

SOLABS QM 10: Guide to the DOCUMENT Section for General Users

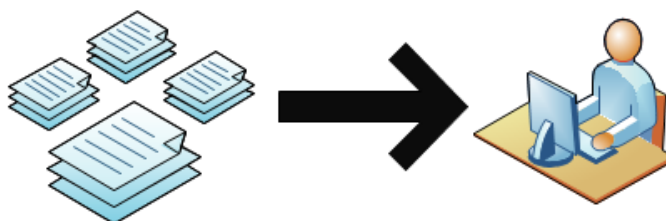
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Introduction

This document covers functions that the General User might need to use in **SOLABS QM**. To find additional information on use of the **SOLABS QM DOCUMENT Section**, enter the word “Document” in the Search field of the SOLABS Knowledge Base.

A Document in SOLABS QM 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 software files that are visible and accessible from the **Document > View** page.

The first file is the document being created or revised.

- During the **Authoring** and **Review Cycle** stages of its lifecycle, it will be an editable file such as Microsoft Word.
- During the **Approval Cycle** and when it becomes **Approved & Effective**, it will usually be rendered to a non-editable file such as PDF.

A second file associated with a document being revised is a **Change Summary** or a **Compare** file, that helps highlight revisions being made to a Document.

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 Document level.

The **System Attributes** section includes additional information that are 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.

The **Document Ownership** section includes the Author, Document Owner and Document Coordinator for the document.

Document File

File:



Equipment Calibration Program.docx(10 KB)

Open

Get Unmarked PDF

Get Editable File Format

Change Summary:



Compare-1.5-1.0_b004e68f-cd7f-4990-a176-f3a019540e04.pdf (31 KB)

Open

Standard Attributes

Document Type: Standard Operating Procedure

Name: Equipment Calibration Program

Description: SOP defining the GDP Equipment Calibration Program and related requirements

Unique ID: b004e68f-cd7f-4990-a176-f3a019540e04 Internal Version: 2.0

Version: 2.0

Control Number: ENG-001

Effective Date: 08-Sep-2017

Next Review Date: 08-Sep-2020

Document Life Cycle:

Life Cycle (in months): 36

Planned Review Task Duration (in months): 3

Location: /Root/Standard Operating Procedures/Engineering/Equipment Maintenance

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

Reason for Change: Add section for preventative maintenance of checkweighers.

Cosmetic Change

System Attributes

Additional Information: <empty>

Applicable Div: GDP Medical Device Products; GDP Pharmaceutical Products

Document Ownership

Originator (Author): jnorman (Jeffery Norman)

Document Owner: FCT_Manager Engineering

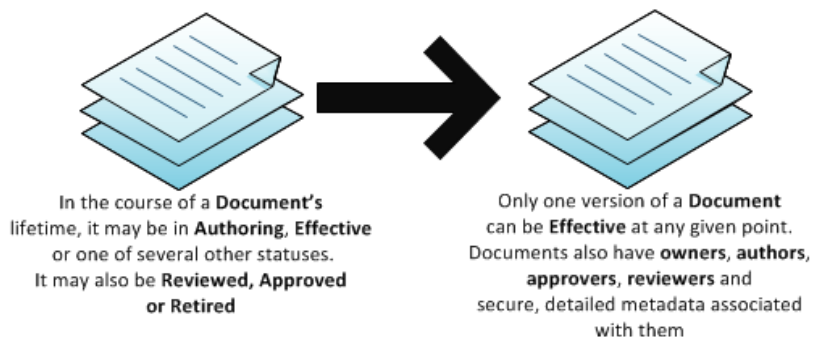
Document Coordinator: FCT_Documentation Coordinator

<p>The Document Workflows section includes information on the Reviewers and Approvers 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 Engineering</td> <td>myoung (May Young)</td> </tr> <tr> <td>Approved</td> <td>1</td> <td>N/A</td> <td>FCT_Associate Director Quality Assurance</td> <td>rgonzales (Ronald Gonzales)</td> </tr> </tbody> </table> <p>Related Items</p> <table border="1"> <thead> <tr> <th colspan="2">Training Activities for this Document</th> </tr> </thead> <tbody> <tr> <td>Name: SOP ENG-001, Equipment Calibra[...]</td> <td>Due: Completion: 75.0 % Status: Active</td> </tr> </tbody> </table>	Status	Order	Due Date	Approver (Role)	Approver (User)	Approved	1	N/A	FCT_Manager Engineering	myoung (May Young)	Approved	1	N/A	FCT_Associate Director Quality Assurance	rgonzales (Ronald Gonzales)	Training Activities for this Document		Name: SOP ENG-001, Equipment Calibra[...]	Due: Completion: 75.0 % Status: Active
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<p>The Related Items section includes other existing SOLABS QM documents, Training Activities or Processes that are associated with or linked as reference information to the document.</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



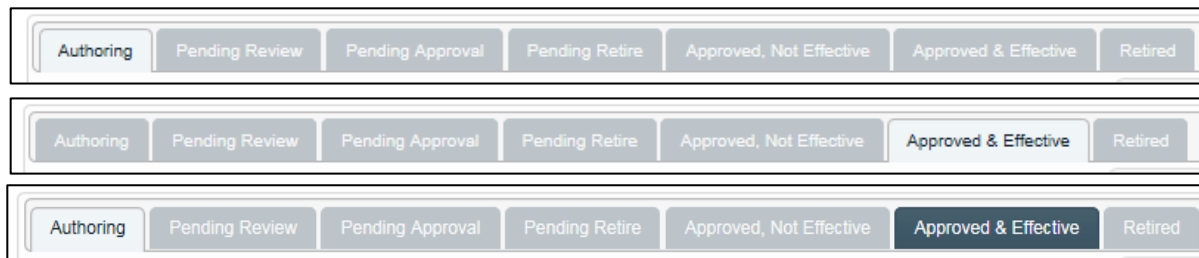
One way you can tell the status of a document is to check the **Status** metadata displayed with Document Views and Search results. For example, the View for Document >In process – all brings up documents in various stages of their life cycle, and therefore various statuses.

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 documents and folders to limit Users from seeing documents at all stages of their life cycle. For example, Train ID Users – those using SOLABS QM just to complete Training Activities – will have the **Read Only** privilege (called Summary View

in versions before 10.8) and will be limited to viewing documents that are at the **Approved & Effective** status. Users with **Review/Approve** privileges (called View in versions before 10.8) can act on document Review and Approval tasks so will be able to see documents that are **Pending Review** or **Pending Approval**. 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.

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

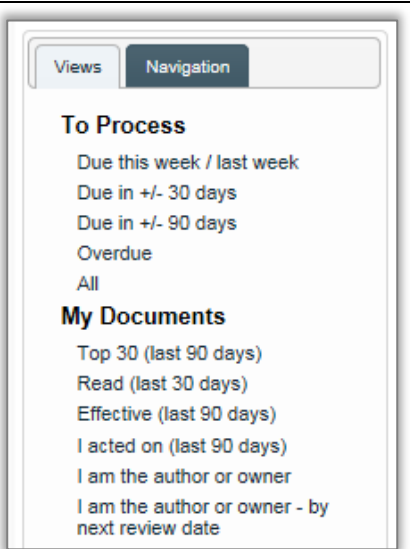


Document Status Meanings	
Authoring	This Document is being actively created or revised. It is editable only by Author/Owner or the assigned Document Coordinator .
Pending Review (Review Cycle is Optional)	This Document is currently in a Review Cycle , and is Awaiting Review from the assigned Reviewers .
Pending Approval (Approval Cycle is Mandatory)	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 Retirers .
Approved, Not Effective	This Document has completed the Approval Cycle , but has not yet been made Effective . NOTE: Documents frequently 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 Approval, or after an Effective Date delay.
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.
<p>NOTE:</p> <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. 	

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	
Due this week/last week: Documents due to act on this week or in the previous week	
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 with tasks that are overdue on the part of the User	
All: All documents currently requiring action 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 by the date of their next Periodic Review	

Document Coordinators, with the SOLABS Document Administrator role assignment will see additional Views in a **Document Coordinator** section.

Document Listing Tables

- Results from a Document View or Search selection 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: Employee Training	No.: QADT-001	Due: <empty>	Status: Approved, Not Effective Open View
Name: Employee Training Document Type: Standard Operating Procedure Control Number: QADT-001 Effective Date: <empty> Document Coordinator: FCT_Documentation Coordinator Originator (Author): gdixson (Gretchen Dixson) Document Owner: FCT_Manager QA Compliance			
Name: SOLABS QM 10 System Administra[...]	No.: UM000001	Due: <empty>	Status: Approved & Effective Open View
Name: Internal Audit Program	No.: QAC-001	Due: <empty>	Status: Approved & Effective Open View
Name: Solabs eQMS	No.: VR-CV-001	Due: <empty>	Status: Approved & Effective Open View
Expand all ↑			

Searching for/Locating a Document

When Users are required to take action on a document (such as Review or Approval) they will usually receive an **Email Notification** that includes a link to the document. If Email Notifications are not enabled, or if the user simply needs to view a document, there are several ways to locate it.

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.

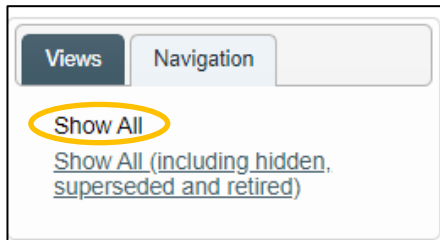
DOCUMENTS			
All			
Name: Clinical Protocols and Checkli[...]	No.: COP-001	Due: <empty>	Status: Pending Review Edit View Review
Expand all 1			

Method 2: Navigation > Show All > Treewiew

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

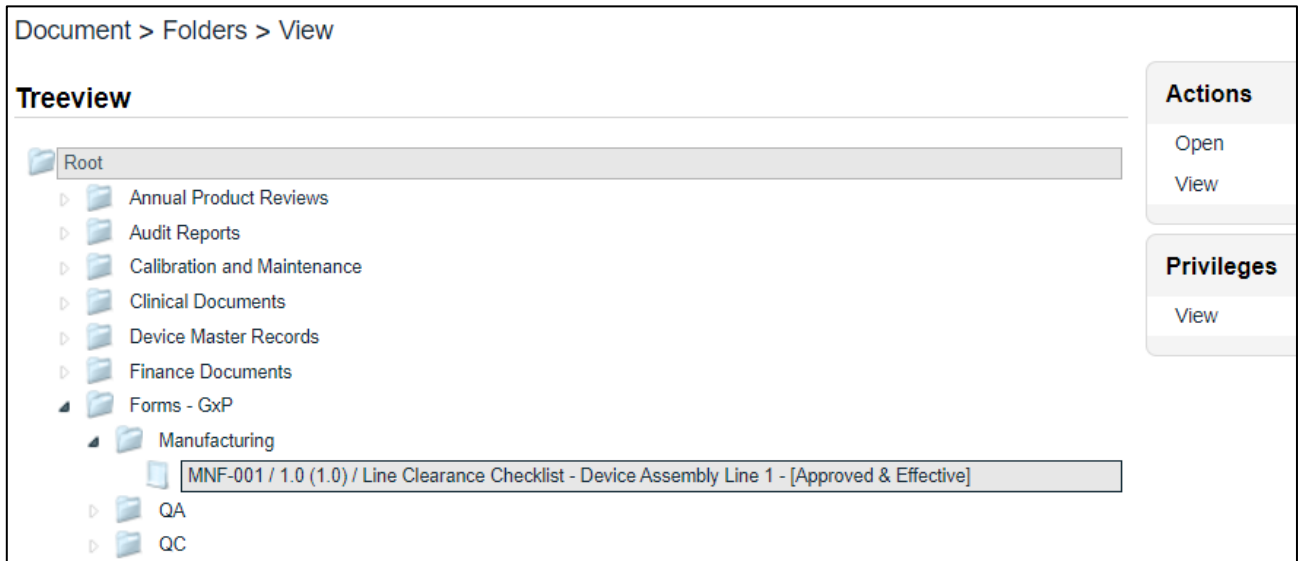


- From the Left Side Menu, click the **Navigation** tab and then choose **Show All**.

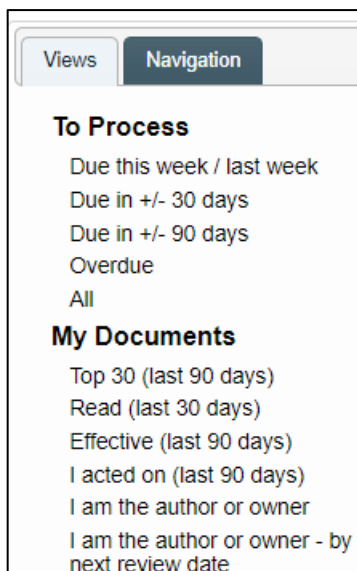


The option **Show All (including hidden, superseded and retired)** is available only to Document Administrators with appropriate privileges, who can then also see Hidden documents and folders such as those used to store Related Documents for Training Activities or Processes and documents that are superseded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

Navigate through the folders as required to locate the document. 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 Tab

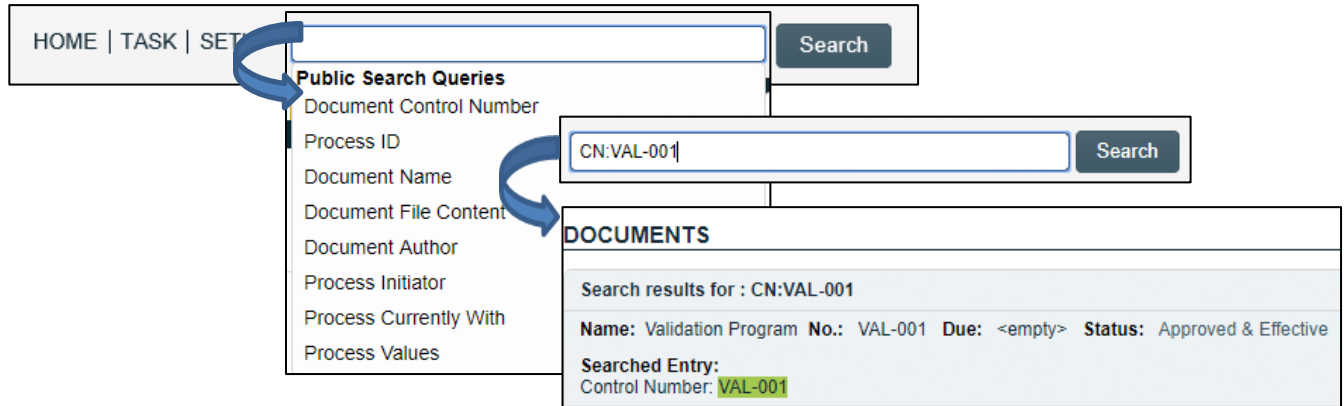


These **Views** are a handy way to keep track of documents that you are involved with in different ways. You may also track your work obligations and prioritize your work on documents using these Views.

See Page 5 of this document for more detail on these options.

Method 4: Targeted Searching

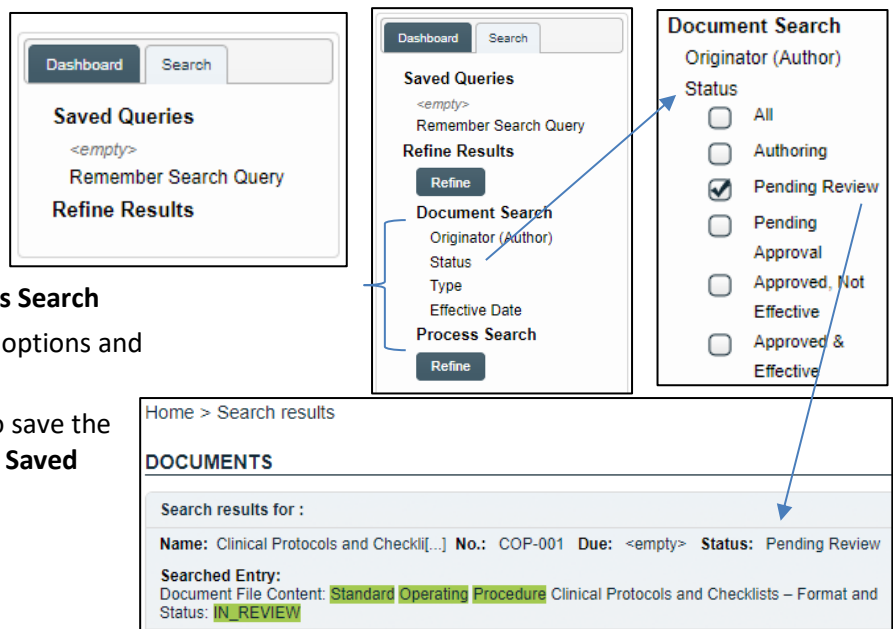
The Search field at the top of the screen can be used for Targeted Searches for Documents or Processes. Additional, more advanced Search capability is available starting with SOLABS QM 10.5, and is described in a separate Knowledge Base document titled **SOLABS QM 10: Enhanced Search Features**.



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 of this document.

Reviewing or Approving a Document

As a General User, you may be assigned to review or approve a document as part of a **Review Cycle** or an **Approval Cycle**.

Reviewers and approvers will receive an Email Notification that includes a link to the **Document > View** page of the file to be reviewed or approved. Click the link, in the notification, sign into SOLABS QM if required, and the document will be listed in the DOCUMENTS section of the **HOME** screen.

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

DOCUMENTS							
All							
Name:	Equipment Calibration Program	No.:	ENG-001	Due:	<empty>	Status: Pending Approval	Open View Approve
Name:	Device Manufacture - 2017	No.:	IA000001	Due:	<empty>	Status: Pending Approval	Open View Approve

The actual transactions involved in the Review Cycle and the Approval Cycle are covered in other documents in the SOLABS Knowledge Base, such as:

- **SOLABS QM 10: Document Review Cycle**
- **Introduction to SOLABS QM 10 Document Section**