

SOLABS QM10: Introduction for General Users

Table of Contents

Login Page.....	2
HOME Page	3
Center Panel.....	3
Header Layout	3
Left Hand Side Menus.....	4
Search Engine	5
Using the Search Field at the Top of the Screen	5
Search Tab and Saved Queries	6
PROCESS Section	7
Introduction	7
Left Hand Side Menus.....	7
Right-Hand Quick Access Process Menu.....	8
Start Process.....	8
Process Flowchart.....	8
Right-hand Side Menus from Within Process View Pages.....	9
Process Actions.....	9
Act on.....	9
Related Items	9
Linking Documents to a Process.....	10
Linking another Process to a Process.....	11
Related Information.....	11
DOCUMENT Section	12
Introduction	12
Left Hand Side Menus.....	12
Right-Hand Quick Access Document Menu	13
Right-hand Side Menu from Within Document View Page.....	13
Acting On a Review Cycle.....	13
Acting On an Approval Cycle.....	14
TRAINING Section.....	16

Introduction 16

Left-hand Side Menus 16

Right-hand Quick Access Training Menu 16

Right-hand Side Menu from Within a Training Activity View Page 18

View and Confirm a Training Activity 18

TASK Section 20

 Introduction 20

 Left-hand Side Menus 20

 Right-hand Quick Access Task Menu 20

 Right-hand Side Menu from Within Task Details Pages 20

 Acting on a Task 21

SETUP Section 22

 Introduction 22

 Left-hand Side Menus 23

 Email Notifications 23

 User Account Information 24

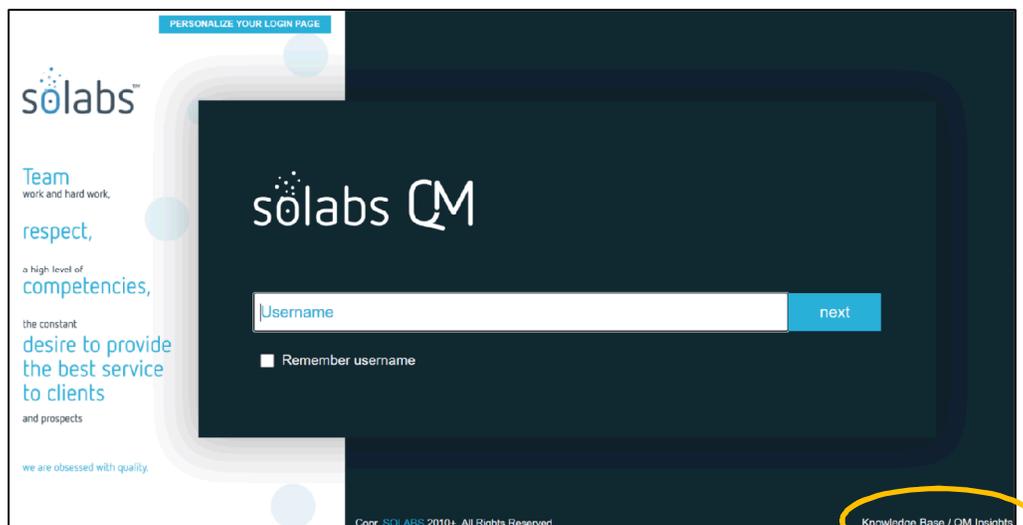
 Login Page Background 24

Login Page

You will log into SOLABS QM10 using a Username and a Password, unless your company has arranged to configure SOLABS QM10 with single sign-on (SSO) from either Azure AD or One Login. After a pre-determined number of consecutive failed attempts, your account will be locked and will need to be unlocked by an Administrator.

This image is the Login Page for a SOLABS Identity Login Type. Access using SSO with Azure AD or One Login will look different.

There is a link to the SOLABS Knowledge Base at the bottom right-hand corner of the Login Page, as well as one to the QM Insights Podcast Series.



HOME Page

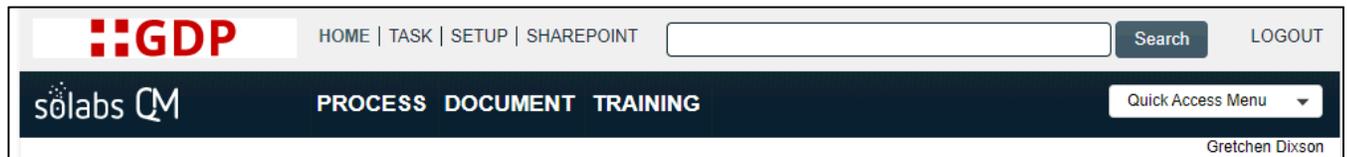
Center Panel

The **HOME** page Center Panel displays all outstanding tasks assigned to the user, categorized by section.

- The **PROCESSES** section defaults to list the outstanding process steps for which the user needs to take action.
- The **DOCUMENTS**, **TRAININGS** and **TASKS** sections default to list all items currently assigned to the user.

NOTE: Prior to QM10 Version 10.9, the default setting for all of the above lists was items with due dates either in the current week or the previous week. With 10.9, the broadest views are the defaults so that users can see everything pending – whether it has a due date or not and whenever it may be due. Users can then change the view to tighter timeframes if needed.

Header Layout



The SOLABS QM header displays:

- Company logo – if set up by the SOLABS System Administrator in System Configurations
- Links to the main areas of the application:
 - **TASK**
 - **SETUP**
 - **SHAREPOINT** – provides access to Reports Portal for those who have permissions to it
 - **PROCESS**
 - **DOCUMENT**
 - **TRAINING**
- **HOME**: Returns to the homepage from anywhere in the application.
- **Search** field
- **LOGOUT** link
- **Quick Access Menu**: Allows you to quickly access commonly-used actions, updating those actions to correspond to whatever section of the application you are currently using.
- Username for the logged in user

NOTE: Always use **LOGOUT** to end a **SOLABS QM** session as opposed to simply closing your web browser. A session is established with the **SOLABS QM** server as soon as the login page is accessed. As a timeout is configured for **SOLABS QM**, you might have to log back in if you have left a page idle for more than 15 minutes or so (depending on the timeout configuration). Once the session has become inactive, clicking anywhere on the user interface will take you back to the Login Page.

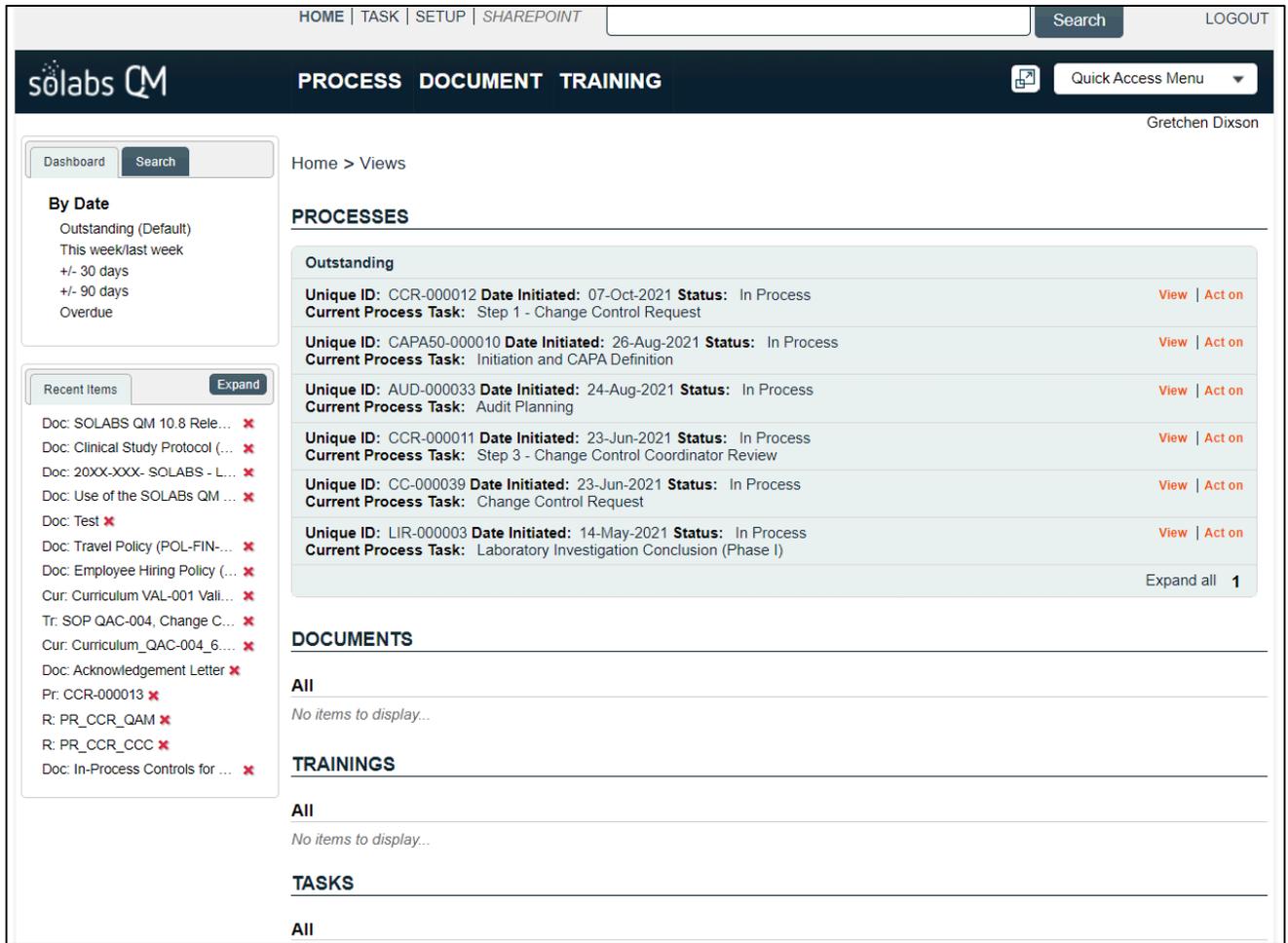
Left Hand Side Menus

The left-hand side of the **HOME** page includes **Dashboard** and **Search** tabs, as well as a **Recent Items** section.

The **Dashboard** tab provides menu options to sort pending tasks by timeframes other than the default of all outstanding tasks.

- Outstanding (default view starting with version 10.9)
- This week/last week
- +/- 30 days
- +/- 90 days
- Overdue

All of these filters produce user-specific results. Your Role assignments, permissions and process task schedules will impact what is displayed.



The screenshot shows the solabs QM interface. At the top, there is a navigation bar with 'HOME | TASK | SETUP | SHAREPOINT' and a search box. Below this is a dark header with the solabs QM logo, 'PROCESS DOCUMENT TRAINING', and a 'Quick Access Menu' dropdown. The user's name 'Gretchen Dixon' is displayed in the top right.

The left-hand side menu is visible, showing 'Dashboard' and 'Search' tabs. Under 'By Date', there are options: 'Outstanding (Default)', 'This week/last week', '+/- 30 days', '+/- 90 days', and 'Overdue'. Below this is the 'Recent Items' section with an 'Expand' button. The list of recent items includes:

- Doc: SOLABS QM 10.8 Rele... x
- Doc: Clinical Study Protocol (... x
- Doc: 20XX-XXX- SOLABS - L... x
- Doc: Use of the SOLABS QM ... x
- Doc: Test x
- Doc: Travel Policy (POL-FIN... x
- Doc: Employee Hiring Policy (... x
- Cur: Curriculum VAL-001 Vall... x
- Tr: SOP QAC-004, Change C... x
- Cur: Curriculum_QAC-004_6... x
- Doc: Acknowledgement Letter x
- Pr: CCR-000013 x
- R: PR_CCR_QAM x
- R: PR_CCR_CCC x
- Doc: In-Process Controls for ... x

The main content area shows 'Home > Views' and a section titled 'PROCESSES'. Under 'Outstanding', there is a table of processes:

Unique ID	Date Initiated	Status	Current Process Task	View	Act on
CCR-000012	07-Oct-2021	In Process	Step 1 - Change Control Request	View	Act on
CAPA50-000010	26-Aug-2021	In Process	Initiation and CAPA Definition	View	Act on
AUD-000033	24-Aug-2021	In Process	Audit Planning	View	Act on
CCR-000011	23-Jun-2021	In Process	Step 3 - Change Control Coordinator Review	View	Act on
CC-000039	23-Jun-2021	In Process	Change Control Request	View	Act on
LIR-000003	14-May-2021	In Process	Laboratory Investigation Conclusion (Phase I)	View	Act on

Below the processes section, there are sections for 'DOCUMENTS', 'TRAININGS', and 'TASKS', each with an 'All' link and a message 'No items to display...'.

The **Recent Items** section displays the last 15 items accessed and saves a list of up to 100 items that the logged in user has recently accessed, including documents, folders, curricula, training activities, processes, etc. The **Expand** option opens this list in a separate window.

Search Engine

The search engine searches all content of the **PROCESS** and **DOCUMENT** sections, including the content of the documents (where editable file types were originally uploaded). The search returns results based on your privileges, i.e. you will not obtain search results for documents to which you do not have access. There are 2 different ways to use the Search engine.

Using the Search Field at the Top of the Screen

Enter your search term and select **Search**. The searches are not case sensitive.

If you have entered multiple words, you will obtain all results that include **either** of those words.

Unique ID: DOC-000082 **Date Initiated:** 07-Apr-2022 **Status:** Completed
Current Process Task: N/A

Searched Entry:
 Process Name: Document **Control**
 Process Values: 2022-04-29 00:00:00.0 5195 New test Method Action on a **Change Control** Process Compendial Testing

Unique ID: CC-000039 **Date Initiated:** 23-Jun-2021 **Status:** Cancelled
Current Process Task: N/A

Searched Entry:
 Process Name: **Change Control**
 Process Values: 00:00:00.0 3903 CC-000039 3900 3897 Demo **Change** Request Implement QM10 **Change Control** Process to

If you put quotation marks on either side of a multi-word search, you will obtain only results that include that exact term.

Unique ID: CC-000006 **Date Initiated:** 12-Jul-2018 **Status:** Cancelled
Current Process Task: N/A

Searched Entry:
 Process Name: **Change Control**

Unique ID: CC-000026 **Date Initiated:** 09-Jan-2019 **Status:** Completed
Current Process Task: N/A

Searched Entry:
 Process Name: **Change Control**
 Process Values: 1717 CC-000026 1714 1711 Test **Change Control** Baker Product Stage 1 Internal Manufacturing Site 2

To narrow your search, hit the Backspace key while in the Search field. A list of available **Public Search Queries** will be displayed to help you narrow the search. Choosing an option will bring up a prefix, after which you type in your search term.



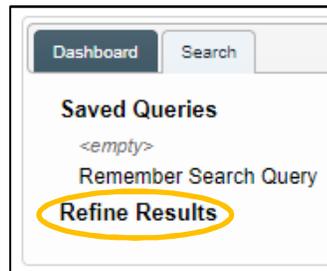
The above example shows the prefix for Document Control Number. Prefixes for the other choices are Pid:, DN:, DFC:, DA:, PIN:, PCW: and Pdata:. Depending on your version of SOLABS QM, there may be other options available.

Search Tab and Saved Queries

The **Search** tab on the left-hand side of the **HOME** page provides options to further **Refine Results** for your searches, and also to save them.

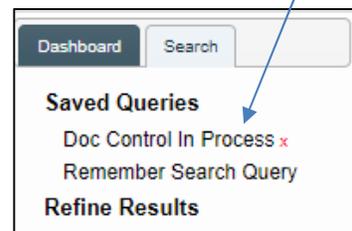
After clicking on **Refine Results**, a number of options to refine searches will be available, for both Document Section and the Process Section.

Make a selection and then click on the **Refine** button. The results will then be displayed on the the HOME page. As mentioned previously, the listing will be based on the privileges you have QM10 sections.



Click **Remember Search Query**, enter a name for the search and then click on the **Save** button.

The saved **Query Name** is added to the **Search** tab under **Saved Query** and is available for future use.



PROCESS Section

Introduction

A process consists of various process steps (or process tasks) assigned to users or roles, as shown on a process flowchart, and is known as a Workflow.

The **SOLABS QM10 PROCESS Section** is used to electronically assign workflow tasks related to those processes, such as Change Control approvals, Deviation investigations, CAPA approvals, etc. that are part of these controlled business processes. These processes are known as **SOLABS QM10 APPs**.

To access the **PROCESS** Section, click on the **PROCESS** link in the Header.

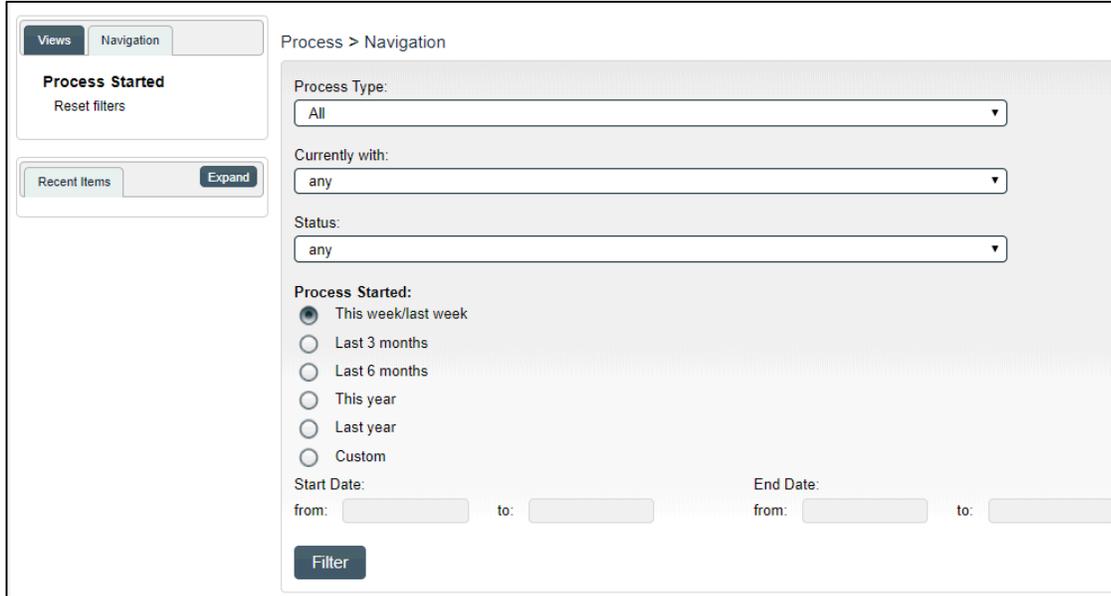
Views	Navigation	Process > Outstanding	
My Processes Outstanding Received this week / last week Received in last 30 days Received in last 30 to 60 days Received in last 60 to 90 days Acted on in the last 90 days		Outstanding	
		Unique ID: CCR-000012 Date Initiated: 07-Oct-2021 Status: In Process Current Process Task: Step 1 - Change Control Request	View Act on
		Unique ID: CAPA50-000010 Date Initiated: 26-Aug-2021 Status: In Process Current Process Task: Initiation and CAPA Definition	View Act on
		Unique ID: AUD-000033 Date Initiated: 24-Aug-2021 Status: In Process Current Process Task: Audit Planning	View Act on

Left Hand Side Menus

The **Views** tab provides various options to search for process tasks that are assigned to you and require action.

- **Outstanding:** This view (default view starting with version 10.9) contains all active process steps assigned to the logged in User that have not yet been acted upon.
- **Received this week/last week:** This view (default view with earlier versions) contains the active process steps assigned to the logged in User in the previous week or the current week and have not yet been acted upon.
- **Received in the last 30 days:** This view contains the active process steps assigned to the logged in User in the past 30 days, that have not yet been acted upon.
- **Received in the last 30 to 60 days:** This view contains the active process steps assigned to the logged in User in the past 30 to 60 days, that have not yet been acted upon.
- **Received in the last 60 to 90 days:** This view contains the active process steps assigned to the logged in User in the past 60 to 90 days, that have not yet been acted upon.
- **Acted on in the last 90 days:** This view contains all process steps accessed by the logged in User in the last 90 days.

The **Navigation** tab provides filters to search for Processes by **Process Type**, who they are **Currently with**, the **Status** and when the **Process Started**. You can choose specific timeframes by choosing **Custom** under **Process Started** and then using the date fields. To get ALL processes in your search criteria, choose **Custom** and leave the date fields empty.



Right-Hand Quick Access Process Menu

When the User is in the **PROCESS** Section of SOLABS QM10, the **Quick Access Menu** changes to a **Process Menu**. For general users, it includes one option: **Start Process**. Users with the **SOLABS System Administrator** role assignment will also have an option to **Manage Privileges**.

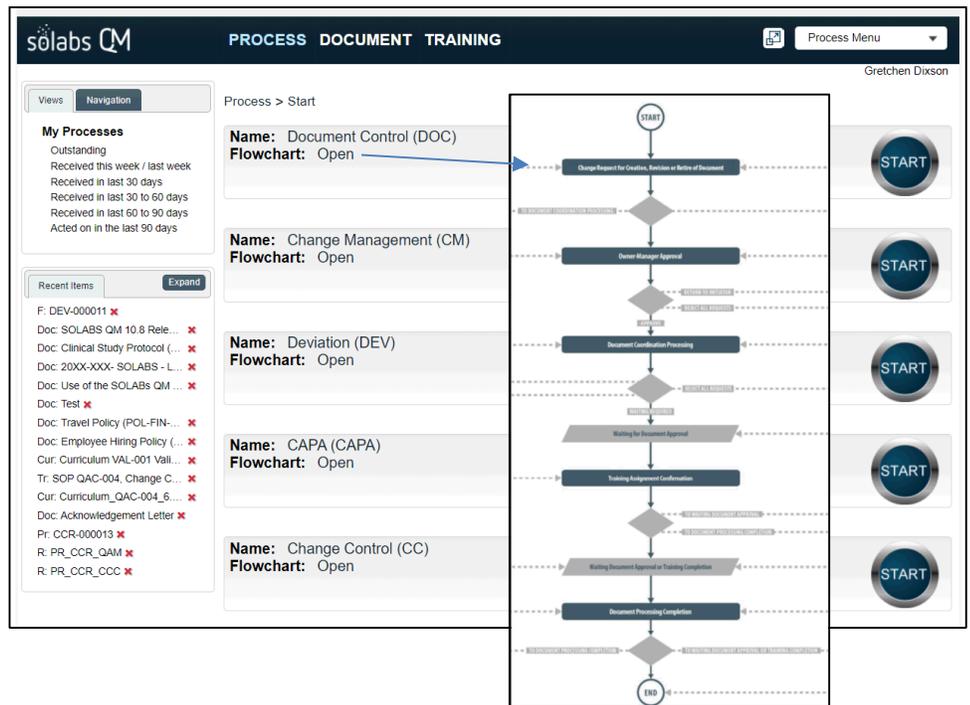
Start Process

Clicking on the **Start Process** option from the Quick Access Process Menu will load a list of all the processes that the logged in User has the privileges to start.

To start a process, click the **START** button. You can also review the process before starting by clicking on the **Open** link next to **Flowchart**.

Process Flowchart

Every process available in **SOLABS QM** has a flowchart to help visualize the process flow. As the process advances, the active step in the process will be highlighted.



Right-hand Side Menus from Within Process View Pages

After starting a process, the **Process View** page will be displayed. Throughout the process workflow, the right-hand menus from within the **Process View** pages allow various process functions.

Process Actions

- **View:** The Process View page shows the current step of the process. The **Process Values** table can be expanded to allow you to quickly see all the values that have been added to the process so far. At the bottom of the view page, you can see the **Related Items** that have been linked to the process so far. The **Secondary Tasks** section shows all the secondary tasks that have been created and assigned to different users or roles for the process so far.
- **Modify Values:** This option allows you to modify information for your step of the process.
- **Reassign Tasks:** This option allows you to reassign your task if needed.
- **Cancel:** If a user has initiated a process by mistake, the process can be cancelled at Step 1. The cancelled process and the number it was automatically assigned (by clicking **Start** in the **Start Process** section) remain in the system. The status will be changed to **Cancelled**.
- **Get Link:** This option will provide a URL link to the process.
- **Email Link:** This option will open an email with the URL link, allowing you to send it to another person.
- **Move Out of Waiting:** This option applies only to process steps that are defined as Waiting Periods.



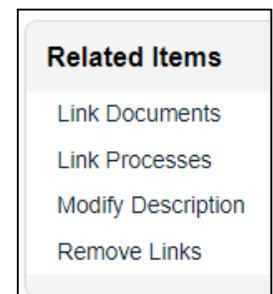
Act on

- **Act on:** This option is used to advance the process along by entering the required information and selecting any related decision for the process step assigned to you. If enabled for the step being acted upon, this action also allows creation of Secondary Tasks related to the process.

Related Items

The **Related Items** section allows you to attach supporting information to the process. This information will then be available from the Process View page at every step of the process.

- **Link Documents:** This option allows you to link an existing document from within SOLABS QM or a new document from outside SOLABS QM. See the next page for more detail on this option.
- **Link Processes:** This option allows you to link another existing SOLABS QM Process that may be related to the one you are working on. For example, a CAPA Process may have a related Deviation Process. See page 10 for more detail on this option.
- **Modify Description:** When linking documents or processes, you will provide descriptions of the linked document or process. This option allows you to modify those descriptions if needed.
- **Remove Links:** This option allows you to remove documents or processes that you had previously linked.



Linking Documents to a Process

There are two types of Documents that can be linked to a task in **SOLABS QM10**.

- **New Document**
- **SOLABS QM Document**

Linking a New Document

This provides the opportunity to upload a document from outside SOLABS QM10 as either **Effective** or **Draft** (in authoring status). Either option stores the document within the SOLABS QM10 database as a Hidden document in the Treeview. The document will be visible to the people assigned process steps. From the Treeview administrators can see the documents by selecting the Show Hidden documents option.

The screenshot shows the 'Related Items' form. At the top, there are radio buttons for 'Type': 'New Document' (selected) and 'SOLABS QM Document'. Below this is a large dashed blue box containing a cloud upload icon and the text 'Drag & drop file here' and 'OR SELECT FILE TO UPLOAD'. Underneath, there are two columns of radio buttons: 'Uploaded as' with 'Effective' (selected) and 'Authoring (Draft)', and 'Published as' with 'Non editable format' (selected) and 'Editable Format'. There are two text input fields: 'Linked Item Description' and 'Item Description'. At the bottom, there is a '+ADD' button, a 'Remove' link, a 'Copy>>' link, and 'Submit' and 'Cancel' buttons.

Upload Status Options

- **Effective:** If you upload the document as Effective, your e-signature will be required and you will be set as the final Approver of this document, with the upload date as the **Approved and Effective** date of the document.
- **Authoring (Draft):** Selecting this option simply uploads the document in authoring status and will not change the format of the document.

Upload Publishing Type Options

- **Non-Editable Format:** Document will be converted into PDF format.
- **Editable Format:** Document format will not be altered.

Description Fields

- **Linked Item Description:** This is the description of the item to which you are linking.
- **Item Description:** This is the description of the current item.

Linking a SOLABS QM Document

SOLABS QM Documents can be found by searching by the **Name** and/or **Control Number**, or by the **Location**.

All documents that meet the search criteria will be displayed in **Available** box. Documents can be selected and, after clicking **+ADD**, they go to **Linked** box.

The screenshot shows the 'Related Items' form for linking a SOLABS QM document. At the top, there are radio buttons for 'Type': 'New Document' and 'SOLABS QM Document' (selected). Below this is a 'Filter by:' section with radio buttons for 'Document Name and/or Control Number' (selected) and 'Location'. There is a text input field for the search criteria and a 'Filter' button.

Linking another Process to a Process

SOLABS QM Processes can be found by searching on the **Unique ID**. The process will then be displayed in **Available** box and, after clicking **+ADD**, will go to **Linked** box.

Linked Item Descriptions and **Item Descriptions** of linked documents can be modified. Simply select **Modify Description**, select the item to modify, make your changes, **Submit**, and verify your changes then **Confirm**.

Once submitted and confirmed, linked processes will be available in the Related Items section of the Process View screen, where anyone acting on a step in the process can view them.

Any **Linked process** can be discarded at any time before **Submit** by clicking **Discard**.

Related Items

Filter by:

Unique ID

CAPA-

Filter

Available:

- CAPA-000006
- CAPA-000007
- CAPA-000008
- CAPA-000009
- CAPA-000010

Select all Deselect all

Linked Item Description:	Item Description:

Linked:

Related Process

Unique ID: DEV-000008 Date Initiated: 29-Nov-2017 Status: In Process Discard

Current Process Task: QA Assessment

Expand all Discard all

Related Information

The **Related Information** menu contains access to the Audit Trail and Summary Report.

- **Audit Trail:** This option will display all information entered into the process so far.
- **Summary Report:** This option allows the creation of process reports for the selected process.

Related Information

Audit Trail

Summary Report

DOCUMENT Section

Introduction

The **DOCUMENT Section** is used to manage, process (i.e. review, approve or retire) and publish controlled documents.

The **DOCUMENT Section** also stores documents used in other **SOLABS QM** sections, such as those attached to Processes, Tasks and Training Activities.

Access to documents is controlled through user privileges, set by the Administrator at the Folder or Document level.

Left Hand Side Menu

The **Views** tab provides various options to search for documents that are assigned to you. The view loaded is user specific and contains only documents for which the logged in user must take action.

To Process

- **All** (default view starting with version 10.9)
- **Due this week / last week** (previous default view)
- **Due in +/-30 days**
- **Due in +/-90 days**
- **Overdue**

My Documents

This menu option provides options to search for documents previously acted on.

Document Coordinator

The menu options ending in “-my” are available for Users with privileges to review, approve or create/modify documents. The menu options ending in “-all” are available only for Document Coordinators.

The **Navigation** tab “Show All” loads the **Treeview** structure (hierarchical folders) of all **SOLABS QM** Documents. Users will see only the documents for which they have privileges.

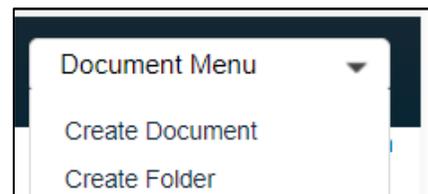
By highlighting a document title and then clicking **Actions > View**, the selected Document View page is loaded. This page contains document metadata and current status.

The screenshot shows the 'Views' tab selected. Under 'To Process', options include 'All', 'Due this week / last week', 'Due in +/- 30 days', 'Due in +/- 90 days', and 'Overdue'. Under 'My Documents', options include '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', and 'I am the author or owner - by next review date'. Under 'Document Coordinator', options include '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', and 'Rejected during approval'. The main content area shows 'Documents > All' with a document titled 'Name: HPLC System Suitability No.: QC-001'.

The screenshot shows the 'Navigation' tab selected. The 'Show All' option is highlighted, with a sub-option 'Show All (including hidden, superseded and retired)'. Below this, the breadcrumb 'Document > Folders > View' is shown. The 'Treeview' section displays a hierarchical structure of folders: 'Root', 'Annual Product Reviews', 'Audit Reports', 'Calibration and Maintenance', 'Master Calibration and Maintenance Checklists', 'Scanned Copies - Completed Calibration and Maintenance Checklists', and 'Clinical Documents'. The selected document is 'CAL-001 / 2.0 (1.2) / Calibration Checklist - Packaging Line Checkweighers - [Authoring]'. The 'Actions' menu is open, showing 'Open' and 'View' options. The 'Privileges' menu is also visible, showing 'View'.

Right-Hand Quick Access Document Menu

This menu will be empty for a general User in the system. For a User with at least Modify privileges on some documents, it will include the **Create Document** and the **Create Folder** options.

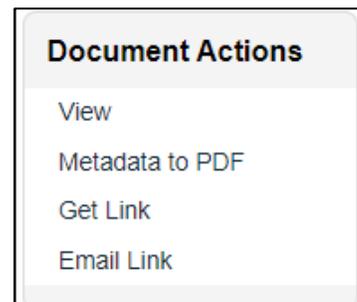


Right-hand Side Menu from Within Document View Page

The right menus contain actions available according to the document status and the privileges assigned to the logged in User.

Document Actions Menu Options (for General Users with only Summary View permissions)

- **View:** Loads Document View page
- **Metadata to PDF:** Displays the document metadata in the Solabs cover page view
- **Get Link:** Generates the direct link to the selected document in SOLABS QM10
- **Email Link:** Automatically pastes the link into an email using your email client



Document Workflow Menu Options (for Users with Review/Approve, Modify or Administer permissions)

The menu options in this section will change depending on the status – Authoring, Pending Review, Pending Approval – of the document. These options are used to **Act on** those tasks and are described in other User Guides related to document creation, review, approval or administration activities.

Acting On a Review Cycle

To access a **Document** assigned to you for review, click **View** or **Review** from your HOME page, or access it via the link in the email **Notification**.



Clicking **View** takes you to the **Document View** page, where you can see the metadata as well as access the document itself. Simply double click the **Document Name** or the **Edit** button to open and view the file. If significant comments are warranted save the document to your desktop to make changes using the Word Track Changes capability. It can then be imported and attached as part of a **Reviewed See Comments** Feedback Decision.

If your company is using Office 365 and has enabled the Collaborative Review feature, you will also see an **Edit Online** button. This will alleviate the need to export, edit and then import the document to make revisions since changes can be made and retained right in the system.

A **Compare** file is also available in the Change Summary section if your company has chosen to use this option. This file will highlight the proposed changes in a Track-Changes format.

To take action in the Review Cycle task assigned to you, select the **Provide Feedback** option under **Document Workflow**.

The screenshot displays the document management interface for 'View SOLABS QM 10 System Administration Menus'. The document is currently in the 'Approved & Effective' state. The interface includes a 'Document File' section with a Word document icon and an 'Edit' button. Below it is a 'Change Summary' section with a PDF icon and an 'Open' button. The 'Standard Attributes' section lists document metadata such as 'Document Type: Computer System User Guide', 'Name: SOLABS QM 10 System Administration Menus', 'Description: User Guide for SOLABS QM 10 System Administration Menus', 'Unique ID: 2284dada-0b52-461e-9d9d-f4bc840f5db8', 'Internal Version: 1.2', 'Version: 2.0', 'Current Version: 1.0', and 'Control Number: UM000001'. On the right side, there are three panels: 'Document Actions' (View, Metadata to PDF, Get Link, Email Link), 'Document Workflow' (Provide Feedback, highlighted with a yellow circle), and 'Related Information' (Authoring History).

You are then provided 3 **Decision** options:

- **OK, no change:** Cycle progresses
- **Reviewed, see comments:** You must provide comments in the **Comments** field and also have the ability to upload a file with your tracked changes (if Office 365 feature is not enabled).
- **Cycle stopped with comments:** You must provide your rationale for stopping the cycle in the **Comments** field and also have the ability to upload a file.

Acting On an Approval Cycle

To access a **Document** assigned to you for approval, click **View** or **Approve** from your Home page, or access it via the link in the email **Notification** sent to you.

The screenshot shows a table of documents under the heading 'DOCUMENTS'. The table has a filter 'All' and a row for a document with the following details: 'Name: In-Process Controls for Check [...]', 'No.: MFG-002', 'Due: <empty>', and 'Status: Pending Approval'. To the right of the status are three buttons: 'Open', 'View', and 'Approve', with 'View' and 'Approve' highlighted by a yellow circle. Below the row is an 'Expand all 1' link.

Clicking **View** takes you to the **Document View** page, where you can see the metadata as well as access the document itself. Simply double click the **Document Name** to open and view the file. The **Compare** file is also available in the Change Summary section if your company has chosen to use this option. This file will highlight the proposed changes in a Track Changes format.

NOTE: Before you can approve or reject a document it must be opened. If it is not opened, you receive an error message.

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

Document > View In-Process Controls for Check Weighers

Visibility: Visible

Document File

File:

 InProcess Controls for Checkweighers.docx(9 KB)

[Open](#) [Get Unmarked PDF](#) [Get Editable File Format](#)

Change Summary:

 Compare-3.4-3.0_ced8e03e-26d2-4386-a62a-8db57e3289a9.pdf (27 KB)

[Open](#)

Standard Attributes

Document Type: Standard Operating Procedure

Name: In-Process Controls for Check Weighers

Description: In-Process Controls for Check Weighers

Unique ID: ced8e03e-26d2-4386-a62a-8db57e3289a9 Internal Version: 3.5

Version: 4.0 Current Version: 3.0

Control Number: MFG-002

Document Actions

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

Document Workflow

- Approve/Reject**
- Stop Cycle

Related Information

- Audit Trail
- Authoring History

To take action on the Approval Cycle task assigned to you, select the **Approve/Reject** option under **Document Workflow**.

The **Approval Cycle** section will then be displayed. You can also go directly to this section by selecting **Approve** from your **HOME** page.

Select the **Awaiting Approval** option next to your name. You will then have 2 **Decision** options.

Document > Document Workflow > Approval Cycle

Visibility: Visible

Document File

File:

 InProcess Controls for Checkweighers.docx(9 KB)

[Open](#) [Get Unmarked PDF](#) [Get Editable File Format](#)

Standard Attributes

Name: In-Process Controls for Check Weighers

Document Type: Standard Operating Procedure

Version: 4.0

Control Number: MFG-002

Unique ID: ced8e03e-26d2-4386-a62a-8db57e3289a9

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_Manager Manufacturing / egriffin (Emily Griffin)	<empty>	<empty>	<empty>
<input type="radio"/> Awaiting Approval	1	N/A	FCT_Associate Director Quality Assurance / rgonzales (Ronald Gonzales)	<empty>	<empty>	<empty>

Document Actions

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

Document Workflow

- Approve/Reject**
- Stop Cycle

Related Information

- Audit Trail
- Authoring History

- **Approve:** You must enter a **Meaning** of either Originator(Author) or Approver.
- **Reject:** You must enter a reason in the Comments field. The **Approval Cycle** is then stopped for all participants.

Decision:

Approve

Reject

* Comments:

* Meaning:

Originator (Author)

Approver

TRAINING Section

Introduction

The **TRAINING Section** is used by Users who have the SOLABS Training Administrator role assignment, to create and assign training activities. It is used by General Users to access and complete Training Activities assigned to them, and to check their Training Status.

Left-hand Side Menus

The **Views** tab has a number of different options under **Outstanding Activities**, to search for training activities assigned to you.

- **All** (default view starting with version 10.9)
- **Due this week / last week** (default view with earlier versions)
- **Due in + -30 days**
- **Due in + -90 days**
- **Overdue**
- **Confirmed in the last 90 days** (but awaiting further action from the Trainer, Manager or Training Administrator such as Second Confirmation or a Grade)

Views Navigation

Outstanding Activities

All

Due this week / last week

Due in +-30 days

Due in +-90 days

Overdue

Confirmed in the last 90 days

Managers and Trainers

For Users who are Managers or Trainers, they can use the options under **Managers and Trainers**, to search for any Second Confirmations that may be waiting for them to perform.

Managers and Trainers

Second confirmation required

Confirmation overdue

Users who have the **SOLABS Training Administrator** role assignment have additional Views under **Training Coordinators** and options on the **Navigation** tab, that help them manage training for the organization. Refer to the Training Administration User Guide if you have this responsibility.

Right-hand Quick Access Training Menu

The Training Status option on this menu can be used by the logged in User to view the Training Activities associated with their Function Roles and to check their status on Training Activity assignments.

Training Menu

Training Status

The first section of the Training Status screen provides a color-coded visual display of any **Overdue Training Activities** and of overall **Training Compliance Status**. Clicking on the **View** option above the red bar will bring the User directly to any Overdue assignments.

Training > Training Status

Overdue Training Activities: 100.0% (2/2)

[View](#)

Profile Actions

[Training Status](#)

[Assign Myself Activities](#)

Training Compliance Status: 87.5% (14/16)

87.5%
(14/16)

- Part of my Job Title Profile
- Other activities assigned

Overview

Training activities per Job Title (number)

FCT_Engineering (Engineering) : 0

FCT_Supervisor Site Maintenance (Supervisor Site Mainter) : 0

Other training activities (number)

Doreen Kim (dkim) : 0

Details [Open](#)

Job Title: FCT_Engineering (Engineering) [Open](#)

Job Title: FCT_Supervisor Site Maintenance (Supervisor Site Maintenance) [Open](#)

Activities linked to my Job Title Profile and not assigned:

Job Title: FCT_Engineering (Engineering) [Open](#)

Job Title: FCT_Supervisor Site Maintenance (Supervisor Site Maintenance) [Open](#)

Other activities currently assigned:

Doreen Kim (dkim) [Open](#)

Details [Close](#)

Job Title: FCT_Engineering (Engineering) [Close](#)

<empty>

Job Title: FCT_Supervisor Site Maintenance (Supervisor Site Maintenance) [Close](#)

Curriculum: Curriculum VAL-001 Validation Program

Activities	Due Date	Status
GDP Validation Program View	12-Jun-2017	Trained
SOP VAL-001 Validation Program View	12-Jun-2017	Trained

Curriculum: Curriculum_ENG-001_3.0_V.3.0

Activities	Due Date	Status
SOP ENG-001, Equipment Calibration Program View	22-Nov-2017	Awaiting End-User Confirmation

Curriculum: Employee Orientation

Activities	Due Date	Status
GDP HR Policies View	16-May-2017	Trained
GDP Medical Products - Company Overview View	16-May-2017	Trained
Introduction to GMPs View	16-May-2017	Trained
Safety Orientation View	16-May-2017	Trained
SOLABS QM 10 - Introduction for General Users View	16-May-2017	Trained

Curriculum: MFG-001 Dress Code for GMP Areas

Activities	Due Date	Status
OJT - Gowning Procedures for GMP Areas View	31-Jul-2017	Trained
SOP MFG-001 Dress Code for GMP Areas View	15-Jun-2017	Trained
Working in a GMP Manufacturing Environment View	30-Jun-2017	Trained

Curriculum: QADT-001_3.0_V.3.0

Activities	Due Date	Status
SOP QADT-001, Employee Training View	09-Oct-2017	Awaiting End-User Confirmation

Curriculum: Supervisor/Manager Training

Activities	Due Date	Status
Employee Development View	16-May-2017	Trained
GDP Performance Management Program View	21-Nov-2017	Trained
Labor Law Regulations View	16-May-2017	Trained

The **Overview** section provides the User with information on the number of **Training activities per Job Title** (Function Role) and any **Other training activities** assigned to them.

The **Details** section has various **Open** links that provide more detailed information on those assignments. After clicking on the **Open** option, each assigned activity is listed, along with the current status of the activity. Each listed Training Activity has a **View** option next to the title, that will bring the User directly to the **Training Activity View** Page for that Training Activity, if they would like to see even more detailed information.

Right-hand Side Menu from Within a Training Activity View Page

Most of these menus are used by Training Administrators, so are not discussed within this document. The Activity Confirmation menu will be available to General Users to confirm their training or to provide Second Confirmations.

View and Confirm a Training Activity

When a **Training Activity** is assigned to a User, it appears in their HOME Page, and they also receive an email **Notification** with a link directly to the activity in **SOLABS QM**. From the **Home** page, the user can click **View** or **Train**. (In versions prior to 10.9 these options were listed as View or Confirm.)

TRAININGS			
All			
Name:	SOP QADT-001, Employee Trainin[...]	Due: Completion: 7.6 % Status: Active	View Train
Name:	SOP QADT-003, Initiating a Doc[...]	Due: 28-May-2021 UTC-04:00 Completion: 11.8 % Status: Active	View Train
Name:	SOP QA-001, Batch Record Revie[...]	Due: Completion: 12.5 % Status: Active	View Train

Clicking **View** takes the user to the **Training Activity View** page, where all details of the activity are provided.

The large **Record my Training** button is new with version 10.9.

The **Completion Percentage** is for all people assigned, and not the logged in user.

Training > Curriculum_QADT-001_4.0_V.4.0 > SOP QADT-001, Employee Training > View

Status: Active
Completion Percentage : 7.6 %

Record my Training

Curriculum Document [\(Details\)](#)

File:

Training Program.doc(494 KB)

Open
View

Change Summary:

Compare-3.2-3.0_8303254f-3585-4870-9327-cd1fe1e839b5.pdf (669 KB)

Open

Training Activity Details

Name: SOP QADT-001, Employee Training **# of Attempts Allowed:** Unlimited

Category: Read and Confirm

Training Video(s):

Description:
Read and confirm understanding of SOP QADT-001, Employee Training

Purpose :
Required Knowledge

Method of Instruction:
Read and Confirm

Method of Evaluation:

Estimated Duration: 0.00 hour(s) **Cost:** 0.00\$

Estimated Start Date: 06-Jul-2021 UTC-04:00 **Estimated End Date:**

Created by: Automatically by System **Creation Date:** 06-Jul-2021 UTC-04:00

My Schedule

User	Estimated Start Date	Estimated End Date
eblake (Evan Blake)	06-Jul-2021 UTC-04:00	

Activity Actions

[View](#)

[Get Link](#)

[Email Link](#)

Activity Confirmation

[Record my Training](#)

Job Title Profile

[View](#)

Training Activity Assignment

[View End Users](#)

If the **Training Activity** is linked to a document within **SOLABS QM**, the name of the document is there with a link that allows them to easily access the document. A **Compare** file is also available (if this option is used by your company), so that the User can easily identify what has been changed since the previous version they trained on.

The **Training Activity Details** section provides additional information on the Category and the Description for the assignment.

Once the User has completed their training, they can select the **Record my Training** button or the option under **Activity Confirmation**.



The Activity Confirmation menu will also include an option for **Open Assessment** if your company is using the interface with SOLABS' partner Questionmark and has linked an online Training Assessment to the Training Activity. This is covered in a separate document available in the SOLABS Knowledge Base. Starting with version 10.9 there is also an **Open Assessment** button at the top of the screen is an assessment is linked.

Open Assessment

NOTE: If the Training Activity is for reading of a document, the document will have to be opened first before the Record my Training option can be used. Otherwise, the following message will be displayed.

Training Activity cannot be confirmed because the related Master Document has not been opened

A similar message will be displayed if a Training Assessment is linked and has not been opened and completed.

In order to confirm your training, you need to complete the related assessment. Access the assessment by using the Open Assessment option.

After opening the document and/or assessment, if applicable, choosing the **Record my Training** option displays the **Record as End User** fields. Users can also access the **Record as End User** fields by selecting **Train** (or **Confirm** prior to version 10.9) directly from their HOME Page.

To record completion of a Training Activity, simply enter the hours and minutes spent on the training. Then click **Submit**. You will be prompted to enter your E-signature (Username and Password) and then **Confirm**.

Record as End User

Activity Completed:

Confirm

Not Applicable

Confirm Later

Time spent on Training:

hours

minutes

0	15	30
45	60	75
90	105	120

Record as End User

Activity Completed: Confirm

Time Spent: 1 hour(s) 00 minute(s)

E-Signature required

* Username:

* Password:

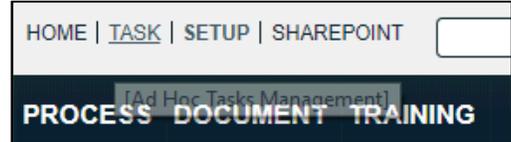
Electronic signature is the legally binding equivalent to a handwritten signature.

Logged in Audit Trail

TASK Section

Introduction

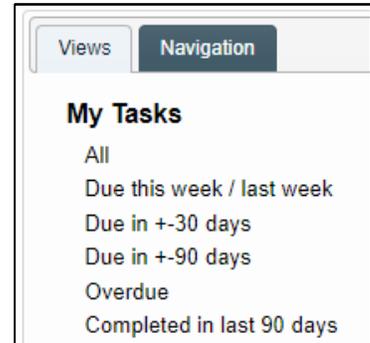
The **TASK** Section is accessible through the top menu bar by clicking **TASK**. This section is used for processing tasks assigned to roles or to specific users. **Tasks** can be created directly from the **TASK** Section or can be initiated as **Secondary Tasks** from within a **SOLABS QM Process**.



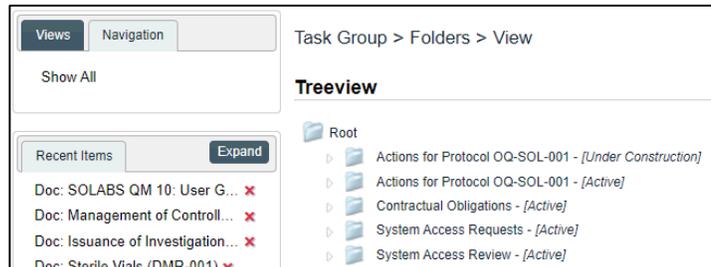
Left-hand Side Menu

The **Views** tab is loaded by **Default** and has different options to display any pending **Tasks** assigned to the user.

- **All** – default view starting with version 10.9
- **Due this week / last week** - previous default view
- **Due in + -30 days**
- **Due in + -90 days**
- **Overdue**
- **Completed in last 90 days**



The **Navigation** tab displays all tasks in a **Treeview** format if your company is using Task Types and Task Groups to create and assign Ad Hoc Tasks (those not associated with Process Apps).



Right-hand Quick Access Task Menu

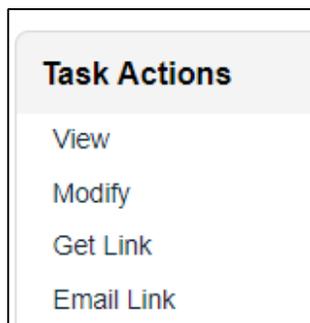
The Quick Access Task Menu contains 2 main items: **Create Task** and **Create Task Group**.



Right-hand Side Menu from Within Task Details Pages

Task Actions - displays actions according to the privileges set for the user.

- **View**
- **Act on**
- **Modify**
- **Cancel**
- **Get Link**
- **Email Link**



Task Related Items - allows attachment of supporting information

- *Link Documents*
- *Link Processes*
- *Modify Description*
- *Remove Links*

Related Items

- Link Documents
- Link Processes
- Modify Description
- Remove Links

Acting on a Task

If you have an Ad Hoc **Task** or a **Secondary Task** assigned to you to complete it will be listed in your HOME Page, and you would also have received a link to the task via email **Notification**.

Secondary Tasks are created as part of an active Process Workflow, such as a Change Control or Deviation Process.

Click on the **Act on** link from the HOME Page (or the link in the email) and you will be taken to the **Act on** page for the task.

As a general user assigned a **Task**, you cannot modify any details in the task; you can simply update the status and provide **Comments**.

Task > Act on

Task Details

Name: Secondary Task 1

Type: CAPA Task Unique ID: CAPA-00000001

Description: Demo

Reference Date:

Location: Root/test

Available Task Groups

Estimated Start Date Offset: Estimated End Date offset:

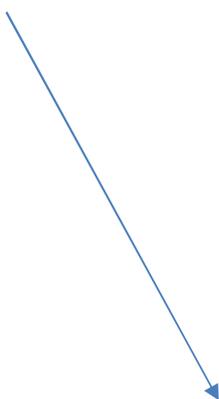
Estimated Start Date: Estimated End Date: 31-Jan-2018

Start Date: Clear End Date: Clear

Status:

- Not Started
- In Progress
- Pending
- Completed
- Return to Originator

Comments:



SETUP Section

Introduction

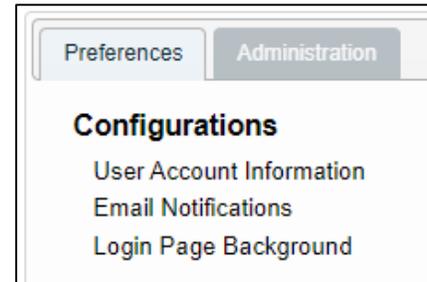
The **SETUP Section** is used by general users as well as administrative users. This section deals mainly with account configurations visible to the General User.

To access the **SETUP Section**, click **SETUP** in the top menu. This will bring the logged in User to their User > View page, where they can view their **User Account Information**.

Setup > User > View		Status: Active
User Account Settings		
Account Type: Standard	Signature Graphic :	
Login Type: Database		
Sharepoint Access: N/A		
User Account Details		
Username: eblake	Language: English	
Full Name: Evan Blake	Alias: EB	
Email Address:	Employee ID:	
Time Zone: America/Montreal (UTC-04:00)	SOLABS Unique ID: 6111b3ake	
Company Structure Details		
Department Head: drennold (Delores Rennold)	Manager: rgonzales (Ronald Gonzales)	
Job Title: Employee Orientation Training; Project Plan 1 Team; QA Specialist; Quality; Quality Assurance		
Organization: GDP Medical Products	Division: GDP Medical Device Products; GDP Pharmaceutical Products	
Department: Quality	Sub-Department: Quality Assurance	
Assigned Roles		
FCT_Employee Orientation Training		
FCT_Project Plan 1 Team		
FCT_QA Specialist		
FCT_Quality		
FCT_Quality Assurance		
PR_CAPA_Reviewer		
PR_CCR_CCC		
PR_CC_Approver		
PR_CC_Owner		

Left-hand Side Menu

The **Preferences** tab provides access to **User Account Information**, **Email Notifications** and **Login Page Background**. By default, **User Account Information** for the logged in User is loaded.



Email Notifications

When choosing the **Email Notifications** option on the Left-hand Side Menu, the **Email Notification Actions** menu will be displayed on the Right-hand side from the **User Email Notifications** page. For General Users, it will have the following options:

Users can manage certain email notifications in **SOLABS QM10**. All **Notifications** that are active are listed with a check mark next to them.

Setup > User rcox (Roger Cox) > Active Notifications

Active Notifications

Username: rcox (Roger Cox)

Process Notifications:

- Dependent Process Started
- Process Task Reassigned

Document Notifications:

- Document Feedback Needed
- Document Reviewed on Your Behalf (as Part of Your Role)
- Document Reviewed Reviewed on Your Behalf
- Review Cycle Stopped with Comments
- Document Comments Provided

Email Notification Actions

Enable/Disable Notifications

To manage what **Notifications** you receive, choose **Enable/Disable Notifications**. You now have the ability to check and uncheck some of the notifications. Checking a notification means you wish to receive this notification. You can also check **All** directly under the section heading which will activate all the notifications within that section.

After confirming the action, all checked notifications are displayed in the view page.

Note: Not all notifications in the system can be disabled. Some notifications are not listed in the selection, or are greyed-out, as these are mandatory notifications.

Setup > User > Email Notifications > Manage

Email Notifications Configuration

rcox (Roger Cox)

Process Notifications:

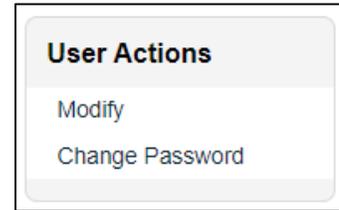
- All
- Dependent Process Started
- Process Task Reassigned

Document Notifications:

- All
- Document Feedback Needed
- Document Reviewed on Your Behalf (as Part of Your Role)
- Document Reviewed Reviewed on Your Behalf
- Review Cycle Stopped with Comments
- Document Comments Provided
- Review Cycle Completed, with Comments
- Review Cycle Completed, no Comments
- Document to Approve
- Document Approved on Behalf of a Role

User Account Information

When choosing the **User Account Information** option on the Left-hand Side Menu, the **User Actions** menu will be displayed on the Right-hand side from the **User View** page. For General Users, it will have the following options:



Modify

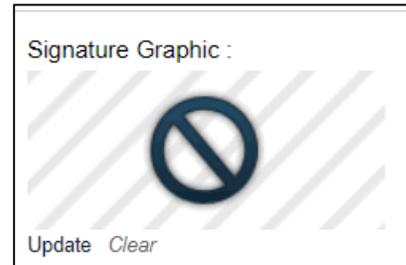
Language can be chosen from the available language list. English is the only option currently.

Language:

A Signature Graphics can be uploaded at any time after user is created.

There are certain restrictions for signature files:

- Cannot exceed 180x80px
- Must be less than 100K
- Accepted formats are jpeg, gif or png



Change Password

The **User** will be asked to provide current password and new password. The **Password** will be changed after confirmation.

NOTE: Password can only be changed if user's Account Type is **Standard**.

Password

Password:

New Password:

Confirm New Password:

Login Page Background

When choosing the **Login Page Background** option on the Left-hand Side Menu, the **Login Page Background > View** screen will be displayed. It will display the current Login Page background with an option to **Modify**.



Clicking on **Modify** will allow you to change your Login Page Background. The current background will be displayed. There is an **Update** option above the PREVIEW display.

Clicking on the **Update** option will bring up the file size requirements and a **Choose File** button.

Choosing a file will bring it up in PREVIEW. If you like it, you are done. If not, you can choose Update again and select another one.

Setup > User > Login Page Background > Modify

Login Page Background