SOLABS QM10: Introduction to PROCESS Section

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Purpose of this Guide

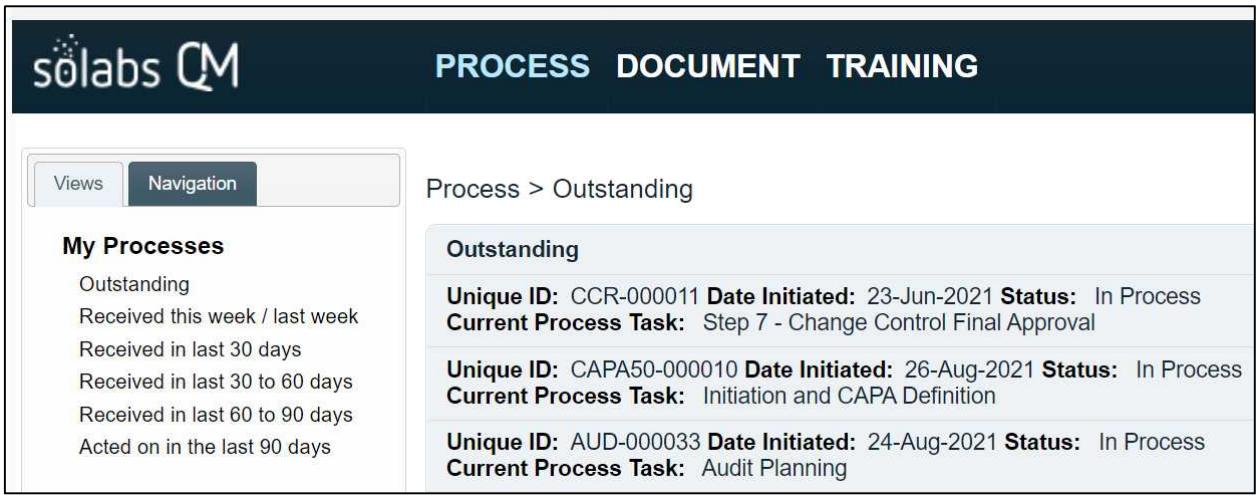
Processes in **SOLABS QM10** (Process APPs) are unique to your place of work and the way you do things. User Guides are available for all off-the-shelf Process APPs. Although each process may be different, there are some things they have in common with respect to navigation and capabilities – that is what this Guide covers.

PROCESS Section

The **PROCESS** section allows you to monitor complex workflows, approvals, reviews—any workflow process that can be flowcharted electronically.

Different steps in a process are assigned to different roles and/or users in the system. You take action on the step assigned to you. For example, you may be assigned a **QA Approval** step in a **Change Control** process. A manager can monitor the status of process tasks assigned to their employees by using the Process Section search capabilities or the Process Reports to query process status by user.

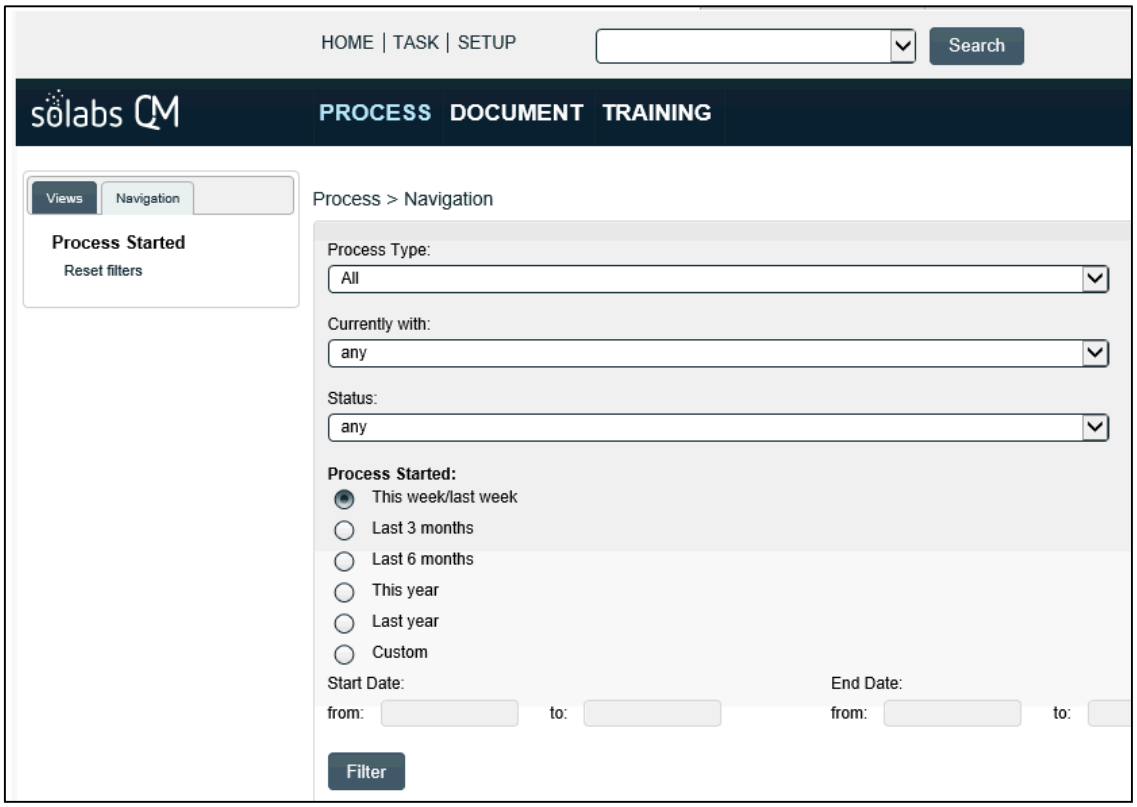
Left-hand PROCESS Section Menu – Views/My Processes



The **Views** tab provides options for the User to find Process tasks/steps that are assigned to them.

- **Outstanding**: This view contains all process steps assigned to the logged in user that have not yet been acted upon. Starting with Release 10.9 this is the default view when the Process section is loaded.
- **Received this week/last week:** This contains all the active processes steps that were assigned to this user in the previous week or the current week. This is the default view for earlier Releases of QM10.
- **Received in the last 30 days:** This contains all the active processes steps that are assigned to the logged in user in the past 30 day that need action taken.
- **Received in the last 30 to 60 days:** This view contains all process steps assigned to the logged in user that have been assigned 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 all process steps assigned to the logged in user that have been assigned in the past 60 to 90 days that have not yet been acted upon.
- **Acted on in the last 90 days**: This view contains the list of all process steps that have been accessed in the last 90 days.

Left-hand PROCESS Section Menu – Navigation/Process Started



The **Navigation** tab provides filters to help the User search for information on a Process.

- **Process Type:** This drop-down list will contain all Process APPs currently deployed in **SOLABS QM**10 for your workplace.
- **Currently with:** This drop-down list will include all your active **SOLABS QM10** users and allows you to get a list of pending Process tasks assigned to a selected user.
- **Status:** This drop-down list allows you to search for Processes that are in the following status: In-Process, Completed, Cancelled
- **Process Started**: The options in this section allow you to more narrowly refine your search by timeframes. If you select "Custom", the Start Date and End Date fields will be enabled. To find ALL processes in a desired category, choose "Custom" and leave the date fields blank.

After you set your search criteria, clicking on the **Filter** button will bring back a list of processes that meet that criteria.

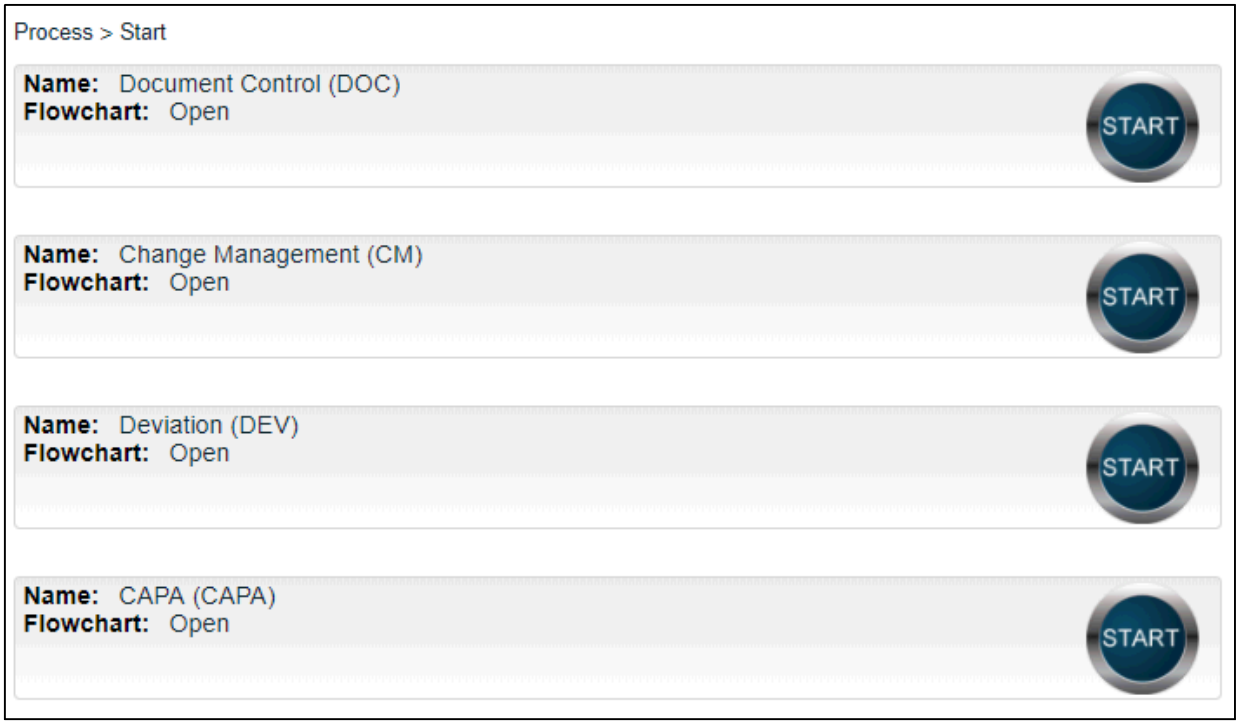
Right-hand PROCESS Section Menu

When you are in the **PROCESS** Section, the right-hand Quick Access **Process Menu** provides the options to **Start Process** and **Manage Privileges.** The Manage Privileges option is available only for System Administrators.

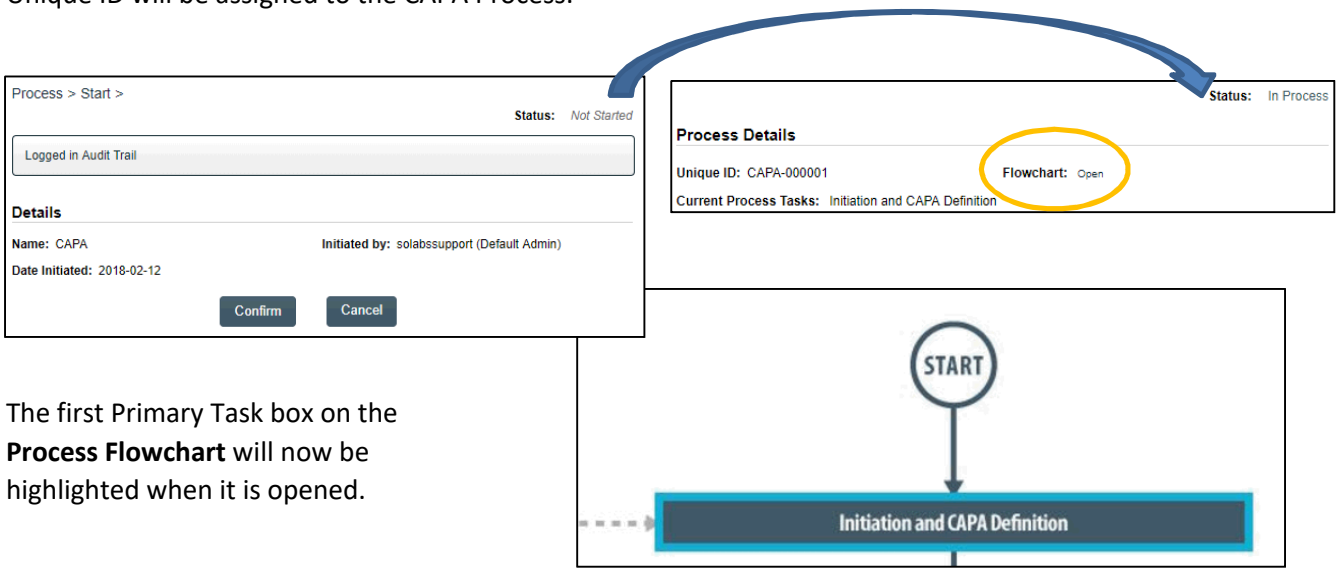
Selecting the **Start Process** option brings up a **START** buttons for any Process APPs deployed in you instance of QM10. The **Document Control Process** and (starting with Release 10.9) the **Audit Process**, are deployed as part of the Core Software QM Essentials Package. Other **Process APPs** may also be deployed for your workplace. The related Flowcharts can be opened from this list.

Starting a Process

Click on the **START** button next to the SOLABS QM10 Process you wish to initiate.



You will then be asked to **Confirm** this action, to move **Status** from *Not Started* to *In Process*. At this point a Unique ID will be assigned to the CAPA Process.



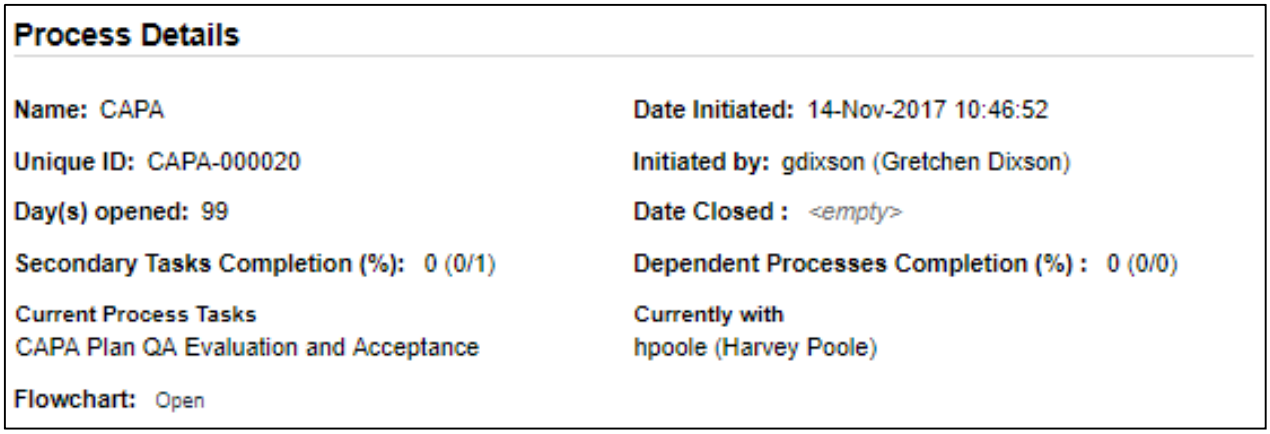
The first Primary Task box on the **Process Flowchart** will now be highlighted when it is opened.

Process Page

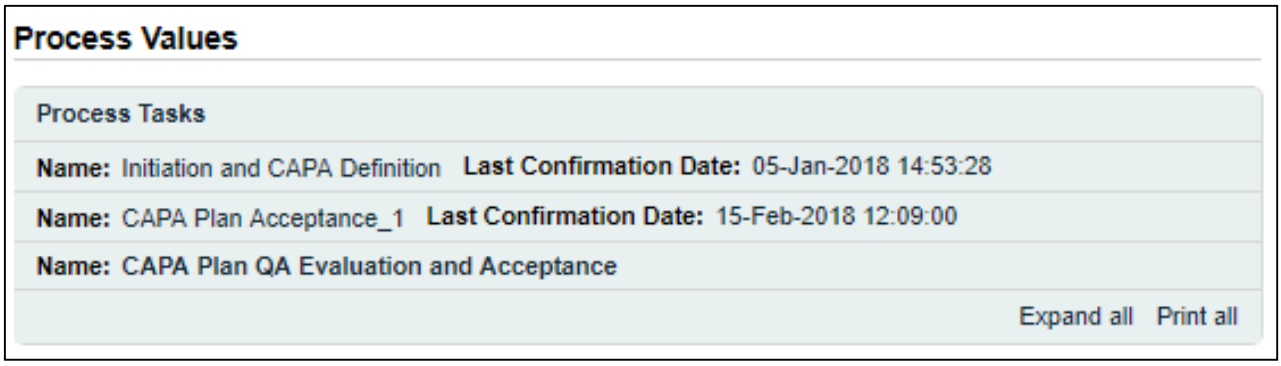
Overview of the Sections

When a Process is started, and at each step as the Process progresses, the **> Act on** page will be displayed to allow entry of required metadata for the first step of the process. That Process Status is now "In Process". The contents of this page will vary for each process but there are some things common to most Processes:

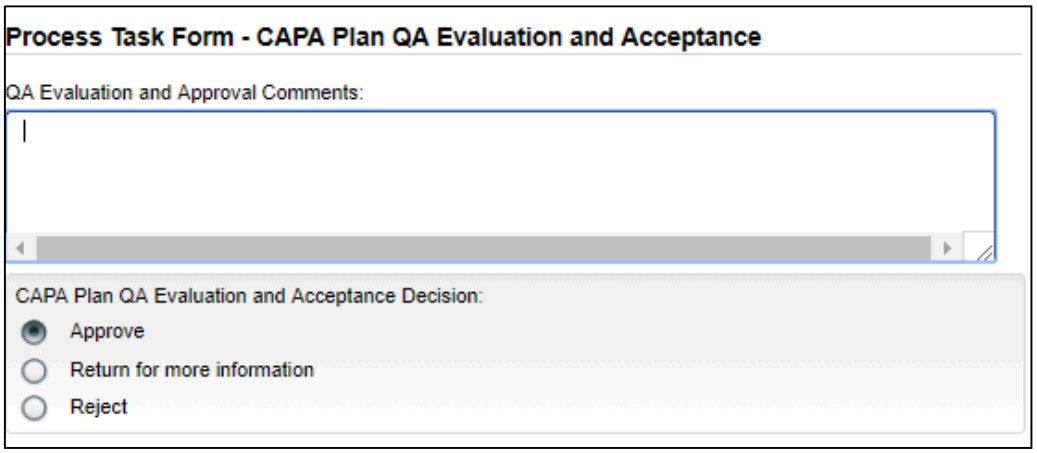
- **Process Details:** This section will display the **Name,** the **Date Initiated**, the **Unique ID** assigned to the process, who it was **Initiated by**, the number of **Day(s) opened**, the **Date Closed**, the status of **Secondary Tasks Completion (%)** and **Dependent Processes Completion (%)**, the **Current Process Task,** who it is **Currently with** and a link to the **Flowchart**.



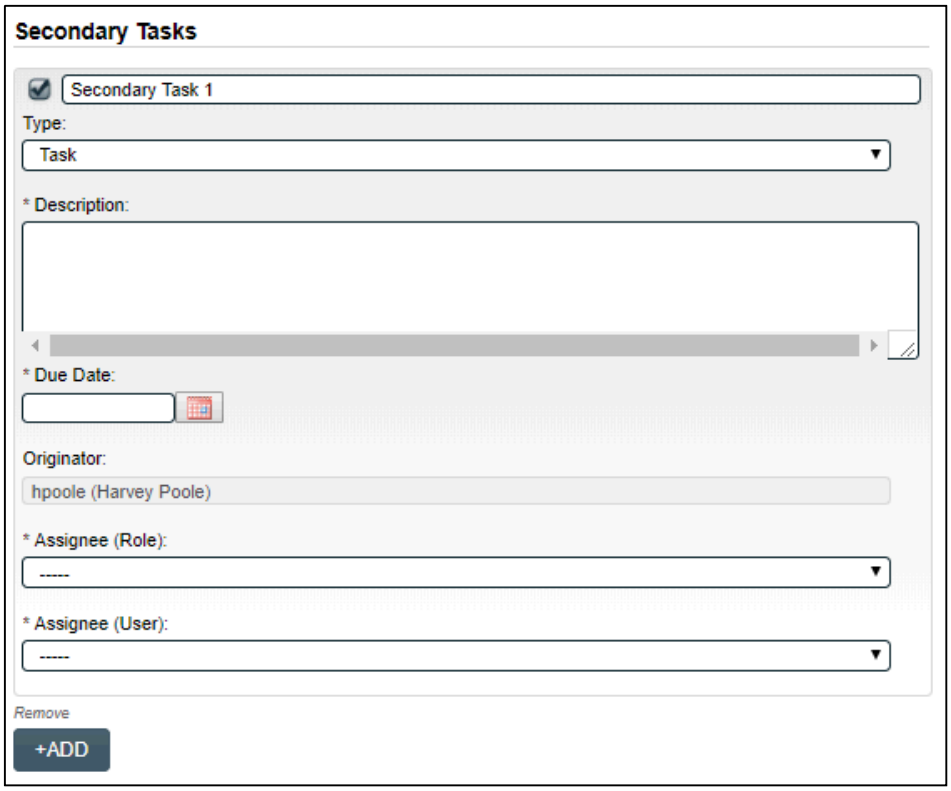
- **Process Values**: When the "Expand all" option is selected, all information that has been entered so far for this process will be displayed. Each listing can also be expanded individually. The expanded views can also be printed.



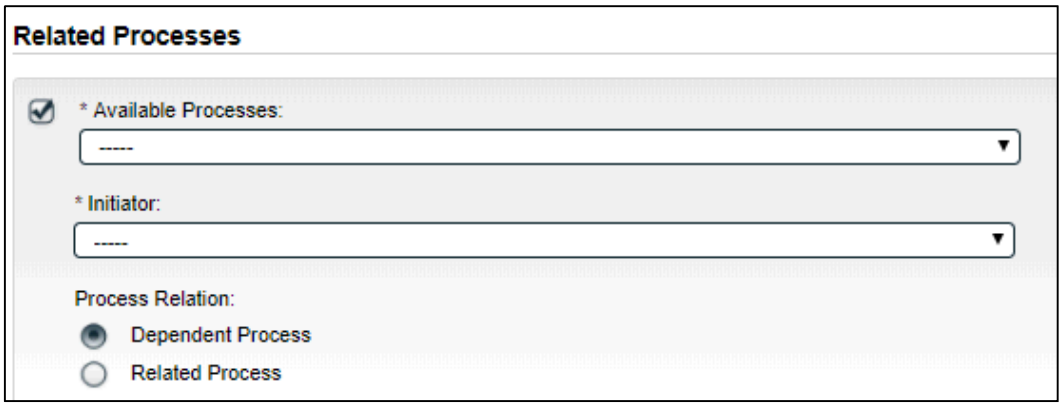
- **Process Task Form**: This section includes the metadata fields associated with the specific Process Step being acted upon. There may be many fields to complete, or only a few. Some of the fields on the **Process Task Form** are editable text fields or text areas. Others are single-item selection or multi-item selection fields. Some of the single-item selection or multi-item selection fields have values from configurable Custom Lists, that can be edited by your Document Administrator to be specific to your company. Fields with an asterisk (*) are mandatory.



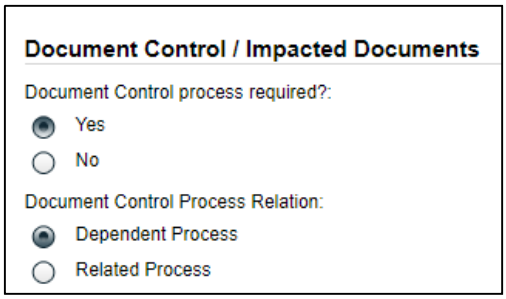
- **Secondary Tasks:** This section allows the person acting on a Process Step to create Secondary Tasks that will be associated with the Process. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the Process but that are not part of the Primary Workflow Tasks. This section may be enabled or disabled, depending on the Process APP, the related workflow steps and any client-specific customizations.



- **Related Processes:** This section allows the person acting on a Process Step to initiate one or more new processes from within the process they are acting on. The process from which the new process was started, is considered the **Parent Process**. The one being started is considered a **Child Process**. This helps avoid initiating multiple related processes and then needing to Modify one or more of them to Link Processes through the right-hand menus. The new process can be set as either a **Dependent Process** (to be completed before the Parent is closed) or a **Related Process.** In either case, each will be a Related Item of the other, listed in the **Related Items** section.



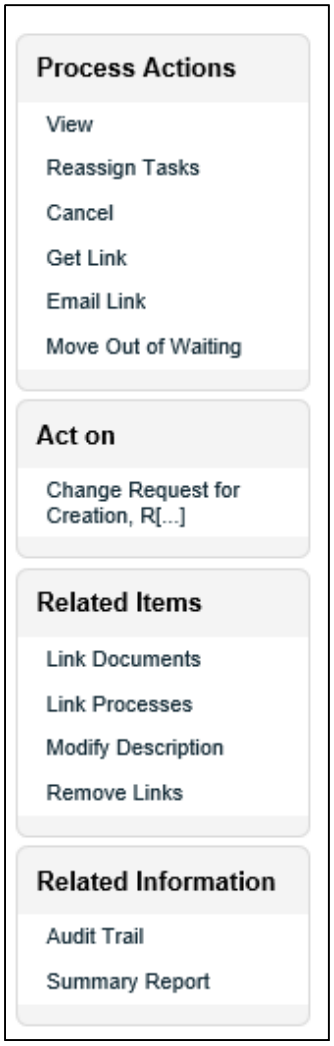
- **Document Control / Impacted Documents:** This section allows the person acting on a Process Step to initiate a **Document Control Process** to facilitate update of any documents impacted by the Parent Process. The Document Control Process can be set as either a **Dependent Process** (to be completed before the Parent is closed), or a **Related Process.**



- At the bottom of the Process Page there is a **Save Draft** option if you cannot complete all the required fields at one time.

CAUTION: If you navigate away from this page without clicking on either **Submit** or **Save Draft**, all entries will be lost. To complete the information after a **Save Draft** option, you can either choose the **Act On** option from the Process section of your HOME Page, or search for the process using the Navigation tab.

Process Page – Right-hand Menus



Process Actions

- **View:** This option brings up the **Process View Page** for the current step of the process. From this page, the **Process Values** table allows you to quickly see all the values that have been added to the process already. At the bottom on the page, you can see all the **Related Items** that have been linked to this process. 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.
- **Reassign Tasks:** This option allows process tasks to be reassigned to a different user, perhaps if the original assignee is out of the office or if another user might be a better choice for that task.
- **Cancel**: If a user has initiated a process by mistake, or it is deemed not necessary at some point in the workflow, it can be put to a status of Canceled. The cancelled process and the number it was automatically assigned (by clicking START in the Start Process section) will remain in the system. The status will be changed to Cancelled.
- **Get Link / Email Link:** These options bring up a https:// link to the process and allow you to email that link to another person.
- **Move Out of Waiting:** This step applies to Processes that include a Waiting Phase as part of the workflow and is available to users with the appropriate level of permission.

Act on

The option listed in this section will always be related to the task currently being acted on in the process. Choosing this option brings up the metadata fields required for that step in the process, which when filled in and Submitted will advance the process to the next step.

Related Items

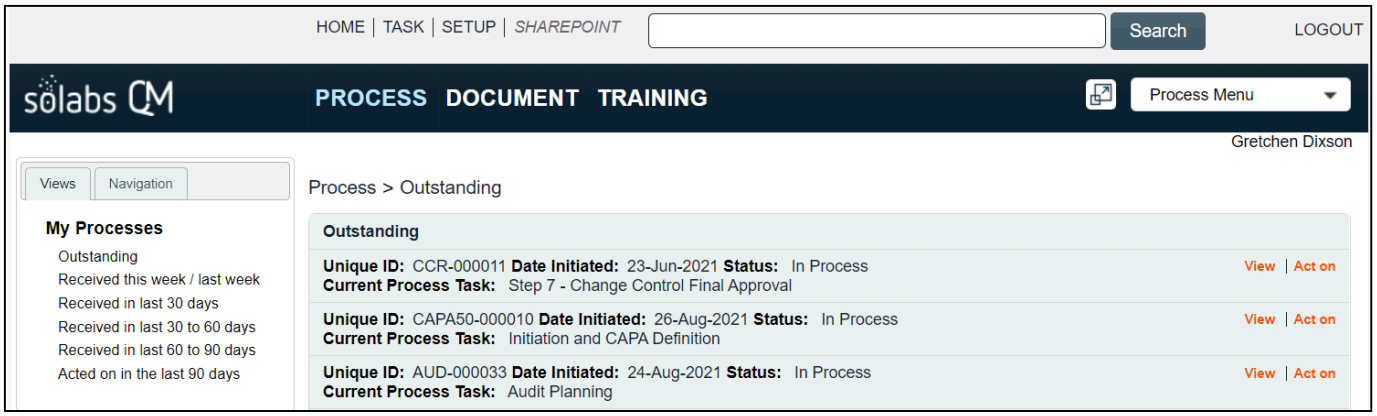
- **Link Documents:** This option allows you to attach supporting documents, either from within SOLABS QM10 or from outside SOLABS QM10. They will then be available to view from the Process View Page at every stop of the process.
- **Link Processes:** This option allows you to attach another related process. For example, a Deviation Process could have a related CAPA Process and could also require updates to documents being revised using the Document Control Process.
- **Modify Description:** This option allows you to edit the Description field that was completed when linking a document or a process.
- **Remove Links:** This allows you to remove any linked documents or processes.

Related Information

- **Audit Trail:** The Audit Trail will list all information entered into the process fields so far.
- **Summary Report:** This option allows you to generate printed reports for information on various stages of the process.

Acting on a Process Step

Process Steps currently assigned to you will be listed on the **HOME Page** center pane, in the **PROCESSES** section. You will also receive an **email Notification** with a **link** to the process.



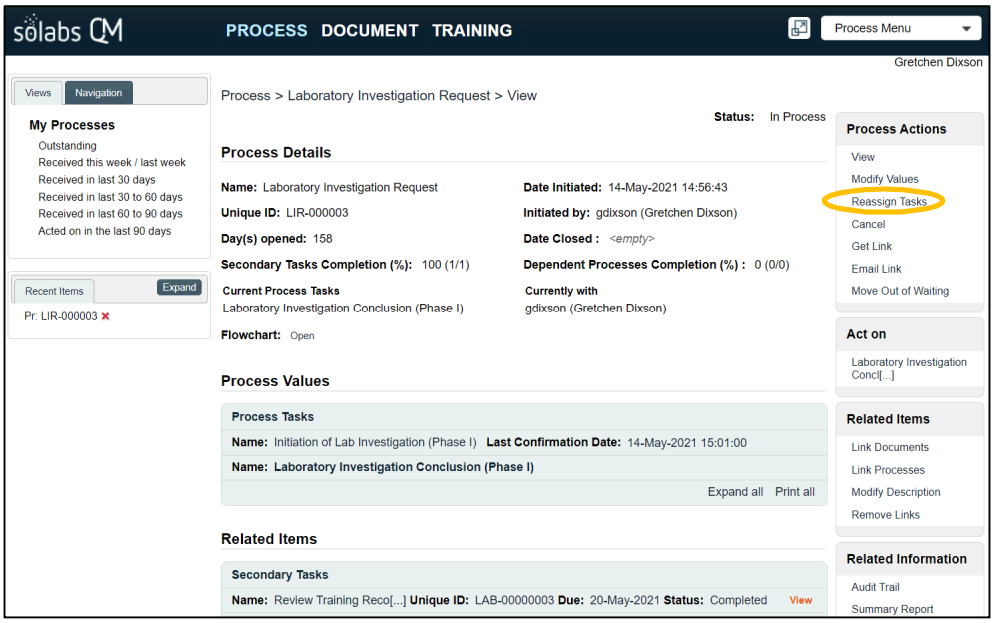
To access the Process Step you need to act on, click the **Act on** option from the listing on your Home Page or click on the link within the email Notification. This will bring you to the **Process Details** screen. You can review all prior information by expanding the **Process Values** table. The fields you are required to complete for your Process Step will be in the **Process Task Form** section. To also see any Related Items, click instead on the ***View*** option. There will be an Act on option within the View Page.

Re-Assigning a Process Step

Your privileges allow you to re-assign only process tasks that are assigned to you.

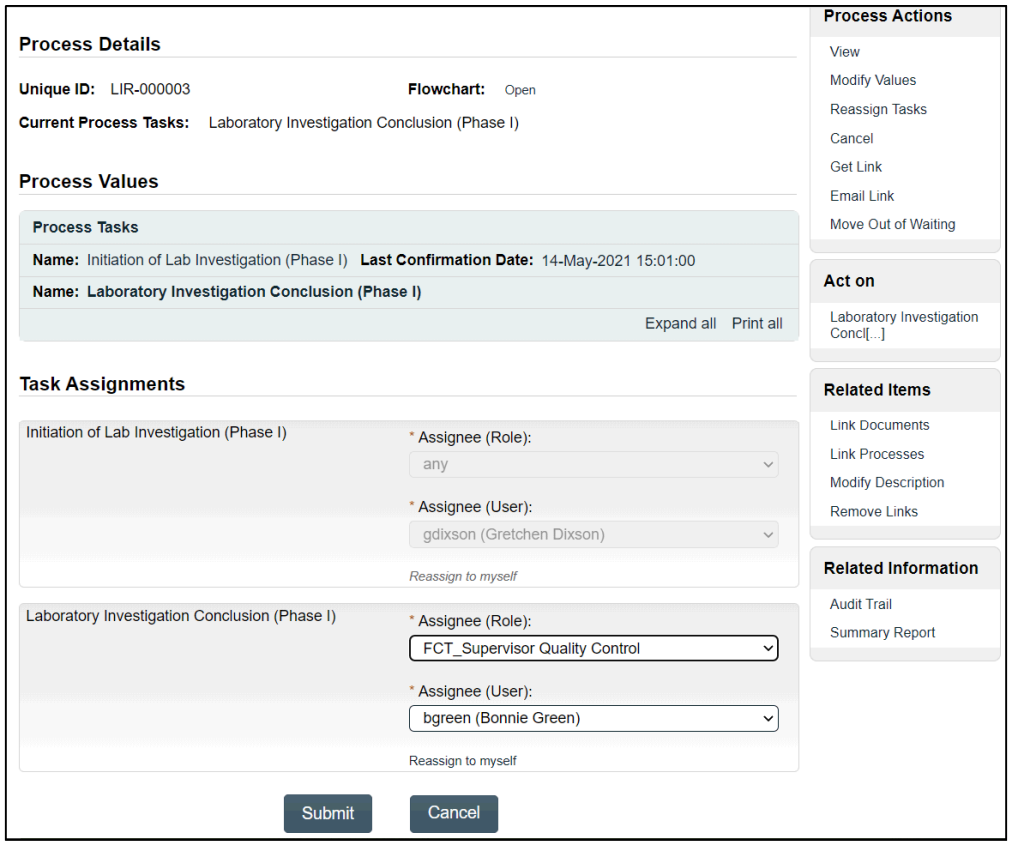
A User with the SOLABS System Administrator role can reassign any steps in an active process.

From the **Process Details** screen, click **Reassign Tasks** in the **Process Actions** menu.



Re-assign the desired task by selecting a different role and/or user for it.

Click **Submit**. You are now required to provide a **Reason for Change** and signoff with your e-Signature before you can confirm the changes. Once you **Confirm,** you are taken to the **Process View** page for the current step of the process.



Creating Secondary Tasks

The initiator of a Process can create **Secondary Tasks** that will be associated with the Process. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the Process but that are not part of the Primary Tasks.

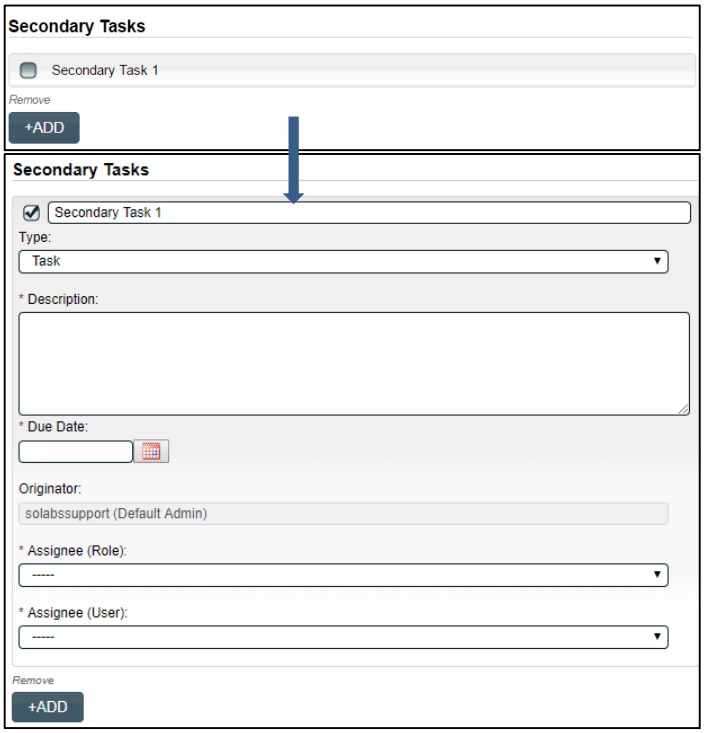
The **Secondary Task** section is under the **Process Task Form**. This section is available at various Primary Task Steps of the Process, allowing others involved in the review, implementation and approval of the Process to assign additional Secondary Tasks.

After selecting **Secondary Task 1**, additional fields will be displayed to define and assign that task.

Replace the text "Secondary Task 1" with an appropriate Title for the task.

The appropriate task **Type** can then be chosen from a drop-down list.

Enter a **Description** and a **Due Date** for the Task. Choose due dates appropriate to ensure tasks are completed in a time frame that supports on time Process closure.

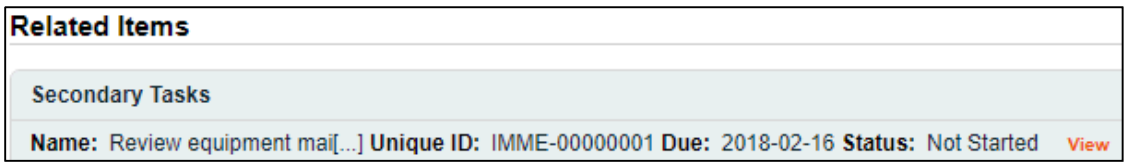


The **Originator** field will default to the User acting on that step of the Process.

The **Assignee** can be chosen either by Role or by User. These drop-down lists will bring up the Active Roles list and the Active Users list.

To assign by **Role**, choose the appropriate Function Role from the list. All Users with that Role will then appear in the **Assignee(User)** drop-down list so that the appropriate person can be selected. To assign by **User**, choose the appropriate User from the list. Their Function Role will then appear in the **Assignee (Role)** drop-down list and must be selected.

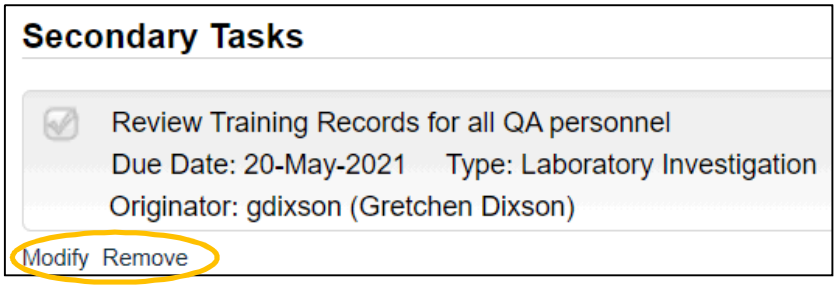
The **+ADD** button can be used to create additional Secondary Tasks. The Assignees will receive email Notifications and see the View/Act On options for their Secondary Tasks only after the applicable approval steps for the Process. Until then the Task status is ***Not Started***. All **Secondary Tasks** are listed under **Related Items** at the bottom of the screen any CAPA Step.



Modifying or Removing a Secondary Tasks

You can modify or remove a **Secondary Task** from within a process step, <u>if that step is currently assigned to you</u> and <u>if you created the secondary task</u>.

From the **Act On** page of a process step, under the **Secondary Tasks** section, select **Modify** or **Remove** under the task you'd like to modify.

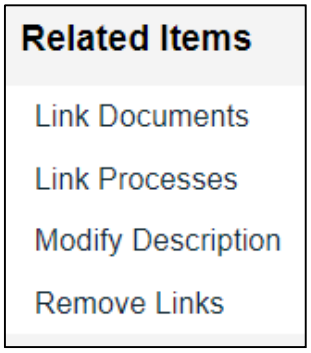


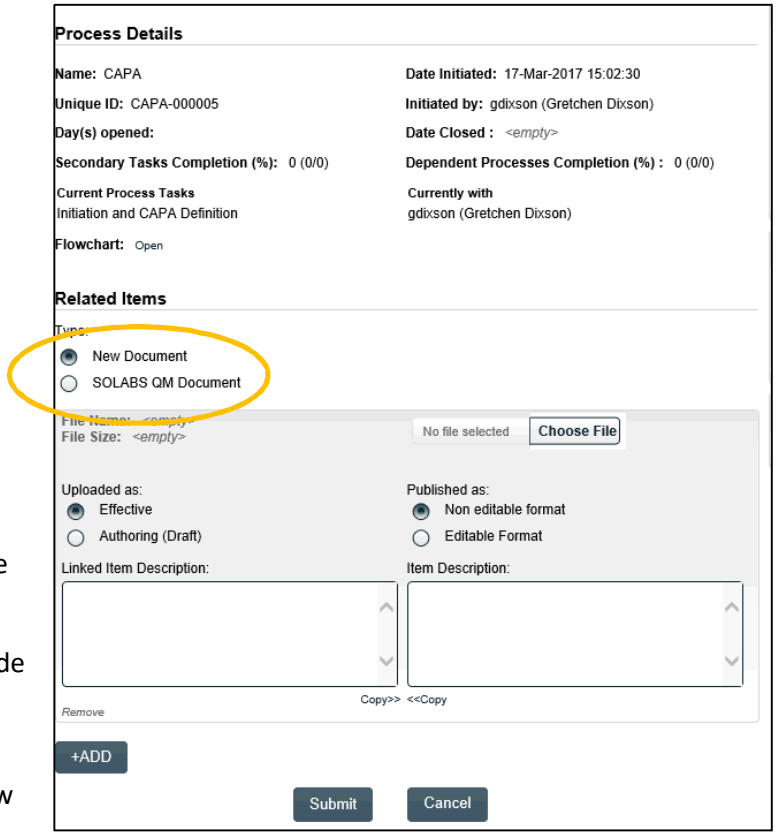
Selecting the **Modify** option will open the **Secondary Task** in **Edit** mode. Once you make your changes and **Submit**, the task will be saved with your modifications.

When modifying or removing a Secondary Task, click on the **Submit** button **ONLY** when you are ready to **Act On** that process step because choosing **Submit** on this screen will also submit your **Process Step Decision**.

Linking a Document to a Process

From within a Process Details or Process Task Details screen, go to the right-hand **Related Items** menu and click on the **Link Document** option.



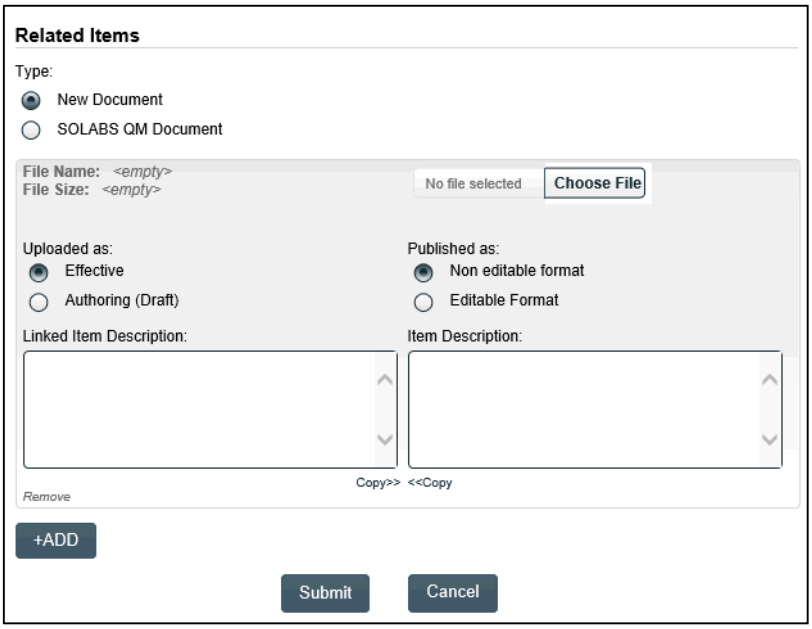


There are two types of Documents that can be linked to a process in **SOLABS QM10:**

- **New Documents** – documents from outside SOLABS QM10
- **SOLABS QM10 Documents** – documents already existing in SOLABS QM10 Treeview

Linking a New Document to a Process

This provides the opportunity to upload a document to **SOLABS QM10** as either Effective or Draft (in authoring) document.



Document Upload Options

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

Document Publishing Type

- **Non-Editable Format**: Document will be converted into PDF format.

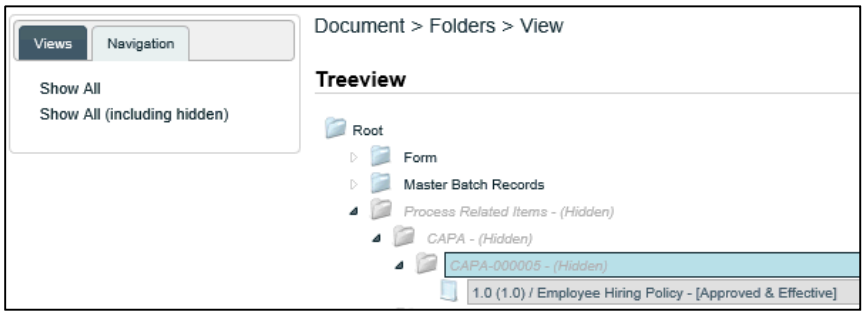
  NOTE: If you do not need the SOLABS Cover Pages, headers or watermarks on your linked document, create a PDF Rendering Template with no cover pages, watermarks or headers and use it as the default template for the Document Type **Support Document for Process**.

- **Editable Format**: Document format will not be altered.

Document Description

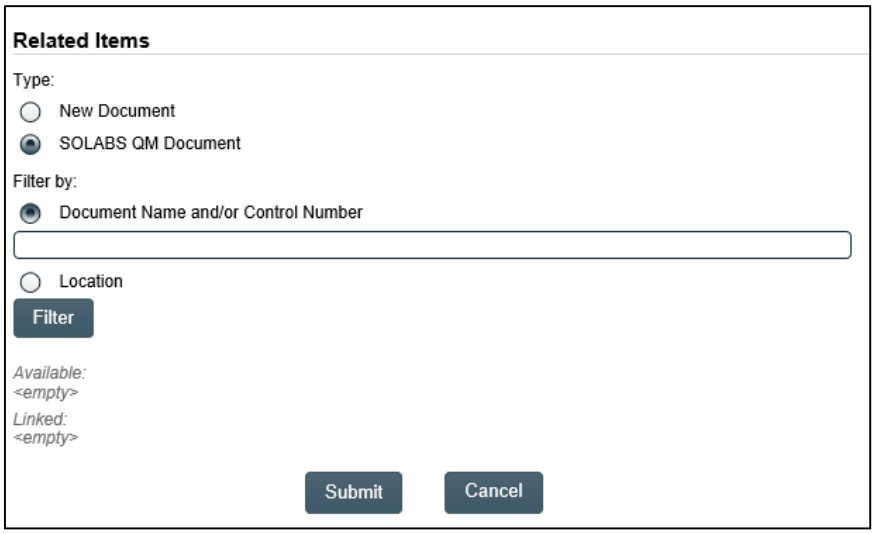
- **Linked Item Description:** This is the description of the document that you are linking.
- **Item Description:** This is the description of the current item – the Process or Process Task that you are linking the document to.

The uploaded document will then be stored within the **SOLABS QM10** database as a **Process Related Item**. It will be in the Treeview but Hidden. Administrators can locate it by choosing the **Show All (including hidden)** option.



Linking an existing SOLABS QM10 Document to a Process

- **SOLABS QM10** documents can be found by searching on their name and/or by Control Number, or by Location.
- All available documents will then display in **Available** box.
- Documents can be selected and after clicking on **+ADD** button, they go to **Linked** box.



Each linked document cannot exceed 50 MB in size. Up to 200 MB can be linked at a time. If you have multiple documents to link and together, and they exceed 200 MG, submit them in groups.

Linking a Process to a Process

You can also link another SOLABS QM10 Process to a Process.

Search for the Process you'd like to link by the **Unique ID**.

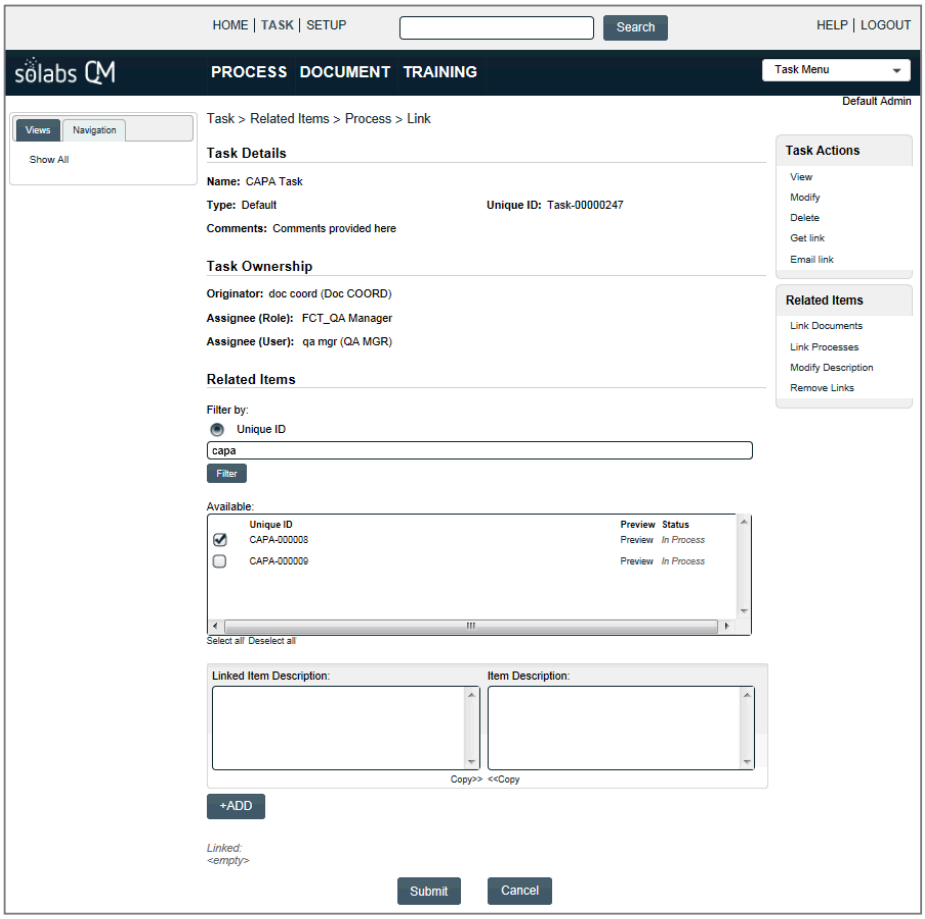
Select the **Process** from the **Available** list, add the **Linked Items Description** and the **Item Description**.

Click the **+ADD** button and the listed Process moves from the **Available** box to the **Linked** box.

Click **Submit**, then check your work and then click **Confirm**.

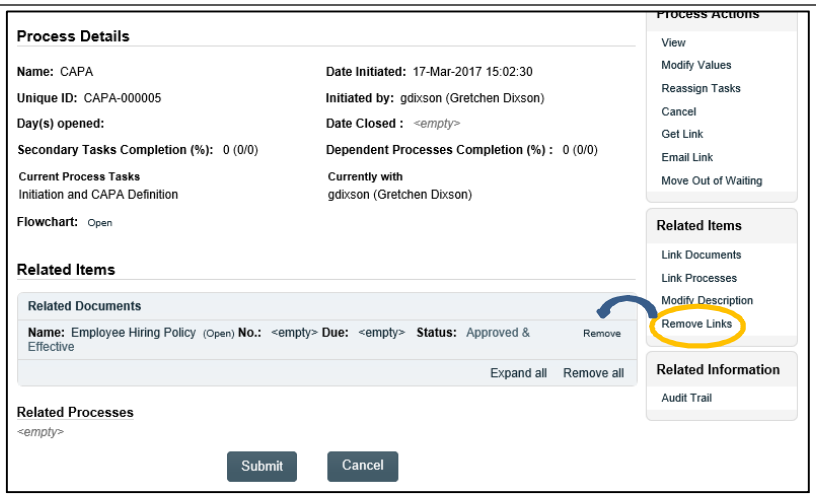
NOTE: Any Linked Process can be discarded at any time before **Submit** by clicking the **Discard** link.

The **Linked Item Description** and **Item Description** of linked documents or processes can be modified at any time. From the **Related Items** menu choose the **Modify Description** option, make your changes, submit, verify your changes and confirm.

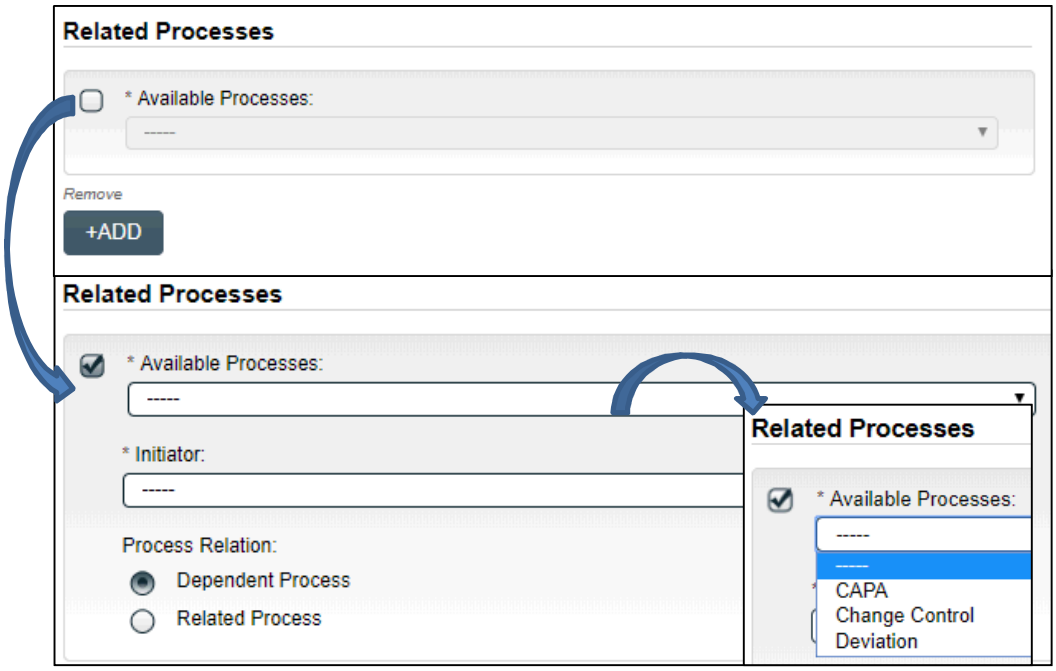


Removing Linked Documents or Processes

Linked Documents and Linked Processes can be removed at any time. From the **Related Items** menu choose the **Remove Links** option. Any linked documents and processes listed under **Related Items** will then have a **Remove** option. Choose that option, Submit and then Confirm.



Initiating a Related Process



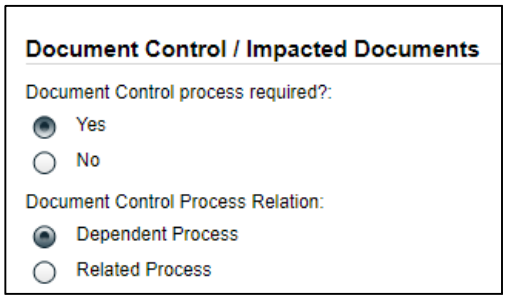
To initiate a new **SOLABS QM10 Process** from within a Process, check the **Available Processes** box.

The **Available Processes** field is a Single-select drop-down list of any Process APPs deployed for your organization.

Choose the Process Relation as either a **Dependent Process** (must be completed before the Parent Process is closed), or a **Related Process.**

The mandatory **Initiator** to field is a Single-select drop-down list fed by the Active User list for your organization. The person chosen in this field will be the person who will be assigned Step 1 of the process you are choosing to initiate. There is also an option to choose **myself**, if you would like to initiate both processes concurrently as the initiator. This process will be the **Parent Process** of the new process being initiated.

Initiating a Document Control Process



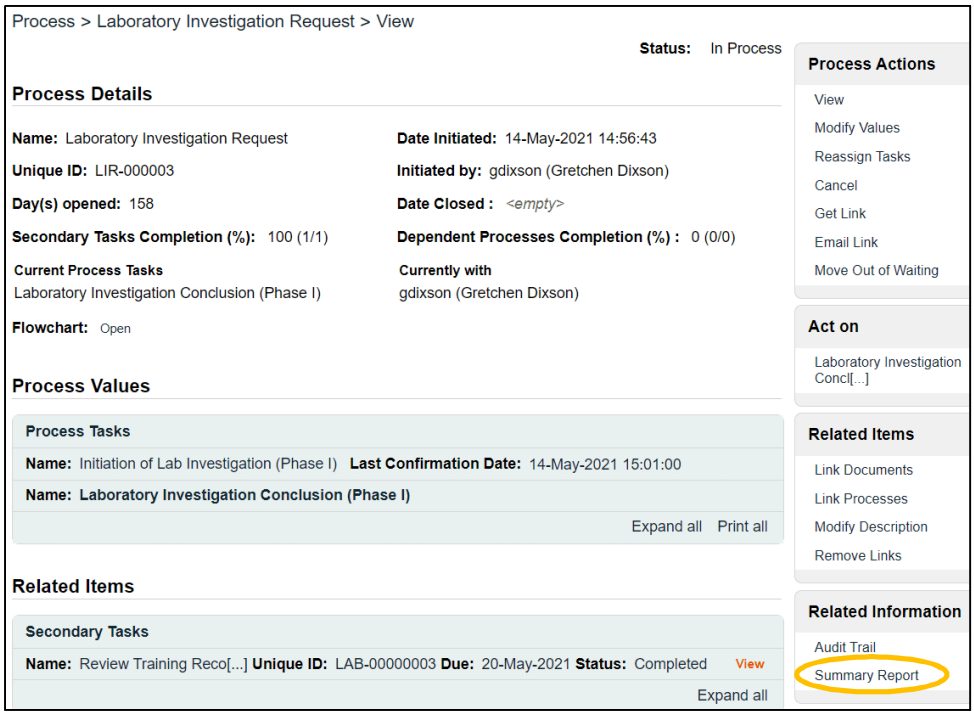
To initiate a new **SOLABS QM10 Document Control Process** to manage any document updates required for this CAPA, select **Yes**. One or more documents can be included in a Document Control Process.

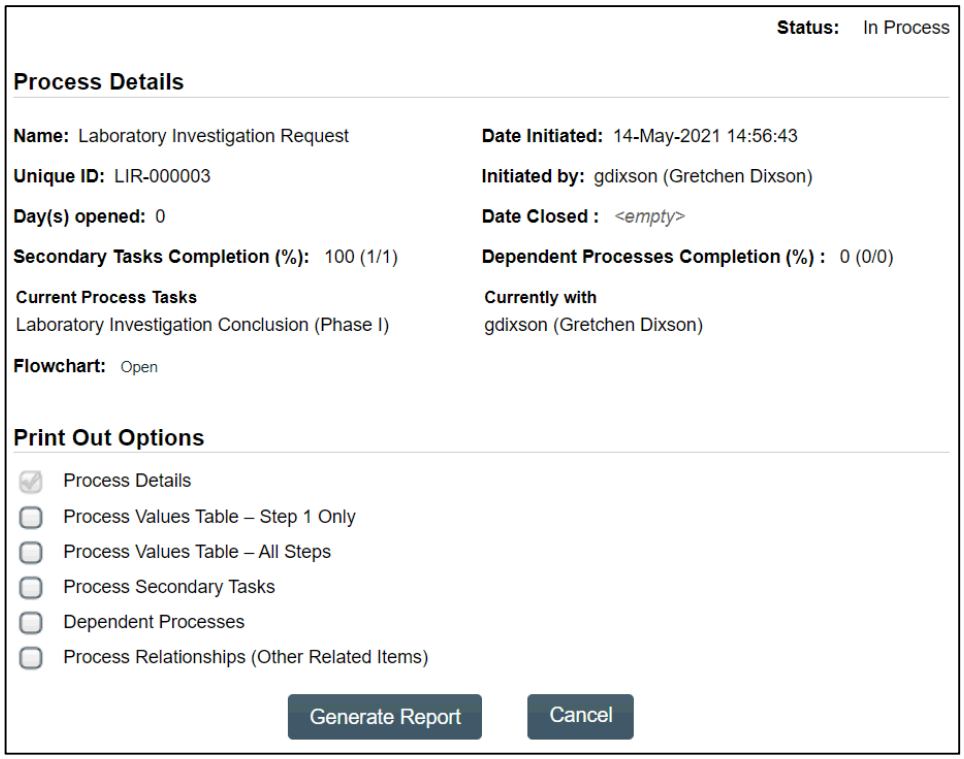
When the **Yes** option is selected, also choose whether it will be a **Dependent Process** (must be completed before the CAPA is closed), or a **Related Process**.

Creating a Summary Report

The **Summary Report** is a PDF document displaying values entered in each field of each process step of a process instance.

Select **Summary Report** from the **Related Information** menu.



Now use the **Print Out Options** to select what items you wish to include in your **Summary Report**.

Click **Generate Report**. Your **Summary Report PDF** is now generated.