and requires at least one Approver).

Start Review/Approval Cycle

The **Start Review Cycle** and the **Start Approval Cycle** options are part of the right-hand **Document Workflow** menu. After clicking on the option, you will need to **Confirm**.

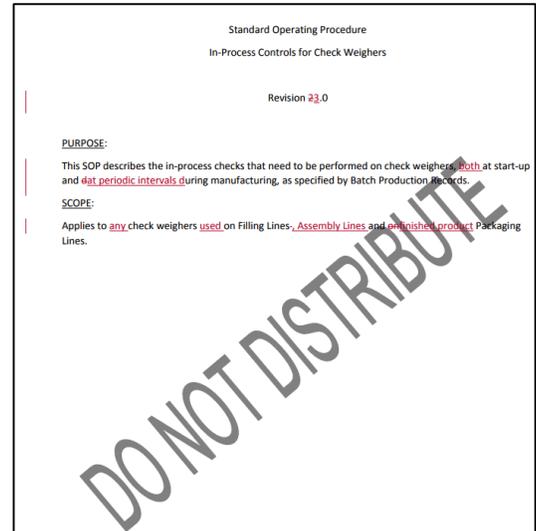
After clicking **Confirm**, the document status tab will move to the next stage of the life cycle. In this example, a Review Cycle was started so the **Pending Review** tab is highlighted. Also, the right-hand **Document Workflow** menu has changed to include a **Provide Feedback** option.



A screenshot of the document management interface. The document is 'Dextrose USP - Assay' and is currently in the 'Approved & Effective' status. The interface shows document file information, a change summary, and standard attributes. On the right-hand side, the 'Document Workflow' menu is visible, and the 'Provide Feedback' option is circled in yellow.

A **Change Summary** section will automatically include a **Compare** file. This file is a PDF file, showing the differences between the two files, and includes a DO NOT DISTRIBUTE watermark.

- For a **Review Cycle**, the Compare file is generated at **Start Review Cycle**. It compares the current file to the last approved document file. If multiple review cycles are initiated for a document revision (versions x.1, x.2, x.3, etc.), the Compare file will compare the current file to the one in the last review cycle performed. **Reviewers** will have a link to the Compare file on either the Document View or Document Workflow screens.
- For an **Approval Cycle**, the Compare File is generated at **Start Approval Cycle**. It compares the current file to the last approved file (previous major internal version). **Approvers** will have a link to the Compare file on the Document View screen only. They can choose the Approve/Reject option after viewing both the Compare file and the document itself, to access the Document Workflow and make their approval decision.



- If the author chooses instead to upload another file into the Change Summary section, the Compare file will not be generated. In that case the Change Summary section will include the file uploaded by the author, in the original format, with no watermark.

The Review Cycle as a User – Provide Feedback

Review Cycle Assignees will receive an email containing a link to the document to be reviewed. The document Review Task will also appear on their SOLABS QM10 HOME page under the **DOCUMENTS** heading. The document status will show as **Pending Review**. If a **Delay to review/approve** option was set on the Workflow, the User will also see a date in the **Due** field.

Click the **link** on the email to access the document or click **View** from your HOME Page.

solabs QM PROCESS DOCUMENT TRAINING Quick Access Menu

Bonnie Green

Dashboard Search Home > Views

By Date
This week/last week (Default)
+/- 30 days
+/- 90 days
Outstanding
Overdue

PROCESSES

Received this week / last week

No items to display...

DOCUMENTS

| Due this week / last week |
|--|
| Name: Dextrose USP - Assay No.: TM-RM-001 Due: <empty> Status: Pending Review Edit View Review |
| Expand all 1 |

TRAININGS

| Due this week / last week |
|---|
| Name: OJT QC-001 HPLC System Suitabi[...] Due: Completion: 33.3 % Status: Active View Confirm |
| Name: SOP QC-001 HPLC System Suitabi[...] Due: Completion: 25.0 % Status: Active View Confirm |
| Expand all 1 |

You are taken to the **View** page of the document and can view the File, the Change Summary/Compare file and all of the document metadata information. There is a menu option for **Provide Feedback**.

Document > View Dextrose USP - Assay

Visibility: Visible

Document File

File:

Dextrose USP - Assay (2).docx(10 KB)

Change Summary:

Compare-3.1-3.0_dd95266e-f339-4350-8e0b-10b7a4ec94e1.pdf (22 KB)

Standard Attributes

Document Type: Test Method
 Name: Dextrose USP - Assay
 Description: Dextrose USP - chromatographic assay
 Unique ID: dd95266e-f339-4350-8e0b-10b7a4ec94e1 Internal Version: 3.2
 Version: 4.0 Current Version: 3.0
 Control Number: TM-RM-001

Document Actions

- View
- Metadata to PDF
- Clear PDF
- Get Link
- Email Link

Document Workflow

- Provide Feedback
- Start Approval Cycle
- Stop Cycle

Related Information

- Audit Trail
- Authoring History

When you are ready to make a Review Decision, the right-hand **Document Workflow** menu includes the **Provide Feedback** option. Choosing this option brings up the **Review Cycle** and **Decision** options.

Review Cycle

| Status | Order | Due Date | Reviewer (Role) / Reviewer (User) | Reviewed by | Review Date |
|--|-------|----------|--|-------------|-------------|
| <input checked="" type="radio"/> Awaiting Review | 1 | N/A | FCT_Supervisor Quality Control / bgreen (Bonnie Green) | <empty> | <empty> |
| <input type="radio"/> Awaiting Review | 1 | N/A | FCT_Manager Quality Control / tgarcia (Theresa Garcia) | <empty> | <empty> |
| <input type="radio"/> Awaiting Review | 1 | N/A | N/A / hsimmons (Helen Simmons) | <empty> | <empty> |

Decision:

OK, no change
 Reviewed, see comments
 Cycle stopped with comments

File with comments:

N/A
 No file selected

Comments:

The **Decision** of **OK, no change** will complete your Review task, after you click on the **Submit** button.

If you have minor comments, the **Decision** of **Reviewed, see comments** enables a **Comments** field where you can provide your feedback.

If the comments are more significant, you can choose the **Edit** option to open and export the Word file, make your changes using Track Changes and then upload it using the **Choose File** option.

For clients who use Office 365, a SharePoint integration option is available, allowing for collaborative editing during the document **Review Cycle**. The **Edit Online** option opens the document for editing. If other Reviewers are also actively editing, that will be visible.

Document File

SOL-OPS-004 - Work Assignment

This feature eliminates the need to export the document to make edits and then upload it with your comments. You could use the **Comment** field to indicate that you made comments within the document but can leave the **File with comments** selection at **N/A**.

When any Reviewers choose **Reviewed, see comments** or **Cycle stopped with comments**, the document will go back to the **Authoring** status so those comments can be addressed. The Author or Document Coordinator can then choose to do another **Review Cycle** or go directly to an **Approval Cycle**.

If all Reviewers choose **OK, no change**, the document will automatically move to the **Approval Cycle**, if one has been set up as part of the Document Workflow.

Regardless of the options selected, you will be taken to a verification screen before you confirm your selection.

Document Workflow

Review Cycle

| Status | Order | Due Date | Reviewer (Role) / Reviewer (User) | Reviewed by | Review Date |
|---------------|-------|----------|--|-----------------------|-------------|
| OK, no change | 1 | N/A | FCT_Supervisor Quality Control / bgreen (Bonnie Green) | bgreen (Bonnie Green) | <empty> |

Logged in Audit Trail

Confirm
Back to Edit
Cancel

The Approval Cycle as a User

Approval Cycle assignees will receive an email containing a link to the document to be approved. The document Approval Task will also appear on their SOLABS QM10 HOME page under the **DOCUMENTS** heading. The document status will show as **Pending Approval**. If a **Delay to review/approve** option was set on the Workflow (see Page 22), the User will also see a date in the **Due** field.

Click the **link** on the email to access the document or click **View** from your HOME Page.

Delores Rennold

Home > Views

PROCESSES

Received this week / last week

No items to display...

DOCUMENTS

Due this week / last week

Name: Dextrose USP - Assay **No.:** TM-RM-001 **Due:** <empty> **Status:** Pending Approval [Open](#) | [View](#) | [Approve](#)

You are taken to the **View** page of the document and can view the File, the Change Summary/Compare file and all the document metadata information. Once the approval cycle is started, the File is converted into PDF format, unless the author intentionally changed the default to publish it in editable format.

You MUST open a document prior to approving or rejecting the document, or you receive this error message.

This Document cannot be approved. The file related to the document has not been opened yet.

Delores Rennold

Authoring
Pending Review
Pending Approval
Pending Retire
Approved, Not Effective
Approved & Effective
Retired

Document > View Dextrose USP - Assay Visibility: Visible

Document File

File:

Dextrose USP - Assay (2).docx(10 KB)

Open

Change Summary:

Compare-3.2-3.0_dd95266e-f339-4350-8e0b-10b7a4ec94e1.pdf (22 KB)

Open

Standard Attributes

Document Type: Test Method

Name: Dextrose USP - Assay

Description: Dextrose USP - chromatographic assay

Unique ID: dd95266e-f339-4350-8e0b-10b7a4ec94e1 Internal Version: 3.3

Version: 4.0 Current Version: 3.0

Control Number: TM-RM-001

Document Actions

- [View](#)
- [Metadata to PDF](#)
- [Get Link](#)
- [Email Link](#)

Document Workflow

- [Approve/Reject](#)

Related Information

- [Authoring History](#)

When you are ready to make an Approval Decision, the right-hand **Document Workflow** menu includes the **Review/Approve** option. Choosing this option brings up the **Approval Cycle** section.

| Document Workflow | | | | | | | |
|--------------------------|-------------------|-------|----------|--|----------|--------------------------|----------------------|
| Approval Cycle | | | | | | | |
| | Status | Order | Due Date | Approver (Role)/Approver (User) | Meaning | Approved By | Approval Date |
| <input type="radio"/> | Awaiting Approval | 1 | N/A | FCT_Director Quality / drennold (Delores Rennold) | <empty> | <empty> | <empty> |
| <input type="radio"/> | Approved | 1 | N/A | FCT_Manager Quality Control / tgarcia (Theresa Garcia) | Approver | tgarcia (Theresa Garcia) | 22-Nov-2017 09:57:45 |

When you select your name, the **Decision** section will be displayed and includes two options – **Approve** or **Reject**.

Document Workflow

Approval Cycle

| Status | Order | Due Date | Approver (Role)/Approver (User) | Meaning | Approved By | Approval Date |
|--|-------|----------|--|----------|--------------------------|----------------------|
| <input checked="" type="radio"/> Awaiting Approval | 1 | N/A | FCT_Director Quality / drenold (Delores Rennold) | <empty> | <empty> | <empty> |
| <input type="radio"/> Approved | 1 | N/A | FCT_Manager Quality Control / tgarcia (Theresa Garcia) | Approver | tgarcia (Theresa Garcia) | 22-Nov-2017 09:57:45 |

Decision:

Approve
 Reject

* Comments:

* Meaning:

* Meaning:

 Originator (Author)
 Approver

A choice of **Reject** will enable the mandatory **Comments** field.

If a document is rejected, the entire **Approval Cycle** will be stopped. Other **Approvers** will no longer see the document **Pending Approval**. The **Document Coordinator** will receive a Notification so the issue can be resolved.

A choice of **Approve** requires selection of a **Meaning**.

Click the **Submit** button and then **Confirm** your Decision.

If all Approvers approved the document, it will automatically to a status of **Approved, Not Effective** or **Approved & Effective**. See Page 5 for explanation.

Pending Review Pending Approval Pending Retire Approved, Not Effective Approved & Effective

Document > View Dextrose USP - Assay

Visibility: Visible

Document File

File:

 Dextrose USP - Assay (2).docx(10 KB)



Reviewing/Approving on Behalf of Another User

Occasionally, there may be the need for a User to review or approve a document on behalf of another user. In this case, that User will receive a warning message, indicating that they are attempting to sign for the other User, that it is assumed they have relevant delegation permission to do so, and the required delegation permissions are on file.

Document Workflow

Approval Cycle

| Status | Order | Due Date | Approver (Role)/Approver (User) | Meaning | Approved By | Approval Date |
|----------|-------|----------|--|----------|----------------------------|---------------|
| Approved | 1 | N/A | FCT_Associate Director Quality Assurance / rgonzales (Ronald Gonzales) | Approver | drennold (Delores Rennold) | <empty> |

E-Signature required

* Username:

* Password:



Electronic signature is the legally binding equivalent to a handwritten signature.

Logged in Audit Trail

You are attempting to sign for user rgonzales (Ronald Gonzales). It is assumed that you have the relevant delegation permission to do so. It is your responsibility to ensure that you have the permission documented (either electronic or paper based).

Confirm
Back to Edit
Cancel

This will be captured and maintained in the Approval Cycle Details:

| Approval Cycle | | | | | | |
|----------------------------|-------|----------|--|-----------------------------|-------------------------|--|
| Status | Order | Due Date | Approver (Role) | Approver (User) | | |
| Approved | 1 | N/A | FCT_Manager Engineering | myoung (May Young) | Details | |
| Approved By | | | Meaning | Approval Date | | |
| myoung (May Young) | | | Approver | 01-Nov-2017 15:43:53 | | |
| Approved | 1 | N/A | FCT_Associate Director Quality Assurance | rgonzales (Ronald Gonzales) | Details | |
| Approved By | | | Meaning | Approval Date | | |
| drennold (Delores Rennold) | | | Approver | 22-Nov-2017 10:30:29 | | |

Document Effective Dates

Once a document has finished the Review Cycle and the Approval Cycle, it does not necessarily become automatically **Effective**.

When the document was created or revised, an **Effective Date** option was selected – either the default for that Document Type or an option specific to that Document.

- If the option selected was **Date of final approval**, the document will automatically become **Approved & Effective** upon successful completion of the Approval Cycle.
- If any of the other options was selected, the approved document will stay in the **Approved, Not Effective** status until its effective date is reached. When that date is reached, the document will automatically become **Approved & Effective**.

Effective Date:

Date of final approval

14 days after final approval

 Clear

Set through Document Control Process

Document Administration Tasks in the DOCUMENT Section

This section includes some Document Administration tasks that are typically performed by the SOLABS System Administrator or the SOLABS Document Administrator.

Add a New Folder

Folders can be created for the beginning of a new project, the addition of a new team, etc. Once created, they appear in the Document Treeview.

From the **DOCUMENT** Section, access the Quick Access **Document Menu** at the top right of the screen and choose the **Create Folder** option. The **Document > Folders > Create** screen will be displayed.

Document > Folders > Create Visibility: Visible

Folder Details

* Name:

Description:

Location:

Available Folders

Folder Name Contains:

Number of levels to display:

Number of levels to display:

- All
- Level 1
- Level 2
- Level 3

Default Location:

- /Root
- /Root
- /Root/Annual Product Reviews
- /Root/Audit Reports
- /Root/Clinical Documents
- /Root/Device Master Records
- /Root/Finance Documents
- /Root/Forms - GxP
- /Root/Human Resources Documents
- /Root/IS/IT Documents
- /Root/Master Production Records
- /Root/Policies

Enter a meaningful, intuitive **Name** for the Folder; one that easily describes the Documents that will be stored in it. The Description field is optional but can be helpful to provide more information on the Documents stored within this folder.

The **Location** field is used to place the new Folder within the Document Treeview. If the parent folder was highlighted before choosing the Create Folder option from the Document Menu, this screen will default to that location. Otherwise, search for the desired Location as follows:

- Click on “**Available Folders**” to bring up search criteria for the Treeview folders.
- Enter the search criteria and then click on the **Filter** button.
- At that point, clicking on the /Root drop-down list will bring up all the available folders that meet the search criteria.
- Click on the folder that will be the parent folder to this new one.
- Submit and Confirm the information to add the new Folder to the Treeview.

Setting Privileges Folders and Documents

The **Privileges** settings define the type of access the Users have to the different folders and/or documents. This access is granted by Roles. When those Roles are assigned to a User, they then have the related Privileges.

To View and Modify Privileges for a Folder, highlight it within the Treeview and then choose **Privileges > View**.

Document > Folders > View

Treeview

- Root
 - Annual Product Reviews
 - Audit Reports
 - Clinical Documents
 - Device Master Records
 - Finance Documents**
 - Forms - GxP
 - Human Resources Documents

Actions

- View
- Privileges**
 - View

The **Document > Folders > Privileges > View** screen will be displayed.

Name: Finance Documents

Description: Finance Documents - Non GxP

Location: /Root

Current Privileges

| Role | Read Only | Review/Approve | Modify | Administer |
|-------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| SOLABS Document Administrator | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| SOLABS System Administrator | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| SOLABS General User | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Privileges

- View
- Remove Inheritance

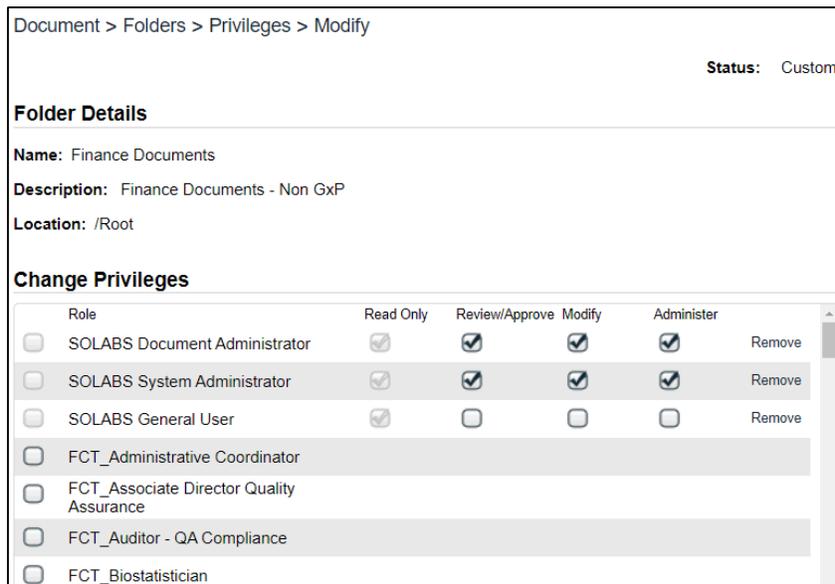
Privileges on folders are either Inherited from the parent folder or are individually set by choosing to Remove Inheritance and then Modifying the Privileges.

By default, Users with the System Roles of SOLABS Document Administrator and SOLABS System Administrator have Administer privilege. Users with only the SOLABS General User role – Train ID Users for example – have the lowest Privilege of View Only.

| | READ ONLY | REVIEW/APPROVE | MODIFY | ADMINISTER |
|--|-----------|----------------|--------|------------|
| Can view APPROVED & EFFECTIVE documents or APPROVED, NOT EFFECTIVE documents that are assigned to them for training purposes. | YES | YES | YES | YES |
| Can view all IN PROCESS documents and can REVIEW or APPROVE documents. | NO | YES | YES | YES |
| Can CREATE and MODIFY documents. | NO | NO | YES | YES |
| Can manage document PRIVILEGES. | NO | NO | NO | YES |

- **Read Only** = Users with this privilege can only view Approved & Effective documents. They can also view documents at a status of Approved, Not Effective if the document is assigned to them for training.
- **Review/Approve** = Users with this privilege can view all in-process documents as well as act on Review or Approval tasks.
- **Modify** = Users with this privilege can do the above and can also create and modify documents.
- **Administer** = Users with this privilege can do all of the above and can also set privileges.

To add additional privileges, first choose **Privileges > Remove Inheritance**. If privileges have been modified in the past, you will instead see a **Modify Privileges** option. After Confirming either choice, the **Document > Folders > Privileges > Modify** screen will be displayed. This screen is used to Remove or Add privileges.



All SOLABS QM10 Users have the **SOLABS General User** role by default so have **Read Only** privileges. This can be replaced by a Security Role unique to your company if you'd like.



To add Review/Approve, Modify or Administer privileges to another Role, scroll through the list and select it. The list contains all active FCT, SEC, PR and SOLABS Roles. After selecting the Role, select the privileges you would like to add to that Role by choosing them at the bottom of the screen and then clicking on **Update**. When you have made changes, click on **Submit**.

| Added | | | | |
|---------------|-------------------------------------|-------------------------------------|-------------------------------------|--------------------------|
| Role | Read Only | Review/Approve | Modify | Administer |
| SEC_Finance | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| FCT_President | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Any privileges you have Added, Removed or Modified will be listed for review. When you have verified the updates, click on **Confirm** to save the changes.

| Current Privileges | | | | |
|-------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Role | Read Only | Review/Approve | Modify | Administer |
| SOLABS Document Administrator | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| SOLABS System Administrator | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| SEC_Finance | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| FCT_President | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SOLABS General User | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

The **Privileges > Set Inheritance** option can be used to set privileges back to those of the parent folder if/when needed.