

SOLABS QM10: Document Review Cycle

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Introduction:

This document covers the process for starting a **Review Cycle** for a new or revised document in **SOLABS QM10**. To manage and start a **Review Cycle**, you will need at least **Modify** privileges in **SOLABS QM10**.

This document also covers how the assigned **Reviewers** will act on that task. To review a document in **SOLABS QM10**, a user will need at least **Review/Approve** privileges.

Locating the Document

A new or revised document is ready for a **Review Cycle** when the author has uploaded the content, has entered/updated all of the required metadata and has Submitted and Confirmed that information.

The level of permissions to author a document is the same as that required to initiate a Review Cycle so authors can start that cycle on their own document after finalizing the updates. Alternatively, they can rely on a Document Coordinator to perform that task, especially if the document is being revised using the SOLABS QM10 Document Control Process.

If a **Document Coordinator** is starting the review cycle for an author who already updated the document, they will need to locate that in-process document in one of three ways:

- The **Search** field at the top of the screen
- The **Views** tab options in the left-hand **DOCUMENT Section** menu
- The **Show All** option (for **Treeview**) in the left-hand **DOCUMENT Section** menu

If you are a **Document Coordinator** and the **SOLABS QM10 Document Control Process** was used by the author to initiate document revision and obtain document owner approval (if necessary), you will have received an email **Notification** and will see a task waiting in the **PROCESSES** section of your **Home Page**.

Home > Views

PROCESSES

Received this week / last week

Unique ID: DOC-000039 **Date Initiated:** 29-May-2019 **Status:** In Process [View](#) | [Act on](#)
Current Process Task: Document Coordinator Processing

Once you have located the document that is ready for its **Review Cycle**, click the **View** option to the right of that listing to access the **Document View** screen. If you are accessing it from a Process task, the **View** option for the document will be at the bottom of the **Process View** where the document is listed under **Related Items**.


Starting the Review Cycle

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

Document > View Training Program **Visibility:** Visible

Document File

File:

 Training Program.doc(479 KB) [Edit](#) [Get Unmarked PDF](#)

Change Summary:
<empty>

Standard Attributes

Document Type: Standard Operating Procedure
Name: Training Program
Description: <empty>
Unique ID: f030f923-a4b7-4917-965b-d3c2abef1a9f **Internal Version:** 1.1

Document Actions

- [View](#)
- [Modify](#)
- [Change Location](#)
- [Cancel in Process](#)
- [Lock File](#)
- [Metadata to PDF](#)
- [Clear PDF](#)
- [Hide Document](#)
- [Get Link](#)
- [Email Link](#)

Document Workflow

- [Set Workflow](#)
- [Start Review Cycle](#)
- [Start Approval Cycle](#)

In the **Document Workflow** box, you will see options to **Set Workflow**, **Start Review Cycle** and **Start Approval Cycle**.

Document Workflow

- Set Workflow
- Start Review Cycle
- Start Approval Cycle

- **Review Cycle** is used when the document is being marked up or edited, and a final version is not yet agreed upon. The content/text could still be changed by readers and involved stakeholders.
- **Approval Cycle** is used when the document is ready to be approved with the electronic signatures of the involved stakeholders. The document is on its way to being made effective.

It is a good practice to click first on the **Set Workflow** option to view the assigned workflow and determine if it is appropriate for this document revision. The reviewers and approvers from the previous version will be assigned by default but may need to be updated. The reviewers and approvers may also have been assigned through use of a default **Document Workflow Template** linked to this **Document Type** but can be changed – or customized – at the document level.

Set Workflow

To check or change the Workflow, click on the **Set Workflow** option to display the Workflow Details screen.

Document > SOLABS QM 10 Guide for Document Treeview Folder Structure > Set Workflow

Workflow Details

Available Templates:

Workflow Parameters

* Cycle Type:

Cycle Assignee:

Custom selection
 Originator (Author)
 Document Owner

* Role:

* User:

Order: 1 Insert Delay to review/approve: N/A day(s)

Review Cycle (Parallel only)

Order	Reviewer (Role)	Reviewer (User)	Delay (days)	
1	FCT_QMS System Administrator	gdixson (Gretchen Dixon)	N/A	Remove
1	FCT_Training Coordinator	ejohnson (Elizabeth Johnson)	N/A	Remove

To see the **Available Templates**, use the drop-down list. Click on the names to view the related users.

Available Templates:

-
-
- Annual Product Review
- Approval by Author Only
- Clinical Documents
- Device Master Record and Work Instructions
- Import of Legacy Documents
- Internal Audit Report
- Master Production Record
- QC Documents

If there is a Default template associated with this Document Type, it will be indicated on the list. If it is not appropriate for this document update, a different one can be used instead, or Reviewers can be selected manually using “Custom Selection”.

Choose a **Cycle Type** of **Review**. You can then choose reviewers by **Role** or **User**, clicking **+ADD** after each one to add them to the Review Cycle list. You can also Remove reviewers.

NOTE: **Review Cycles** are conducted in parallel only, so you do not need to use the **Order** field. All assigned Reviewers will receive the document to review at the same time.

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** 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

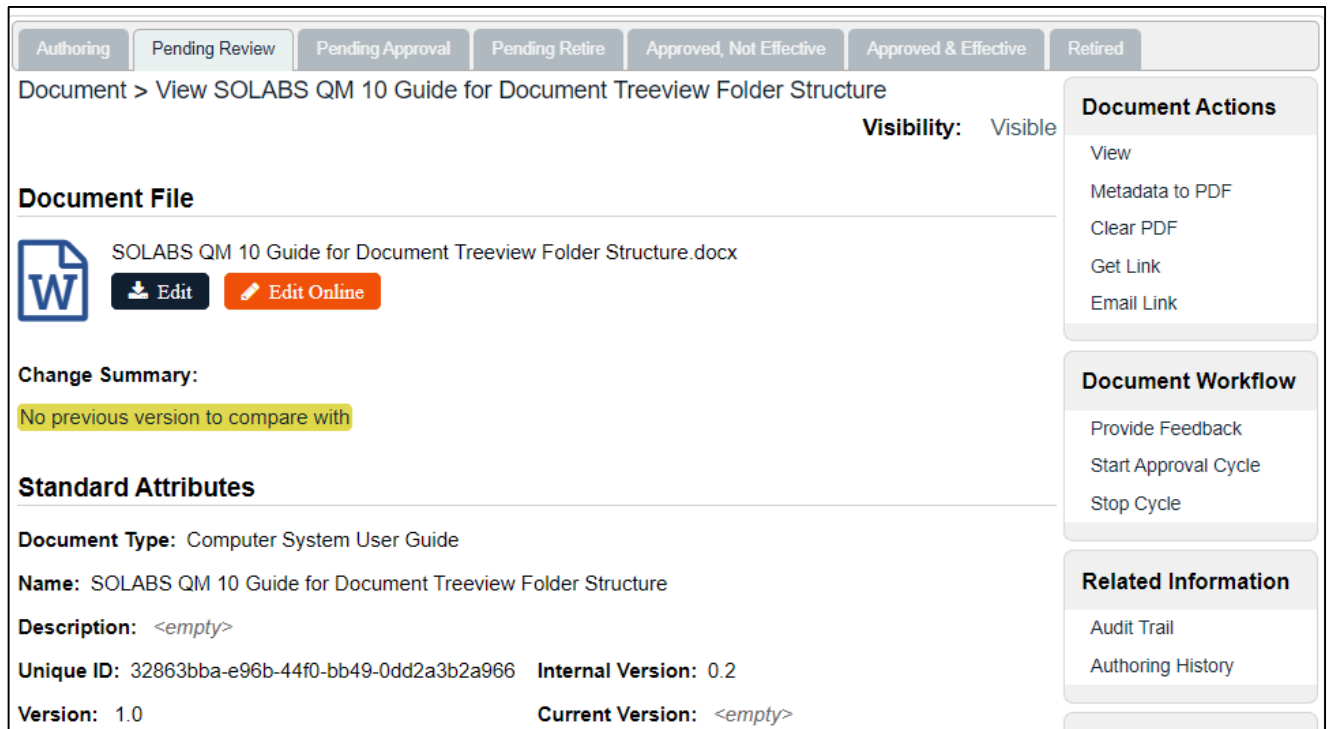
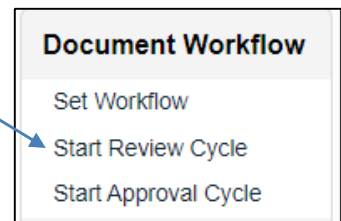
Due Dates on Workflow
 Use due dates set on document workflow tasks

When the list of reviewers is finalized, either by using the appropriate **Document Workflow Template** or by making a **Custom selection**, you are ready to start the **Review Cycle**.

Start Review Cycle

To start the Review Cycle, choose **Document Workflow > Start Review Cycle** on the right-hand side of the Document View screen and then **Confirm**.

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

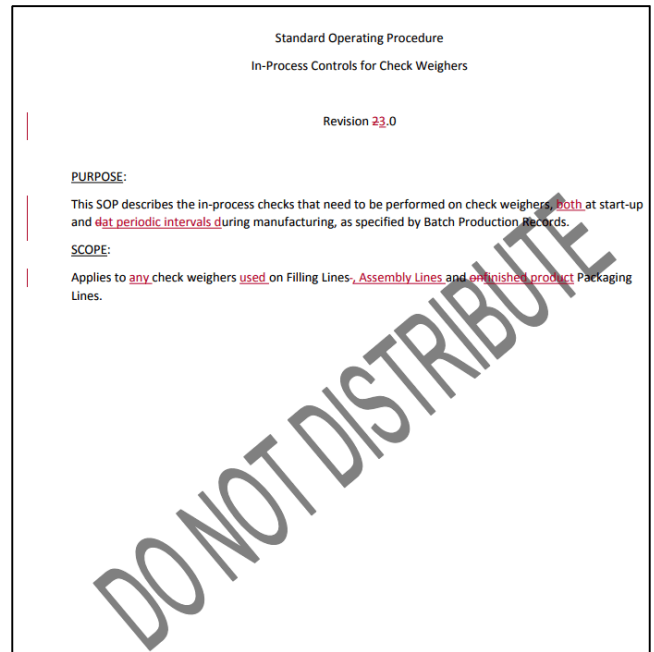


The screenshot shows a document view interface with tabs for workflow stages: Authoring, Pending Review (selected), Pending Approval, Pending Retire, Approved, Not Effective, Approved & Effective, and Retired. The document title is "Document > View SOLABS QM 10 Guide for Document Treeview Folder Structure" and its visibility is set to "Visible". The document file is "SOLABS QM 10 Guide for Document Treeview Folder Structure.docx" with "Edit" and "Edit Online" buttons. A "Change Summary" section indicates "No previous version to compare with". The "Standard Attributes" section lists: Document Type: Computer System User Guide; Name: SOLABS QM 10 Guide for Document Treeview Folder Structure; Description: <empty>; Unique ID: 32863bba-e96b-44f0-bb49-0dd2a3b2a966; Internal Version: 0.2; Version: 1.0; Current Version: <empty>. On the right, the "Document Actions" menu includes View, Metadata to PDF, Clear PDF, Get Link, and Email Link. The "Document Workflow" menu includes Provide Feedback, Start Approval Cycle, and Stop Cycle. The "Related Information" menu includes Audit Trail and Authoring History.

You will also notice that the **Review Cycle** section changes to **Ongoing Review Cycle**.

The **Change Summary** section for documents at version 2.0 or higher will automatically include a **Compare** file. This file is a PDF file with 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.



Reviewing the Document

The users included in the **Review Cycle** will receive a **Notification** and will also see the **Pending Review** task in the **DOCUMENTS** section of their **SOLABS QM10 Home** Page. 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. Depending on the version of SOLABS QM10, the options will be either **View | Review** or **Edit | View | Review** and may be in black or orange text.

DOCUMENTS				
Due this week / last week				
Name:	SOLABS QM 10 Guide for Documen[...]	No.:	UM000003	Due: <empty> Status: Pending Review Edit View Review

To act on the **Pending Review** task, the users selected will need to have at least Review/Approve privileges on the Document or the related Folder.

Clicking on the **View** option from the **Home Page** will bring the Reviewer to the **Document View** screen, allowing them to review all the metadata and open the document before making their review decision. From there they can click on **Document Workflow > Provide Feedback** to document their review.

Document Workflow

- Provide Feedback
- Start Approval Cycle
- Stop Cycle

Clicking directly on the **Review** option from the **Home Page** will bring the reviewer directly to the **Document File Review Cycle** section but the right-hand menus are still available if they feel they need to

Standard Attributes

Document Type: Computer System User Guide

Name: SOLABS QM 10 Guide for Document Treeview Folder Structure

Unique ID: 32863bba-e96b-44f0-bb49-0dd2a3b2a966

Version: 1.0

Control Number: UM000003


Review Cycle

Status	Order	Due Date	Reviewer (Role) / Reviewer (User)	Reviewed by	Review Date
<input type="radio"/> Awaiting Review	1	N/A	FCT_Documentation Coordinator / JC (Jaqueline Clark)	<empty>	<empty>

Opening the Document File and Making Changes

The **Document File** section screen includes a link to the attached document. Click either the document link or one of the Edit buttons to download the document.

Document File

 [SOLABS QM 10 Guide for Document Treeview Folder Structure.docx](#)

A SharePoint integration feature is available for those clients who use Office 365, 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.

After reviewing the document, if you have minor changes to propose, there is a Comment field that you can use to describe them when making your Feedback Decision.

Review Cycle

Status	Order	Due Date	Reviewer (Role) / Reviewer (User)	Reviewed by	Review Date
<input checked="" type="radio"/> Awaiting Review	1	N/A	FCT_Documentation Coordinator / JC (Jaqueline Clark)	<empty>	<empty>

Decision:

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

File with comments:

N/A
 No file selected

Comments:

If you are using the Word Online feature with Office 365 and need to edit the document, click on the orange **Edit Online** button to open the document and make your changes. Your changes will be saved to the file along with edits by any of the other reviewers.

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**.

If you do not have the Word Online feature enabled and need to edit the document, click on the blue **Edit** button to open the document. Choose the **Enable Editing** option, make sure that **Track Changes (Review > Track Changes)** is on in **Word** (it should be gold-colored), and make any changes required. Save your edited document outside SOLABS QM10. There is a Choose File button in the Feedback Decision section to upload your edited document when making your Feedback Decision. Use of Track Changes will help the author and/or the Document Coordinator to easily identify your changes.

PROTECTED VIEW Be careful—files from the Internet can contain viruses. Unless you need to edit, it's safer to stay in Protected View.
Enable Editing

SOP_TEST [Read-Only] - Microsoft Word
Acrobat

Track Changes

Tracking

Final: Show Markup

Show Markup

Reviewing Pane

Accept

Reject

Changes

Previous

Next

Comment [G0B1]: I find this hard to believe

Comment [G0B2]: A little story

Comment [G0B3]: Hahaha "roll eyes"

NOTE: To learn more about **Track Changes**, consult the **MS Word** help file or click **F1** from *within Word*.

Submitting Your Feedback Decision

If you have no changes to make, have minor comments, or are finished making your edits and attaching a File (if necessary), click the radio button labelled **Awaiting Review** to the left of your name to bring up the **Decision** options. Note that you can also see the status of any other reviews.

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

Review Cycle

Status	Order	Due Date	Reviewer (Role) / Reviewer (User)	Reviewed by	Review Date
<input checked="" type="radio"/> Awaiting Review	1	N/A	FCT_Auditor - QA Compliance / any	<empty>	<empty>
<input type="radio"/> Awaiting Review	1	N/A	FCT_Manager Supply Chain / KA (Kelly Allen)	<empty>	<empty>
<input type="radio"/> OK, no change	1	N/A	FCT_Manager QA Compliance / MT (Marilyn Turner)	MT (Marilyn Turner)	08-Nov-2019 14:30:03

Decision:

OK, no change

Reviewed, see comments

Cycle stopped with comments

File with comments:

N/A

No file selected Choose File

Comments:

Submit
Cancel

If you have comments, you can choose the **Reviewed, see comments** option and then either type your comments in the **Comments** field, use that field to indicate that you have included your edits in the attached File (if Word Online was used) or attach your marked-up **Word** file with the **Tracked Changes** using the **File with comments:** option (if Word Online is not enabled). To attach a marked-up file, click **Choose File**, browse for the marked-up document, select the file and click **Open** to attach.

If you need to choose the **Cycle stopped with comments** option, the **Comment** field will become mandatory.

When you have made your **Decision**, click **Submit**. A summary of your review information appears, as well as the **Audit Trail** logging message. Double-check your information and click **Confirm**.

Document Workflow

Review Cycle

Status	Order	Due Date	Reviewer (Role) / Reviewer (User)	Reviewed by	Review Date
OK, no change	1	N/A	FCT_Auditor - QA Compliance / any	csanders (Christina Sanders)	<empty>

Logged in Audit Trail

Confirm
Back to Edit
Cancel

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.

When 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.