# SOLABS QM10: Guide to the DOCUMENT Section for General Users

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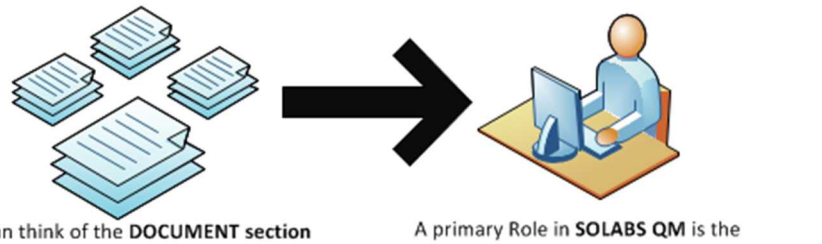
## Introduction

This document covers functions that the General User might need to use in **SOLABS QM10**. To find additional information on use of the **SOLABS QM10 DOCUMENT Section**, enter the word "Document" in the Search field of the SOLABS Knowledge Base.

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.

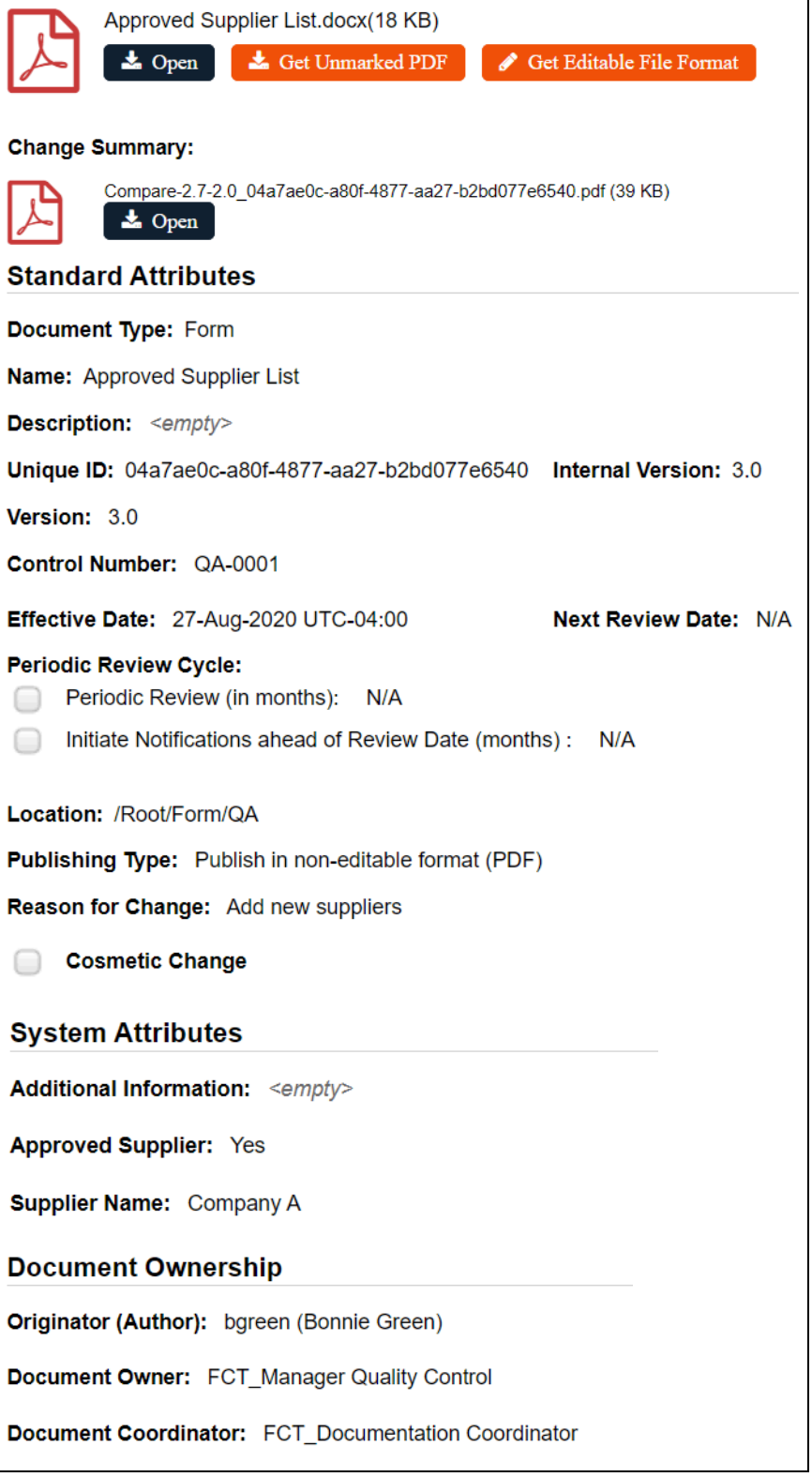
- During **Authoring** and **Review Cycle** stages, it will be an editable file.
- During **Approval Cycle** and when it becomes **Approved & Effective**, it will usually be rendered to a PDF.

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

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.

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.

The **Document Ownership** section includes the Author, Document Owner and Document Coordinator for the document, if set as required for the particular **Document Type**.



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.

**Approval Cycle**

| 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) |

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.

**Related Items**

**References**

**Name:** Validation Program **No.:** VAL-001 **Due:** <empty> **Status:** Approved & Effective Open | View

Expand all

**Training Activities for this Document**

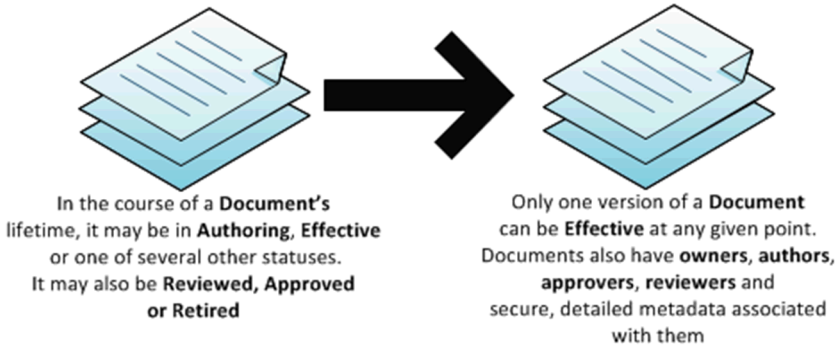
**Name:** SOP ENG-001, Equipment Calibra[...] **Due:** **Completion:** 100.0 % **Status:** Active View

Expand all

## 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

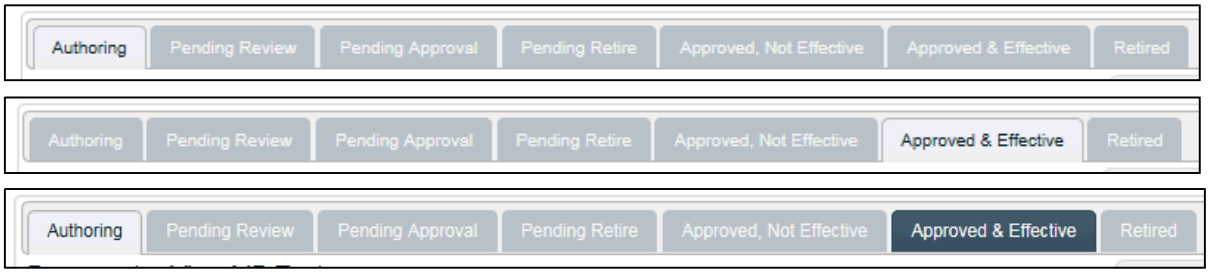
**Name:** Clinical Protocols and Checkli[...] **No.:** COP-001 **Due:** <empty> **Status:** Pending Review

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.<br><br>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. |

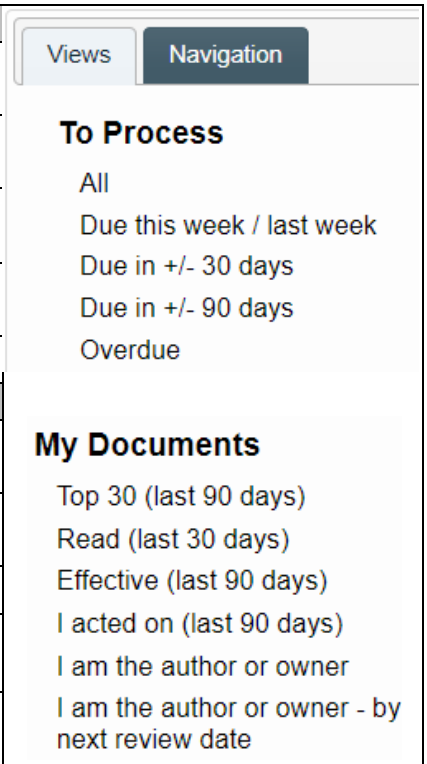
| | |
|---|---|
| **Approved & Effective** | This Document has completed the Approval Cycle and has also been made Effective. Depending on the Document settings, that can happen immediately upon the last Approval, after an Effective Date delay or at a pre-set date. |
| **Retired** | This document has 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. |

- 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.

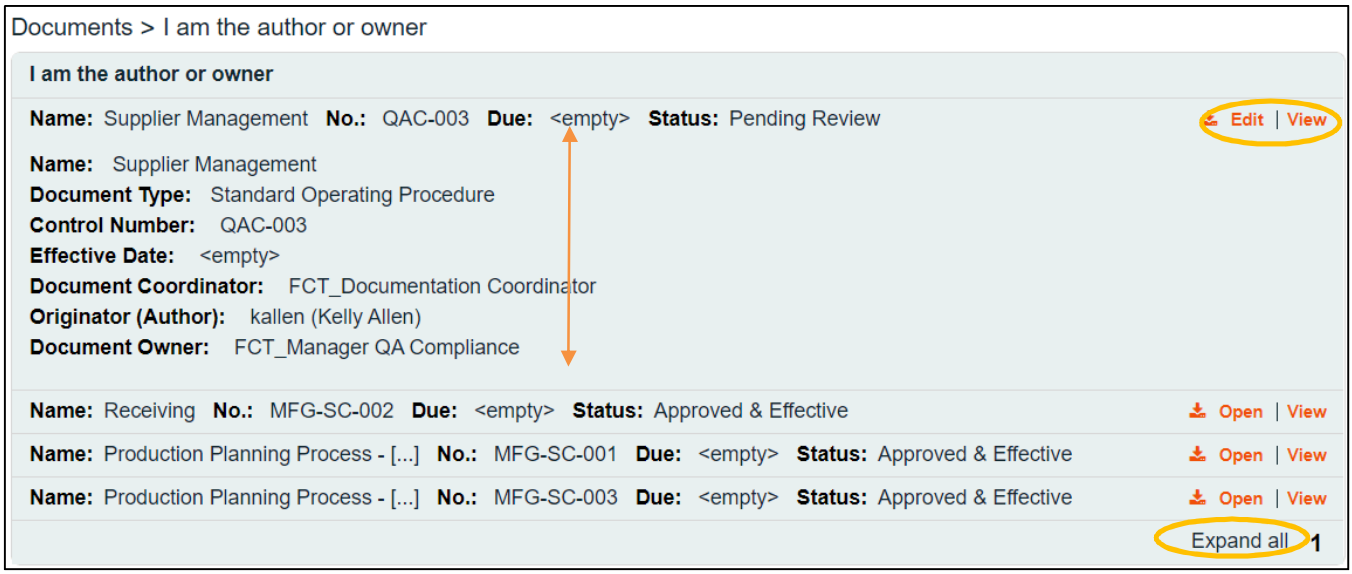
| **To Process** |
|---|
| **All:** All documents currently requiring action on the part of the User. This is the default view starting with Release 10.9. |
| **Due this week/last week:** Documents due to act on this week or in the previous week. This is the default view in Releases 10.8 and earlier. |
| **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 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 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).

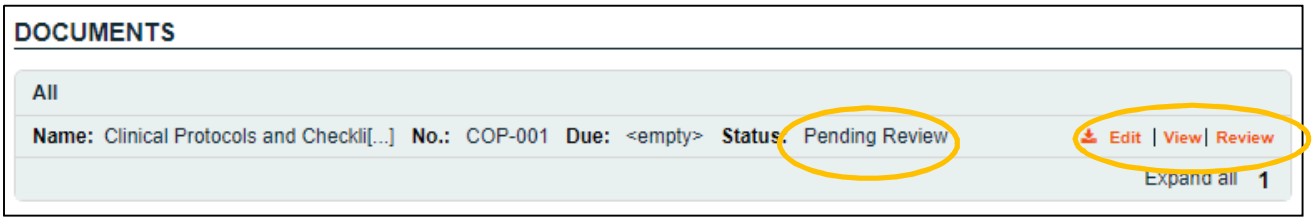



# Searching for/Locating a Document

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.

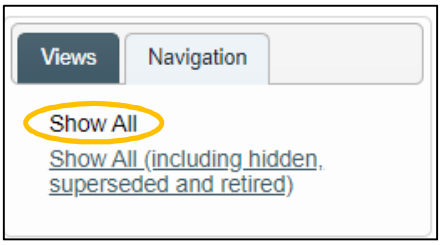



## Method 2: Navigation > Show All > Treeview

- 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.**

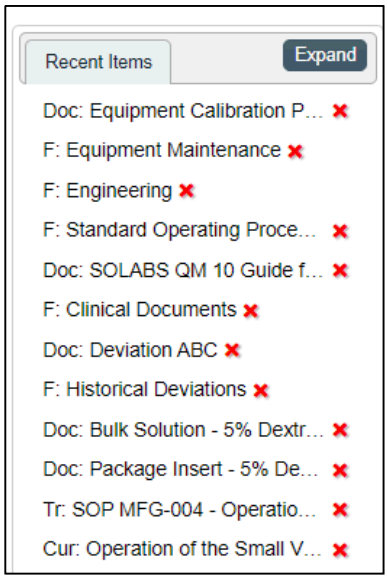
  The option **Show All (including hidden, superseded and retired)** is available only to SOLABS Document Administrators since they have the appropriate privileges, to also see Hidden documents and folders such as those used to store Related Documents for Training Activities or Processes and documents 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 and click **Open** (to open the document) or **View** (to view document metadata) from the right-hand **Actions** menu.

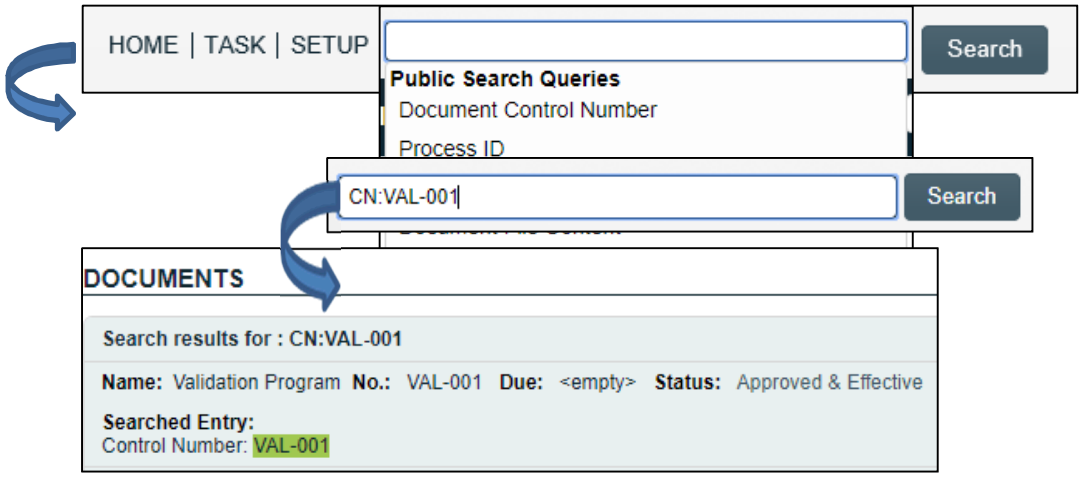
## Method 3: Left Hand Menu Views

The **Views** described on page 5 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

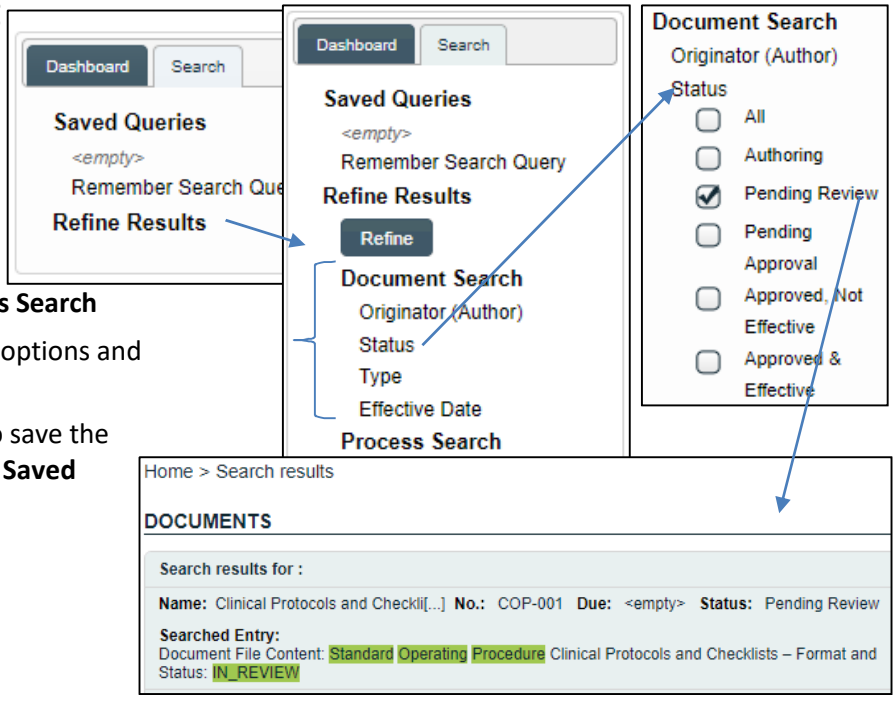
The Search field at the top of the screen can be used for targeted Searches for Documents or Processes. Additional, more advanced Search capability is also available if needed, and is described in a separate Knowledge Base document titled **SOLABS QM10: Enhanced Search Features.**




## 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**.



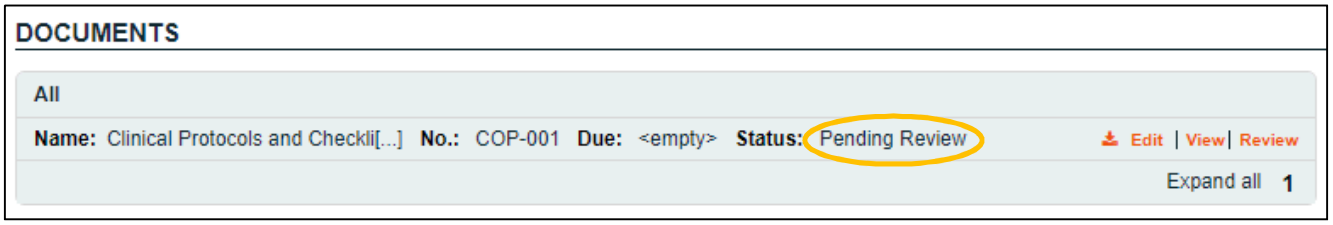
## Viewing a Document

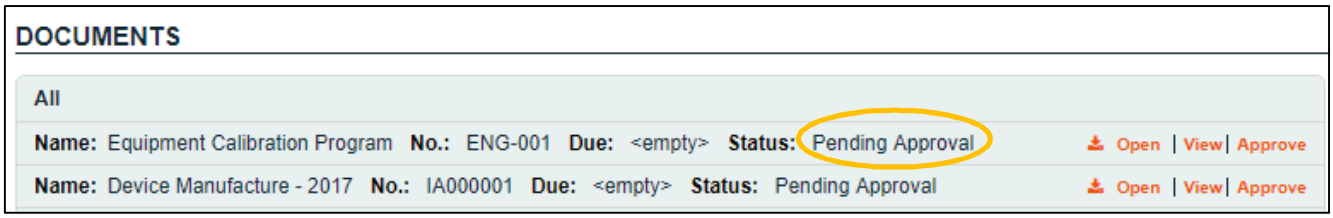
After using any of the above methods to locate a document it will be listed in a Document Listing Table, as described on Page 6 of this document.

## 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 QM10 if required, and the document will be listed in the DOCUMENTS section of the **HOME** screen.




Refer to the following documents in the SOLABS Knowledge Base for the actual transactions involved in completing a Review Cycle and an Approval Cycle:

- **SOLABS QM10: Document Review Cycle**
- **Introduction to SOLABS QM10 Document Section**