

SOLABS QM10: CAPA Process P0050 User Guide

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Introduction

This document provides instructions on the use of the **SOLABS QM10 CAPA Process APP P0050** – by guiding you through each step in the process and providing information on the activities, settings and options associated with each step. Detailed information on this process, including any available options that can be chosen by the client (field labels, additional notifications, etc.) are available in the User Functional Design Specification (UFDS) document that comes with deployment of the Process in your instance of SOLABS QM10. Any options for CAPA Process P0050 will be referenced at the applicable steps.

Refer to the following documents available in the SOLABS Knowledge Base for general information, navigation and functionality common to any **SOLABS QM Process APP** in the **SOLABS QM10 PROCESS Section**.

- **SOLABS QM10: Introduction to PROCESS Section**
- **SOLABS QM10: Notifications Guide**
- **SOLABS QM10 PROCESS Section: Parent/Child Process Relationships**

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 **CAPA Approval** step in a **CAPA** 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.

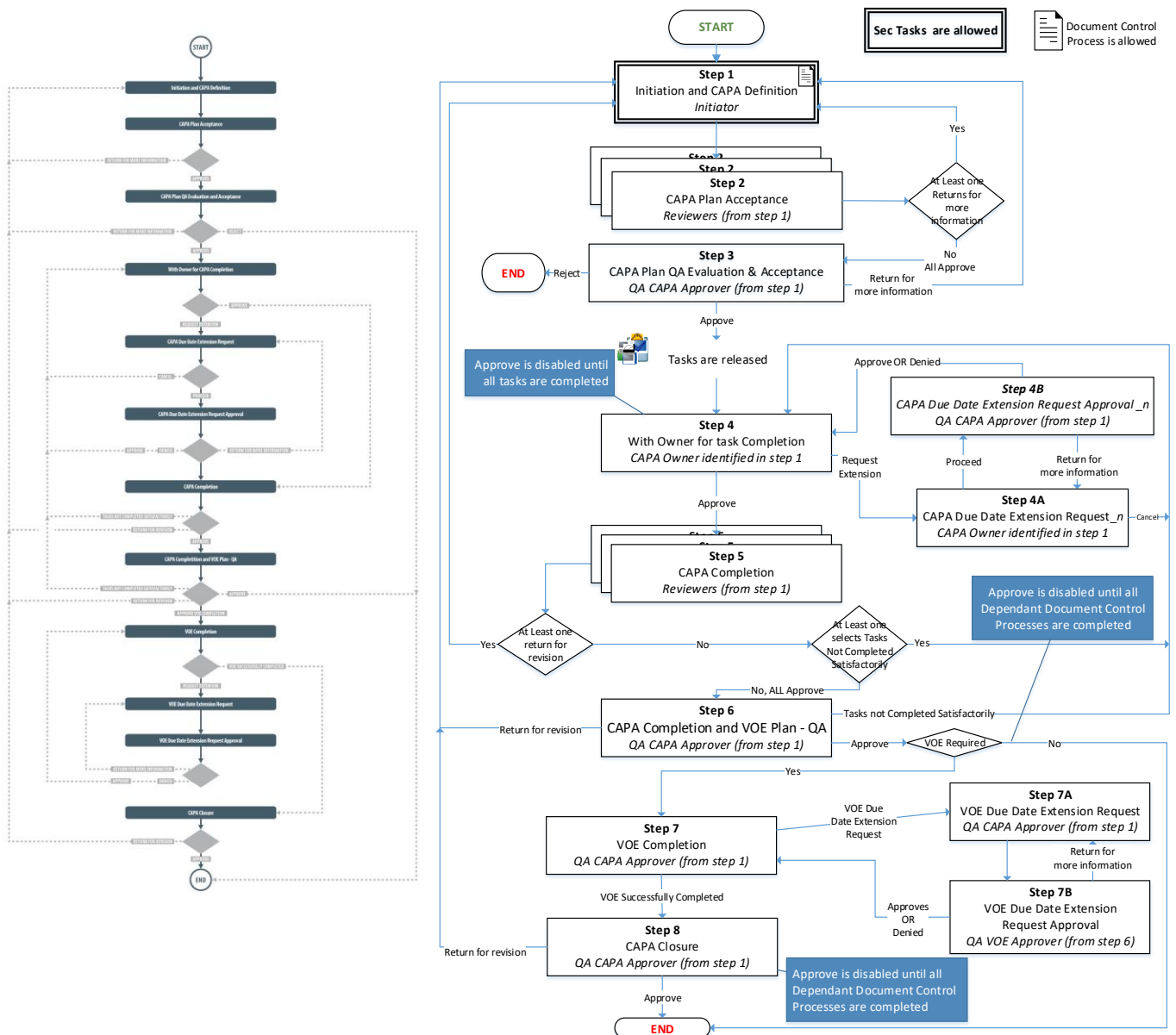
CAPA Process Flowchart

The entire **CAPA Process Flowcharts** are **displayed on this page for informational purposes only** - to show that it is a complex multi-step process with many related decision paths.

This document is organized into sections for each of the Steps in the Change Control Process. **The flowchart section for each of those steps will be displayed in larger, more readable format within those sections.**

The Flowchart on the left is available within the Process App. As the process moves along, the active step in that Flowchart is highlighted.

The more detailed Flowchart on the right is available as part the User Functional Design Specification (UFDS) document that is provided with the Process App.



CAPA Process – Process Roles

Decisions made by those involved in the process act to progress the workflow to the next Step or return it to a prior Step. The following **CAPA Process Roles** are associated with **CAPA Process P0050** and must be assigned to the Users in **SOLABS QM10** who will make the related decisions and/or need to receive process email Notifications.

When SOLABS QM10 Users are assigned a Process Role, their names are then available on drop-down lists to be selected for their assigned steps in the process. The process will automatically notify them to Act On that Step/Primary Task. They will see the task in the Process Section of their SOLABS QM10 HOME Page and will also receive an email Notification.

Contact your SOLABS System Administrator if any of these CAPA Process Roles need to be assigned to additional Users. If these Process Roles are not assigned to any Users, the related process tasks will instead go to Users who have the System Role assignment of SOLABS Documentation Administrator. If that role is not assigned, the process tasks would go to the SOLABS System Administrator.

PR_CAPA_Owner:

This Process Role must be assigned to those Users who would be considered the responsible owner of a CAPA. They will need to Act on the following Primary Tasks in the CAPA Process.

- With Owner for CAPA Completion
- CAPA Due Date Extension Request

If CAPA Due Date is \leq today + 5 days all users with this role assignment will receive an email Notification (notification is sent only once i.e. the first time this condition is met).

PR_CAPA_Reviewer:

This Process Role must be assigned to any Users who will be asked to review the CAPA process at any stage. This may occur as part of the following steps in the CAPA Process:

- CAPA Plan Acceptance
- CAPA Completion

PR_CAPA_Approver:

This Process Role must be assigned to any Users who will be asked to perform the following Primary Tasks in the CAPA Process:

- CAPA Plan QA Evaluation and Acceptance
- CAPA Due Date Extension Request Approval
- CAPA Completion and VOE Plan – QA
- VOE Completion
- VOE Due Date Extension Request
- VOE Due Date Extension Request Approval
- CAPA Closure

If VOE Due Date is \leq today + 5 days the following the person selected at Step 1 as the CAPA Approver will receive an email Notification (notification is sent only once i.e. the first time this condition is met).

Starting the CAPA Process

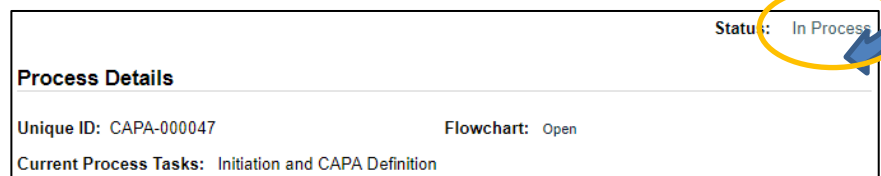
From the PROCESS Section in SOLABS QM10, choose Start Process from the Quick Access Process Menu.



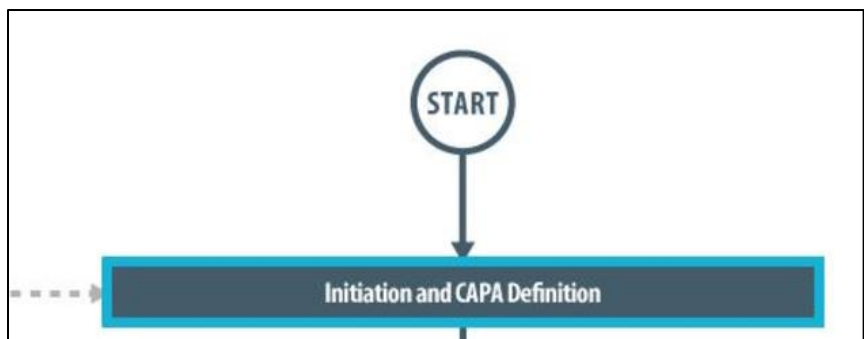
At the next screen, locate the listing for the CAPA Process and click the blue START button.



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.



Step 1: Initiation and CAPA Definition

At Step 1 the user initiating the CAPA enters all the required information and metadata into the **Process Task Form**.

Some of the fields on the **Process Task Form** are drop-down menus, and others are editable text fields, single-select fields or multi-select fields. Those with an asterisk (*) are mandatory.

The right-hand **Related Items** menu allows the initiator to **Link Documents** or **Link Processes**, if applicable.

Refer to the separate document **SOLABS QM10: Introduction to PROCESS Section** for information on use of the **right-hand menus** since they are common to all SOLABS QM Process APP screens.

Each of the fields in the **Process Task Form** will be described starting on the next page.

Some of the information entered at Step 1 will determine how the process flows through the remaining steps.

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

Submit Save Draft Cancel

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 In Process CAPA and then use the right-hand **Act on Menu** to open the Process Task Form fields.

Completing the Process Task Form:

This sub-section covers the information required for the **Process Task Form** at **CAPA Process Step 1**.

See the Options Section at the end of this User Guide for options available at Step 1 which may apply to your implementation and may therefore look different that what is seen below.

Process Task Form - Initiation and CAPA Definition

CAPA No.:
CAPA-000047

The **CAPA No.** field will be automatically populated with the next available CAPA number.

* Type:

Corrective Action
Preventive Action

The **Type** field is a mandatory field where you will choose the type of CAPA being initiated – either **Corrective Action** or **Preventive Action**.

* Title:

* Description of CAPA:

[Quick Text]

The **Title** field is mandatory. Choose a clear, concise and intuitive title for the CAPA that will quickly communicate the subject. Titles will appear in CAPA Reports. The **Description of CAPA** field can be populated with free text or by Quick Text options. Options to label these fields differently are available.

* Implement Site(s):

Site 1
 Site 2
 Site 3

Name: SOL161_Site_List Status: Active
Values : Site 1 ; Site 2 ; Site 3 ; Site A ; Site B

Values : Manufacturing Site 1 ; Manufacturing Site 2 ; R&D Site ; Office Building ; Quality Control Testing Lab

Select all Deselect all

* Source Record Number:

The **Implement Site(s):** field is a mandatory field. It is set up as a Multi-Select field populated from an **editable Custom List** of Site Names that your SOLABS System Administrator can customize for your organization.

The **Source Record Number** field is a mandatory free-text field where you can enter the source of the record. One of the available Options for Step 1 is to for this field to be labeled **CAPA Source**. If it is from a Quality event for which another deployed SOLABS QM10 APP was used, you can also use the right-hand **Related Items** menu and choose **Link Process** to tie the two processes together.

Related Items

Link Documents
Link Processes

Related Items

Filter by:

Unique ID

DEV-000001

Filter

Available:

Unique ID
DEV-000001

Select all Deselect all

* CAPA Due Date:

* CAPA Classification:

-
- Critical
- Major
- Minor
- No Impact

* CAPA Owner:

-
- bgreen (Bonnie Green)
- bgregory (Brandon Gregory)
- csanders (Christina Sanders)
- dbarnes (Donald Barnes)
- dkim (Doreen Kim)
- egriffin (Emily Griffin)
- ejohnson (Elizabeth Johnson)

* Reviewer(s):

- bgreen (Bonnie Green)
- bgregory (Brandon Gregory)
- cjeanes (Conrad Jeanes)
- drennold (Delores Rennold)
- eblake (Evan Blake)
- egriffin (Emily Griffin)

Select all Deselect all

* QA CAPA Approver:

-
- drennold (Delores Rennold)
- hpoole (Harvey Poole)
- mturner (Marilyn Turner)
- rgonzales (Ronald Gonzales)
- tgarcia (Theresa Garcia)

* Identify Probable Root Cause:

CAPA Due Date is a mandatory field that can be populated by a calendar. Try to set a CAPA due date that will include sufficient time for completion of related activities, as well as the approvals. When the CAPA Due Date is within 5 days of the current date, an email Notification will go to ALL users with the PR_CAPA_Owner role assignment.

CAPA Classification is a mandatory field where the criticality of the CAPA can be selected from a Single-select drop-down list. Another available Option for Step 1 is to remove the CAPA Classification of “No Impact”.

CAPA Owner is a mandatory field. It is a drop-down list that will be populated with names of the SOLABS QM10 Users who have been assigned the Process Role **PR_CAPA_Owner**. **This person will be responsible for monitoring the CAPA Process and will be triggered to Act on Steps 4 and 5 of the CAPA Process.** Before assigning the CAPA Owner, check with them first to verify their availability to take on the responsibilities.

Reviewer(s) is a mandatory field. It is a multi-select list that will be populated with names of the SOLABS QM10 Users who have been assigned the Process Role **PR_CAPA_Reviewer**. **The names chosen in this field will be triggered to Act on Steps 2 and 7 of the CAPA Process.** Before assigning Reviewers, check with the CAPA Owner or others to ensure you select the appropriate people.

QA CAPA Approver is a mandatory field. It is a drop-down list that will be populated with names of the SOLABS QM10 Users from Quality who have been assigned the Process Role **PR_CAPA_Approver**. **The name chosen in this field will be triggered to Act on a number of CAPA Process steps as the QA Approver.**

Identify Probable Root Cause is a mandatory free-text field where you can provide an initial probable root cause for the event that triggered the CAPA.

When you complete the above field, a mandatory multi-select field will be displayed to choose **Root Cause Categories**. Depending on which one(s) you select, additional single-select drop down lists for a more specific Root Cause **Category** will appear. The values for this more specific category come from an **editable Custom List** of root causes that your SOLABS System Administrator can customize for your organization. When it is not clear which value to select, consult with the QA Approver.

* Root Cause Categories:

- Man
- Material
- Method
- Machine
- Environment

* Machine Category:

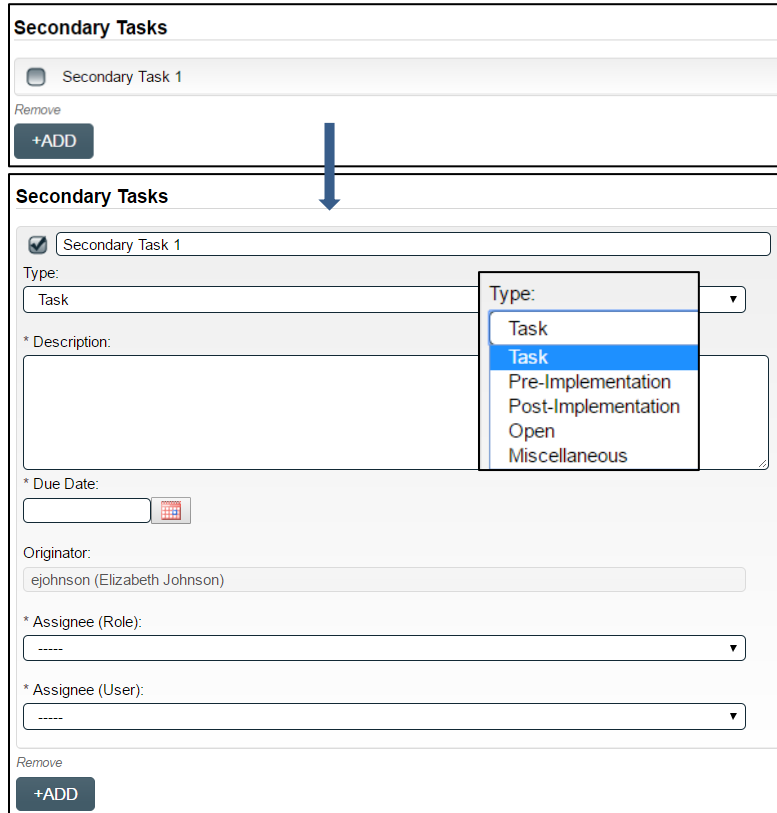
-
- Equipment Malfunction
- Validation/Qualification

Name: SOL094_Machine_Category_List **Status:** Active
Values : Equipment Malfunction ; Validation/Qualification

Creating Secondary Tasks

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

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



The image shows two screenshots of the 'Secondary Tasks' section. The top screenshot shows a simple list with a 'Secondary Task 1' entry, a 'Remove' link, and a '+ADD' button. A blue arrow points down to the second screenshot, which shows the form expanded. The form includes a 'Type' dropdown menu with options: Task, Task, Pre-Implementation, Post-Implementation, Open, and Miscellaneous. Other fields include 'Description', '* Due Date', 'Originator' (ejohnson (Elizabeth Johnson)), '* Assignee (Role)', and '* Assignee (User)'. There are also 'Remove' and '+ADD' buttons at the bottom.

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 task **Type** can then be chosen from a drop-down list. Pre-Implementation tasks will need to be completed prior to CAPA Closure. Do not choose Open as it is not related to the CAPA Process. Additional Task Types are available with Option 7.

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 CAPA closure.

The **Originator** field will default to the User initiating the CAPA Process and completing Step 1.

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. People should not be assigned as task without being consulted first and must understand they are responsible for ensuring completion of the task in a timeframe that supports on time CAPA closure.

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 CAPA Plan QA Evaluation and Acceptance Step of the CAPA Process is completed at Step 3**. Until then the Task status is **Not Started**. The **Secondary Tasks** are listed under **Related Items** at the bottom of the screen any CAPA Step.

Related Items	
Secondary Tasks	
Name: Create a Centerlinin[...]	Unique ID: PRE-00000009 Due: 25-Aug-2017 Status: Not Started View
Expand all	

Document Control / Impacted Documents

Document Control / Impacted Documents

Document Control process required?:

Yes

No

If the **SOLABS QM10 Document Control Process** will be used to manage any document updates required for the CAPA, select **Yes** and then initiate that process.

Submit and Confirm

When all information has been entered in the **Process Task Form**, and any **Secondary Tasks**, **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to change the **Status to In Process** and to progress the process to **Step 2 – CAPA Plan Acceptance**. The Process Flowchart will highlight the next step of the process and any Reviewers chosen at Step 1 will be listed. Those Reviewers will also receive email Notifications and will see the Review task listed on their SOLABS QM10 HOME Page.

Process > CAPA > View

Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks **Currently with**
 CAPA Plan Acceptance_2 Ihussey (Lisa Jazon)

Flowchart: [Open](#)

Process Values

Process Tasks
Name: Initiation and CAPA Definition Last Confirmation Date: 11-Aug-2017 13:35
Name: CAPA Plan Acceptance_1 Last Confirmation Date: 11-Aug-2017 13:35
Name: CAPA Plan Acceptance_2

Related Items

Secondary Tasks
Name: Create a Centerlinin[...] Unique ID: PRE-00000009 Due: 25-Aug-2017 Status: Not Started View

[Expand all](#)

```

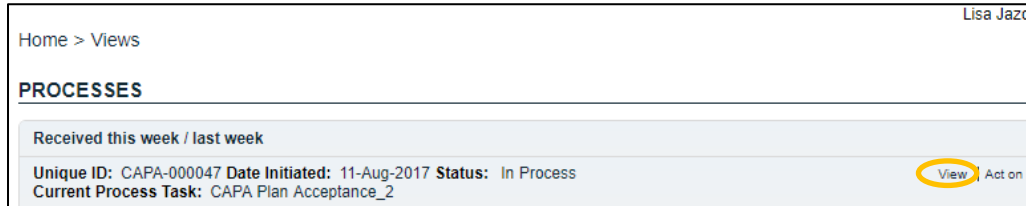
graph TD
    A[Initiation and CAPA Definition] --> B[CAPA Plan Acceptance]
    B --> C{ }
    C -- "RETURN FOR MORE INFORMATION" --> A
    C -- APPROVE --> D[ ]
  
```

Step 2: CAPA Plan Acceptance

At this step in the CAPA Process, any **Reviewers** chosen at Step 1 will receive an email Notification and will see their Review task listed in the Process section of their SOLABS QM10 HOME Page.

Viewing a CAPA Plan Acceptance Task

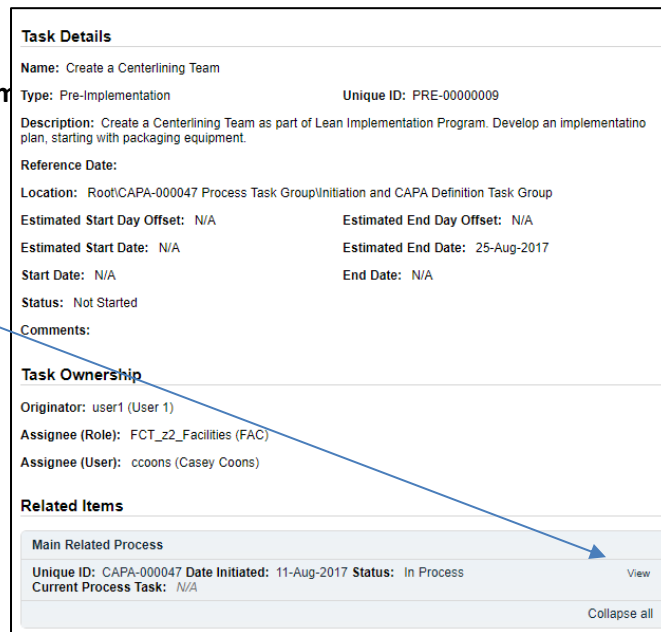
If the Reviewer clicks on the **View** option to the right of the Process Task, they will get the same screen shown on the previous page of this document.



From the View screen, there are **Expand all** options under the **Process Values** table and the **Related Items** table, that can be used to see more detail on the information entered by the initiator at Step 1. They can also click on the **View** option to the right of any individual **Related Items** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens. See example below.

In this example, clicking on View for the Secondary Task listed in CAPA-000047 brings up the Task Details screen for that assigned Task.

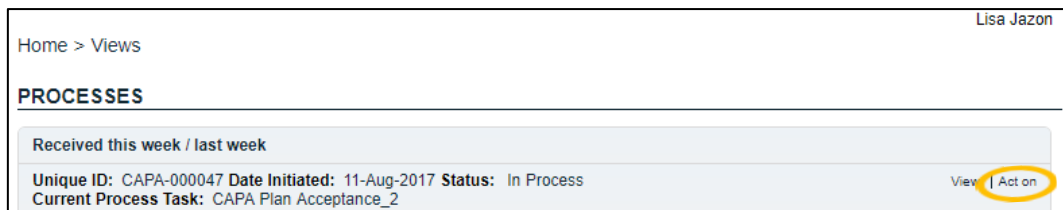
CAPA-000047 is listed as a **Related Item** for that Task. To get back to CAPA-000047, the Reviewer can click on the **View** option.



Since **Secondary Tasks** are used to outline the CAPA Plan, the Reviewers should always look for that particular listing under **Related Items**, use the **View** option to open up the **Task Details** screen for that Secondary Task so they can review and determine whether it is acceptable.

Acting on the CAPA Plan Acceptance Task

If the Reviewer clicks on the **Act on** option to the right of the Process Task, they will go immediately to the **Act on** screen for their **Review** task.



At the **Act on screen** for the **CAPA Plan Acceptance Task**, each Reviewer can view all details of the information entered at Step 1 by choosing the **Expand all** option under **Process Values**.

Each Reviewer can provide **CAPA Approval Comments** – this is not mandatory.

Reviewers can choose the **Modify** option under any **Secondary Task** to see the related fields and make any edits they might need to make, including removal of the Task.

Finally, each Reviewer will make their **CAPA Plan Acceptance Decision**. They will either **Approve** or **Return for more information**.

If they choose to return it, a **Comment** is mandatory. The process will go back to Step 1, after all Reviewers have provided input, so that the **Initiator** make the requested changes. If there are multiple Reviewers, each should check the Process Values table to see if any other Reviewer chose to Return it.

If all Reviewers choose the Approve option, the process will move to the next Primary Task in the Process: **Step 3 – CAPA Plan QA Evaluation and Acceptance**.

Process > CAPA > CAPA Plan Acceptance_2 > Act on Status: In Process

Process Details

Unique ID: CAPA-000047 Flowchart: Open

Current Process Tasks: CAPA Plan Acceptance_2

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	

[Expand all](#) [Print all](#)

Process Task Form - CAPA Plan Acceptance_2

CAPA Approval Comments:

Return for more information

* Comments:

CAPA Plan Acceptance Decision:

Approve

Return for more information

Secondary Tasks

Create a Centerlining Team

Type: Pre-Implementation

* Description: Create a Centerlining Team as part of Lean Implementation Program. Develop an implementation plan, starting with packaging equipment.

* Due Date: 25-Aug-2017

Originator: user1 (User 1)

* Assignee (Role): FCT_22_Facilities (FAC)

* Assignee (User): ccoons (Casey Coons)

[Modify](#) [Remove](#)

Process > CAPA > View Status: In Process

Process Details

Name: CAPA Date Initiated: 11-Aug-2017 13:17:41

Unique ID: CAPA-000047 Initiated by: user1 (User 1)

Day(s) opened: 0 Date Closed: <empty>

Secondary Tasks Completion (%): 0 (0/1) Dependent Processes: <empty>

Current Process Tasks: CAPA Plan QA Evaluation and Acceptance Currently with: jianuzzi (Jacqueline)

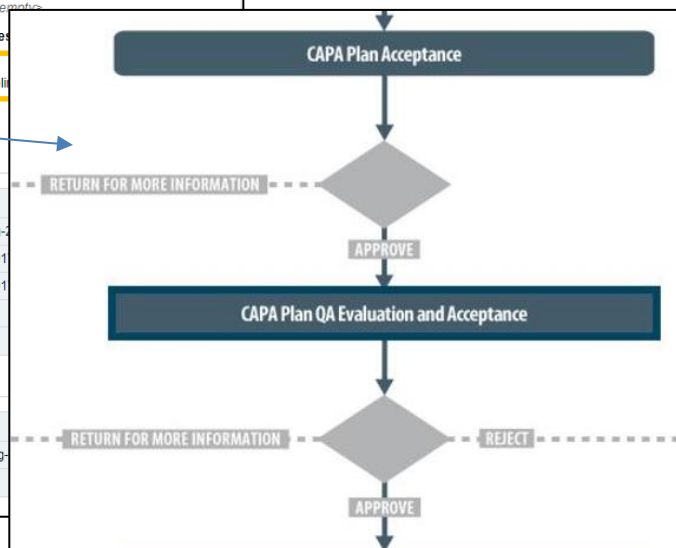
Flowchart: Open

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan QA Evaluation and Acceptance	

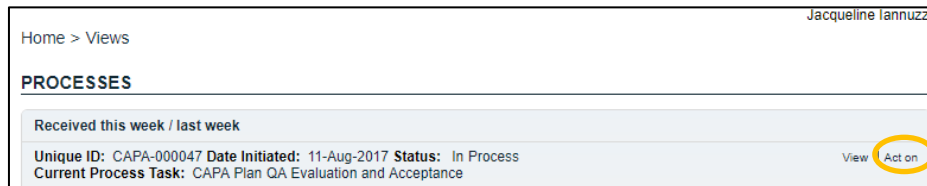
Related Items

Secondary Tasks	
Name: Create a Centerlinin[...]	Unique ID: PRE-00000009 Due: 25-Aug-2017



Step 3: CAPA Plan QA Evaluation and Acceptance

At this step in the CAPA Process, the **QA CAPA Approver** chosen at Step 1 will receive an email Notification and will see their **CAPA Plan QA Evaluation and Acceptance** task listed in the Process section of their SOLABS QM10 HOME Page. As described for Step 2 above, if they choose the **View** option they can access all information ahead of making a decision. If they choose the **Act on** option they can still review the Process Values Table but from their Act on screen.



Acting on the CAPA Plan QA Evaluation and Acceptance Task

When the **QA CAPA Approver** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the **Act on** screen for their **Approval task**.

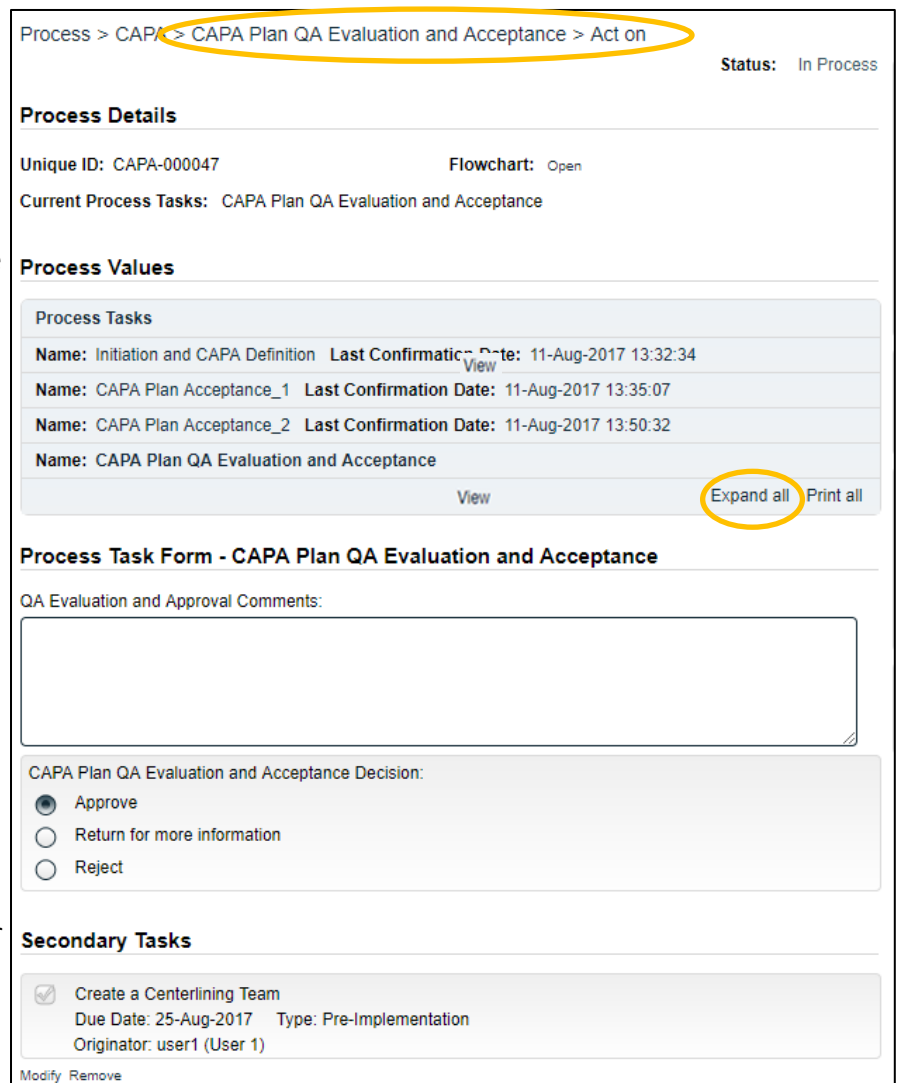
At the **Act on screen** for the **CAPA Plan QA Evaluation and Acceptance** task, the Approver can view information entered at previous steps by choosing the **Expand all** option in the **Process Values** table. Steps can be expanded individually or the entire table can be expanded.

The Approver can provide **QA Evaluation and Approval Comments** – this is not mandatory.

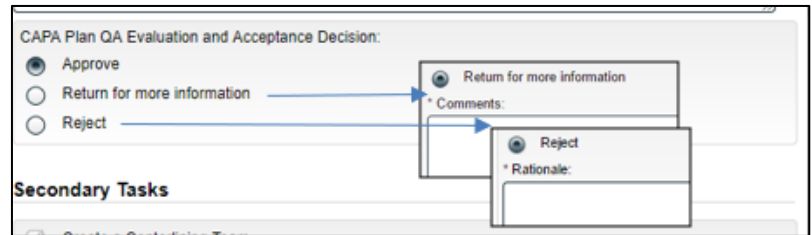
The Approver can review **Secondary Tasks** to see the related fields. They can choose to **Modify** or **Remove** the existing Secondary Tasks and can also choose to **+ADD** one or more Secondary Tasks at this step.

The Approver can review **Related Processes**, including linked Doc Control Processes, and also **Remove** or **+ADD** any as needed.

Finally, the Approver will make their **CAPA Plan QA Evaluation and Acceptance Decision**. They will either **Approve**, **Return for more information** or **Reject**.



If they choose **Return for more information**, a **Comment** is mandatory, and the process will go back to Step 1, where the Initiator will work with the QA CAPA Approver to modify the CAPA plan.



If they choose **Reject**, a **Rationale** is mandatory, and the process will go to the **END**.

If they choose the **Approve** option, the process will move to the next Primary Task in the Process: **Step 4 – With Owner for CAPA Completion**. At this point, Secondary Task(s) and Processes are released and the Assignees receive notification of their assigned tasks.

Process > CAPA > View Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed: <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks: With Owner for CAPA Completion Currently with: jianuzzi (Jacqu...

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017

Related Items

Secondary Tasks	
Name: Create a Centerlinin[...]	Unique ID: PRE-00000009 Due: 25-Aug-2017 Status: Not Started View
Expand all	

Related Processes	
Unique ID: DEV-000028 Date Initiated: 14-Jul-2017 Status: Completed View	Current Process Task: N/A
Expand all	

As the **CAPA Process** progresses from Step to Step, notice how each step is added to the **Process Values** table so that it is available for those acting on later steps to review.

If **Secondary Tasks**, **Related Documents** or **Related Processes** are added along the way, they will be added to the **Related Items** section.

As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the above screen and be able to toggle back and forth between the Process and any Related Items.

At this point in the CAPA Process, **Assignees** of any **Secondary Tasks** will receive email Notifications and see those activities listed in the TASKS section of their SOLABS QM10 HOME Page.

TASKS	
All	
Name: Create a Centerlinin[...] Unique ID: PRE-00000009 Due: 25-Aug-2017 Status: Not Started	View Act on
Expand all 1	

Secondary Task Assignments – Assignee Actions

If there were any **Secondary Tasks** assigned at Step 1, they are now released to Act on since the CAPA Process has been approved by the Reviewers and the QA CAPA Approver.

Viewing the Secondary Task

When the Assignee for a Secondary Task chooses the **View** option from their HOME Page, they are brought to the **Task > View** screen for that Task. They can now review what has been assigned to them and can also toggle to the **CAPA Process** that triggered the Task, since it is listed at the bottom of the screen as a **Related Item**.

The task Assignee has various options under their **Task Actions** and **Related Items** right-hand menus to help manage completion of their task. Any actions they take will be visible to those acting on the Primary Task steps in the CAPA Process if they choose to View a Secondary Task.

Casey Coons

Task > View

Task Details

Name: Create a Centerlining Team
Type: Pre-Implementation **Unique ID:** PRE-00000009
Description: Create a Centerlining Team as part of Lean Implementation Program. Develop an implementatino plan, starting with packaging equipment.
Reference Date: 11-Aug-2017
Location: Root\CAPA-000047 Process Task Group\Initiation and CAPA Definition Task Group
Estimated Start Day Offset: 0 **Estimated End Day Offset:** 14
Estimated Start Date: 11-Aug-2017 **Estimated End Date:** 25-Aug-2017
Start Date: N/A **End Date:** N/A
Status: Not Started
Comments:

Task Ownership

Originator: user1 (User 1)
Assignee (Role): FCT_z2_Facilities (FAC)
Assignee (User): ccoons (Casey Coons)

Related Items

Main Related Process

Unique ID: CAPA-000047 **Date Initiated:** 11-Aug-2017 **Status:** In Process View
Current Process Task: N/A

Collapse all

Task Actions

- View
- Act on
- Modify
- Return to Originator
- Get Link
- Email Link

Related Items

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

Related Information

- Audit Trail

Acting on the Secondary Task

When the Assignee for a Secondary Task chooses the **Act on** option from their HOME Page, they are brought to the **Task > Act on** screen for that Task.

From this screen, the Assignee can also review the **Task Details**.

The fields they have available to them are to select a **Start Date**, enter an **End Date** when they are finished with the task and to change the **Status** as they progress it.

They can also enter free-text **Comments** at any point.

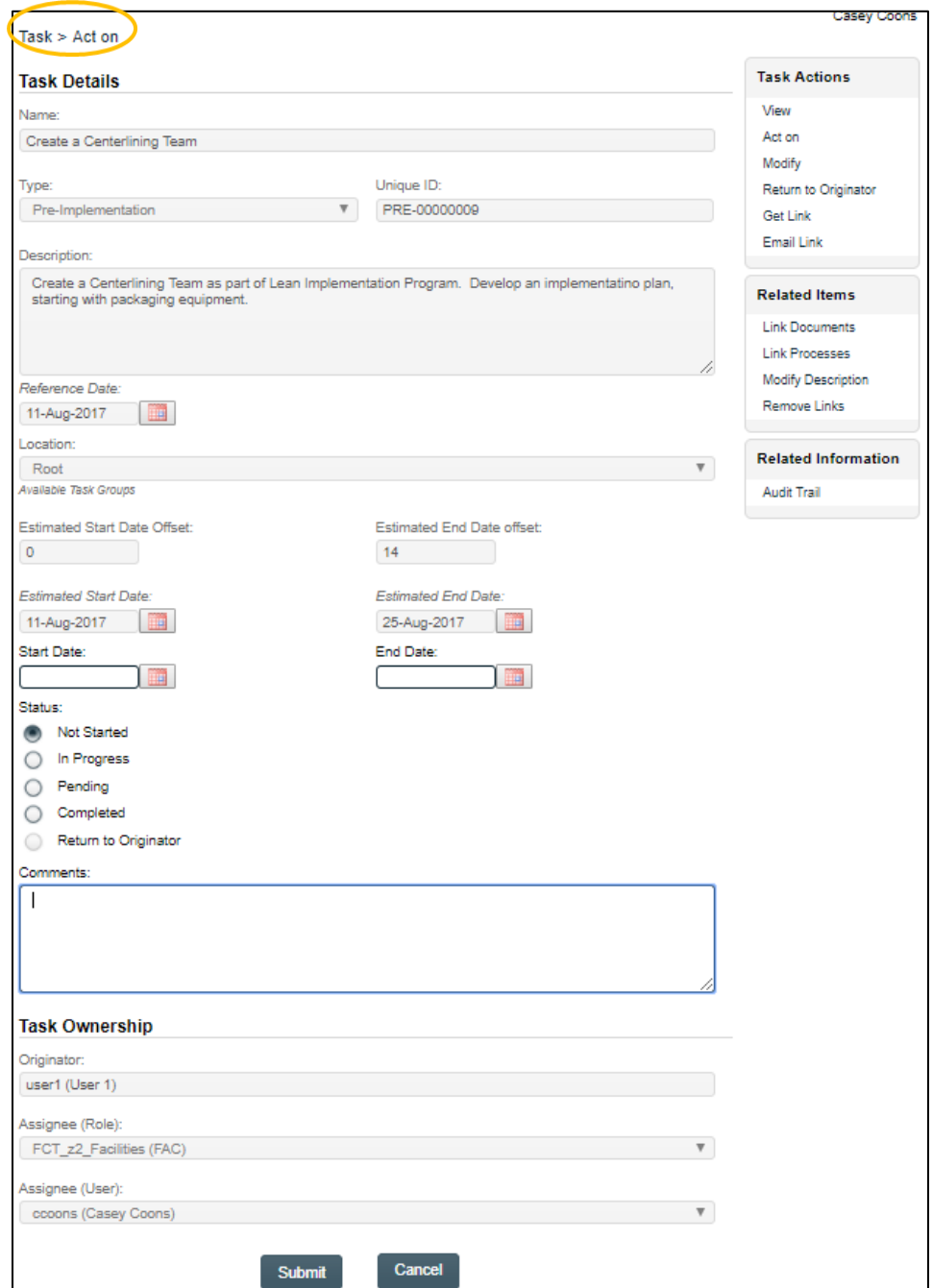
The task will default to a status of **Not Started**. If a status of **In Progress** is selected, the **Start Date** field will be populated with the current date. If a **Start Date** is entered, the Status will automatically move to **In Progress**. For longer term tasks, it is best practice to periodically log in and provide status updates in the **Comments** field.

If a status of **Pending** is selected, the **Start Date** field will be grayed out.

If a status of **Completed** is selected, the **End Date** field will be populated with the current date. If an **End Date** is entered, the Status will automatically move to **Completed**.

The **Return to Originator** option is grayed out since it is currently not available.

If the Assignee would like to add evidence / documentation to support completion of the task, the **Link Documents** option is available on the right-hand menu.



Task > Act on

Task Details

Name: Create a Centerlining Team

Type: Pre-Implementation Unique ID: PRE-00000009

Description: Create a Centerlining Team as part of Lean Implementation Program. Develop an implementatino plan, starting with packaging equipment.

Reference Date: 11-Aug-2017

Location: Root

Available Task Groups

Estimated Start Date Offset: 0 Estimated End Date offset: 14

Estimated Start Date: 11-Aug-2017 Estimated End Date: 25-Aug-2017

Start Date: End Date:

Status:

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

Comments:

Task Ownership

Originator: user1 (User 1)

Assignee (Role): FCT_z2_Facilities (FAC)

Assignee (User): cooons (Casey Coons)

Submit Cancel

Task Actions

- View
- Act on
- Modify
- Return to Originator
- Get Link
- Email Link

Related Items

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

Related Information

- Audit Trail

Step 4: With Owner for CAPA Completion

At this step in the CAPA Process, the **CAPA Owner** chosen at Step 1 will receive an email Notification and will see the **With Owner for CAPA Completion** task listed in the Process section of their SOLABS QM10 HOME Page. The CAPA plan is now approved to be executed. They can choose the **View** option to access all information previously entered. If they choose the **Act on** option they can still review the **Process Values** table but from their Act on screen.

Home > Views		Jacqueline Iannuzzi
PROCESSES		
Received this week / last week		
Unique ID: CAPA-000047 Date Initiated: 11-Aug-2017 Status: In Process		View Act on
Current Process Task: With Owner for CAPA Completion		

Acting on the With Owner for CAPA Completion Task

When the **CAPA Owner** clicks on the **Act on option** to the right of the Process Task, they will go immediately to the **Act on** screen for the **With Owner for CAPA Completion** task. The CAPA Owner is responsible to monitor the CAPA plan, any Secondary Tasks and Related Processes until they are completed. At that point, they can complete this Step.

At the **View** or **Act on** screen the **CAPA Owner** can view information entered at previous steps by choosing the **Expand all** option in the **Process Values** table. Steps can be expanded individually or the entire table can be expanded. They can also view the **Secondary Tasks and Related Processes** associated with the CAPA.

When the CAPA plan / Secondary Tasks have been completed, the **CAPA Owner** will use this screen to enter their **CAPA Task Completion Decision**. In this example, the **Approve** option is grayed out which means some Related Items are not yet complete. Otherwise, the **Approve** option would be available and the process would move directly to **Step 7 - CAPA Completion**.

If needed, a decision of **Request Extension** can be chosen. The request should be made proactively, prior to the CAPA due date. The CAPA Process will move to **Step 5 – CAPA Due Date Extension Request**.

Process > CAPA > With Owner for CAPA Completion > Act on		Jacqueline Iannuzzi												
Status: In Process		Process Actions												
Process Details		View												
Unique ID: CAPA-000047	Flowchart: Open	Modify Values												
Current Process Tasks: With Owner for CAPA Completion		Reassign Tasks												
Process Values		Cancel												
<table border="1"> <tr> <td colspan="2">Process Tasks</td> </tr> <tr> <td>Name: Initiation and CAPA Definition</td> <td>Last Confirmation Date: 11-Aug-2017 13:32:34</td> </tr> <tr> <td>Name: CAPA Plan Acceptance_1</td> <td>Last Confirmation Date: 11-Aug-2017 13:35:07</td> </tr> <tr> <td>Name: CAPA Plan Acceptance_2</td> <td>Last Confirmation Date: 11-Aug-2017 13:50:32</td> </tr> <tr> <td>Name: CAPA Plan QA Evaluation and Acceptance</td> <td>Last Confirmation Date: 11-Aug-2017 15:08:29</td> </tr> <tr> <td>Name: With Owner for CAPA Completion</td> <td></td> </tr> </table>		Process Tasks		Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34	Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07	Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32	Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29	Name: With Owner for CAPA Completion		Get Link
Process Tasks														
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34													
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07													
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32													
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29													
Name: With Owner for CAPA Completion														
		Email Link												
		Move Out of Waiting												
		Act on												
		With Owner for CAPA Completion												
		Related Items												
		Link Documents												
		Link Processes												
		Modify Description												
		Remove Links												
		Related Information												
		Audit Trail												
Process Task Form - With Owner for CAPA Completion														
CAPA Task Completion Decision:														
<input type="radio"/> Approve <input checked="" type="radio"/> Request Extension														
Secondary Tasks														
<input checked="" type="checkbox"/> Create a Centerlining Team Due Date: 25-Aug-2017 Type: Pre-Implementation Originator: user1 (User 1)														
Modify Remove														
Document Control / Impacted Documents														
Document Control process required?:														
<input type="radio"/> Yes <input checked="" type="radio"/> No														
Document Control Process Relation:														
<input checked="" type="radio"/> Dependent Process <input type="radio"/> Related Process														
<input type="button" value="Submit"/> <input type="button" value="Save Draft"/> <input type="button" value="Cancel"/>														

Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks Currently with
 CAPA Due Date Extension Request (1) jianuzzi (Jac

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmat
Name: With Owner for CAPA Completion	Last Confirmation Date:
Name: CAPA Due Date Extension Request (1)	

Related Items

Secondary Tasks

Name: Create a Centerlinin[...]	Unique ID: PRE-00000009	Due: 25-Aug-2017	Status: In Progress	View
---------------------------------	-------------------------	------------------	---------------------	------

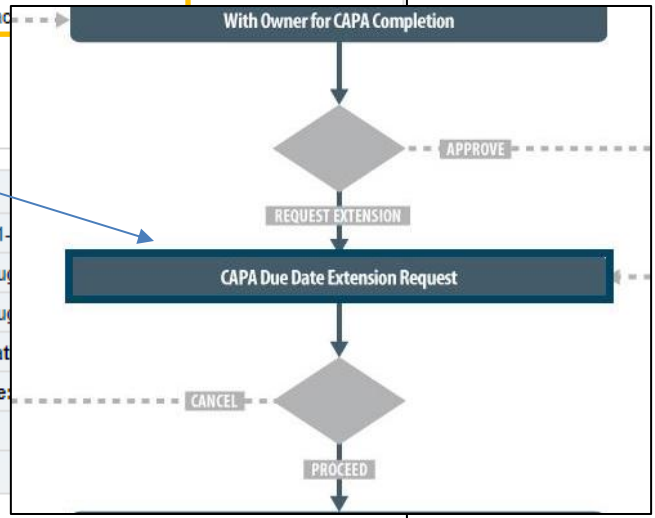
Expand all

Related Processes

Unique ID: DEV-000028	Date Initiated: 14-Jul-2017	Status: Completed	View
-----------------------	-----------------------------	-------------------	------

Current Process Task: N/A

Expand all



Step 5: CAPA Due Date Extension Request

At this step in the CAPA Process, the **CAPA Owner** will receive an email Notification and will see the **CAPA Due Date Extension Request** task listed in the Process section of their SOLABS QM10 HOME Page. Extension Requests are formally captured as a CAPA Process **Primary Task**, even though it will go to the same person. The number in parenthesis – in this case **(1)** – indicates the number of the extension requested by the **CAPA Owner**. If another one should be necessary, it would show **(2)**.

Jacqueline Iannuzzi

Home > Views

PROCESSES

Received this week / last week

Unique ID: CAPA-000047	Date Initiated: 11-Aug-2017	Status: In Process	View Act on
------------------------	-----------------------------	--------------------	---------------

Current Process Task: CAPA Due Date Extension Request (1)

Acting on the CAPA Due Date Extension Request

When the **CAPA Owner** clicks on the **Act on** option to the right of the **CAPA Due Date Extension Request** task, they will go immediately to the **Act on** screen for their **CAPA Due Date Extension Request** task.

At this point, they need to enter a date in the **Proposed CAPA Extension Date** field and complete the mandatory **Reason for the Extension Request** field.

They then need to make their formal **CAPA Due Date Extension Request**. They can choose to **Cancel** the request – perhaps because anticipated delays were resolved – or they can choose **Proceed**, which will send the process to **Step 6 – CAPA Due Date Extension Request Approval**.

Process > CAPA > CAPA Due Date Extension Request (1) > Act on Status: In Process

Process Details

Unique ID: CAPA-000047 Flowchart: Open

Current Process Tasks: CAPA Due Date Extension Request (1)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:32:06
Name: CAPA Due Date Extension Request (1)	

Expand all Print all

Process Task Form - CAPA Due Date Extension Request (1)

* Proposed CAPA Extension Date:

* Reason for the Extension Request:

CAPA Due Date Extension Request Decision:
 Proceed
 Cancel

Secondary Tasks

<input checked="" type="checkbox"/>	Create a Centerlining Team
	Due Date: 25-Aug-2017 Type: Pre-Implementation
	Originator: user1 (User 1)

Modify Remove

Process Actions

- [View](#)
- [Modify Values](#)
- [Reassign Tasks](#)
- [Cancel](#)
- [Get Link](#)
- [Email Link](#)
- [Move Out of Waiting](#)

Act on

- [CAPA Due Date Extension Request\[...\]](#)

Related Items

- [Link Documents](#)
- [Link Processes](#)
- [Modify Description](#)
- [Remove Links](#)

Related Information

- [Audit Trail](#)

Process > CAPA > View Status: In Process

Process Details

Name: CAPA Date Initiated: 11-Aug-2017 13:17:41
 Unique ID: CAPA-000047 Initiated by: user1 (User 1)
 Day(s) opened: 0 Date Closed: <empty>
 Secondary Tasks Completion (%): 0 (0/1) Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks Currently with
 CAPA Due Date Extension Request Approval (1) jiannuzzi

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date:
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11
Name: CAPA Plan QA Evaluation and Acceptance	Last Confir
Name: With Owner for CAPA Completion	Last Confirmation D
Name: CAPA Due Date Extension Request (1)	Last Confirma
Name: CAPA Due Date Extension Request Approval (1)	

CAPA Due Date Extension Request

↓

CANCEL
PROCEED

↓

CAPA Due Date Extension Request Approval

↓

APPROVE
DENIED
RETURN FOR MORE INFORMATION

↓

Related Items

Secondary Tasks

Name: Create a Centerinin[...] Unique ID: PRE-00000009 Due: 25-Aug-2017 Status: In Progress View

[Expand all](#)

Related Processes

Unique ID: DEV-000028 Date Initiated: 14-Jul-2017 Status: Completed View

Current Process Task: N/A

[Expand all](#)

Step 6: CAPA Due Date Extension Request Approval

At this step in the CAPA Process, the **QA CAPA Approver** will receive an email Notification and will see the **CAPA Due Date Extension Request Approval** task listed in the Process section of their SOLABS QM10 HOME Page.

Jacqueline Iannuzzi

Home > Views

PROCESSES

Received this week / last week

Unique ID: CAPA-000047 Date Initiated: 11-Aug-2017 Status: In Process View | Act on

Current Process Task: CAPA Due Date Extension Request Approval (1)

Acting on the CAPA Due Date Extension Request Approval Task

When the **QA CAPA Approver** clicks on the **Act on** option to the right of the **CAPA Due Date Extension Request Approval** task, they will go immediately to the **Act on** screen for their **CAPA Due Date Extension Request Approval** task.

At the **Act on** screen for the **CAPA Due Date Extension Request Approval** task, the **QA CAPA Approver** can view information entered at previous steps by choosing the **Expand all** option in the **Process Values Table**. Steps can be expanded individually or the entire table can be expanded.

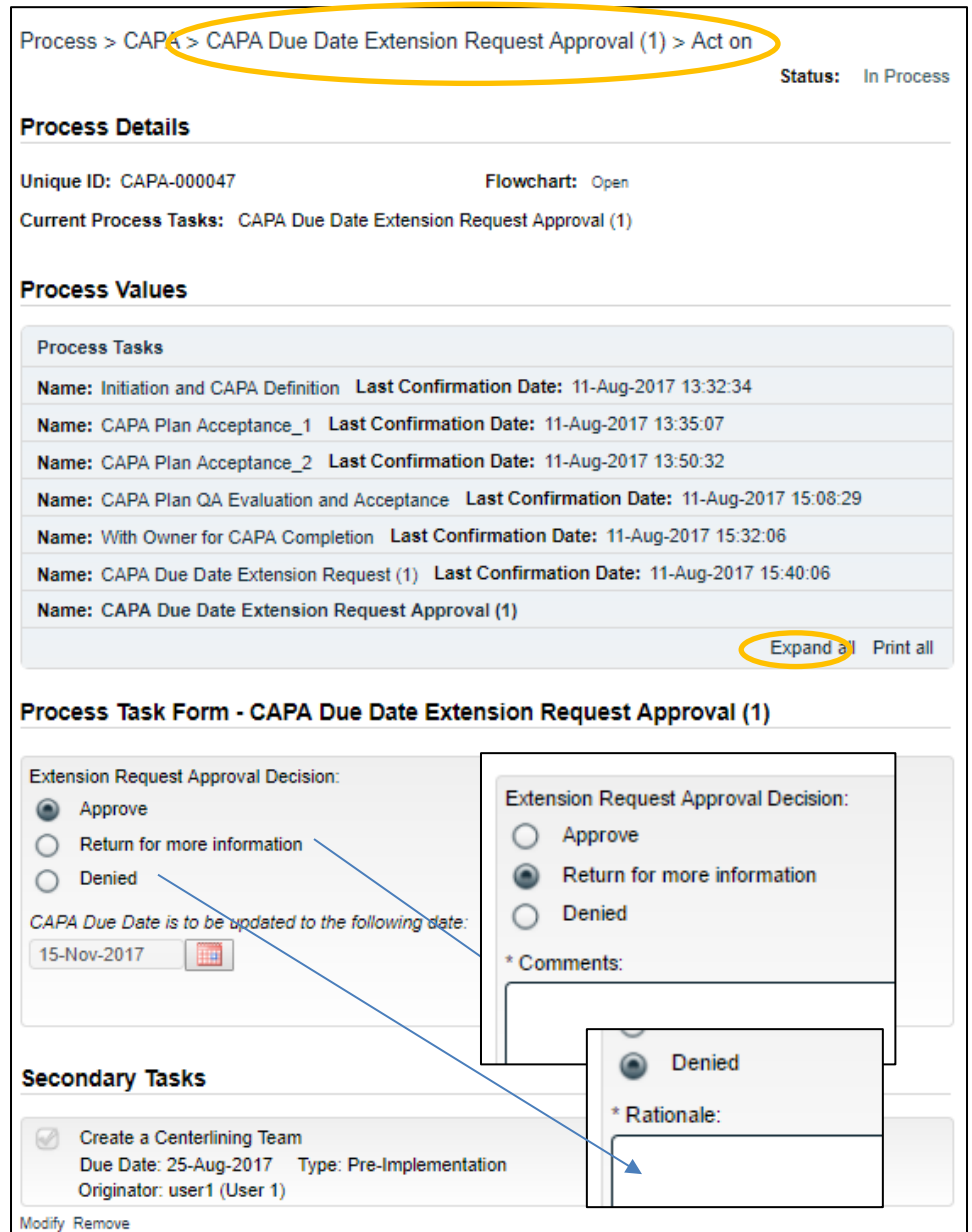
At this point, they need to enter the **Extension Request Approval Decision**.

If they choose **Return for more information**, a **Comment** field is mandatory. The process will go back to the previous Step so that the **CAPA Owner** can address the comment.

If they choose **Denied**, a **Rationale** field is mandatory. The process will again go back to the previous Step.

If they choose **Approve**, the CAPA Process will go back to **Step 4 – With Owner for CAPA Completion** and the CAPA due date is updated with the approved extension date.

At this point the **CAPA Owner** can continue to monitor for completion of related activities.



Process > CAPA > CAPA Due Date Extension Request Approval (1) > Act on Status: In Process

Process Details

Unique ID: CAPA-000047 Flowchart: Open

Current Process Tasks: CAPA Due Date Extension Request Approval (1)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:32:06
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 15:40:06
Name: CAPA Due Date Extension Request Approval (1)	


Expand all Print all

Process Task Form - CAPA Due Date Extension Request Approval (1)

Extension Request Approval Decision:

Approve
 Return for more information
 Denied

CAPA Due Date is to be updated to the following date:

15-Nov-2017 

* Comments:

Secondary Tasks

Create a Centerlining Team
 Due Date: 25-Aug-2017 Type: Pre-Implementation
 Originator: user1 (User 1)

Modify Remove

Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks With Owner for CAPA Completion	Currently with jiannuzzi (Jacqueline Iannuzzi)

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 15:40:06
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017 15:48:19
PRE-00000003	
Expand all Print all	

Related Items

Secondary Tasks

Name: Create a Centerlinin[...] **Unique ID:** PRE-00000009 **Due:** 25-Aug-2017 **Status:** In Progress [View](#)

[Expand all](#)

Related Processes

Unique ID: DEV-000028 **Date Initiated:** 14-Jul-2017 **Status:** Completed [View](#)

Current Process Task: N/A

[Expand all](#)



From the **Process Values** table, we can see that the **CAPA Owner** had requested an extension and that it was approved. At that point, the CAPA Process went back to **Step 4 - With Owner for CAPA Completion**.

The **CAPA Owner** will now receive another Notification – just like they did prior to requesting the extension, and will see the **With Owner for Completion** task listed in the Process section of their SOLABS QM10 HOME Page.

Jacqueline Iannuzzi

Home > Views

PROCESSES

Received this week / last week

Unique ID: CAPA-000047	Date Initiated: 11-Aug-2017	Status: In Process	View Act on
Current Process Task: With Owner for CAPA Completion			

The CAPA Process they own is now accepted for an extension. They can choose the **View** option to access all information previously entered. Looking at the **Related Items** section, the **Secondary Task** has now completed so the **CAPA Owner** can **Act on** the CAPA Process and choose the **Approve** option, to bring it to **Step 7 – CAPA Completion**.

Process Task Form - With Owner for CAPA Completion

CAPA Task Completion Decision:

Approve

Request Extension

Status: In Process

Process Details

Name: CAPA Date Initiated: 11-Aug-2017 13:17:41
 Unique ID: CAPA-000047 Initiated by: user1 (User 1)
 Day(s) opened: 0 Date Closed: <empty>
 Secondary Tasks Completion (%): 100 (1/1) Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks Currently with
 CAPA Completion_1 bschenck (Brandy Schenck)
 CAPA Completion_2 Ihussey (Lisa Jazon)

Flowchart: Open

Process Values

Process Tasks	Last Confirmation Date
Name: Initiation and CAPA Definition	Last Confirmation Date:
Name: CAPA Plan Acceptance_1	Last Confirmation Date:
Name: CAPA Plan Acceptance_2	Last Confirmation Date:
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date:
Name: With Owner for CAPA Completion	Last Confirmation Date:
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date:
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date:
Name: CAPA Completion_1	Last Confirmation Date:
Name: CAPA Completion_2	Last Confirmation Date:

Related Items

Secondary Tasks

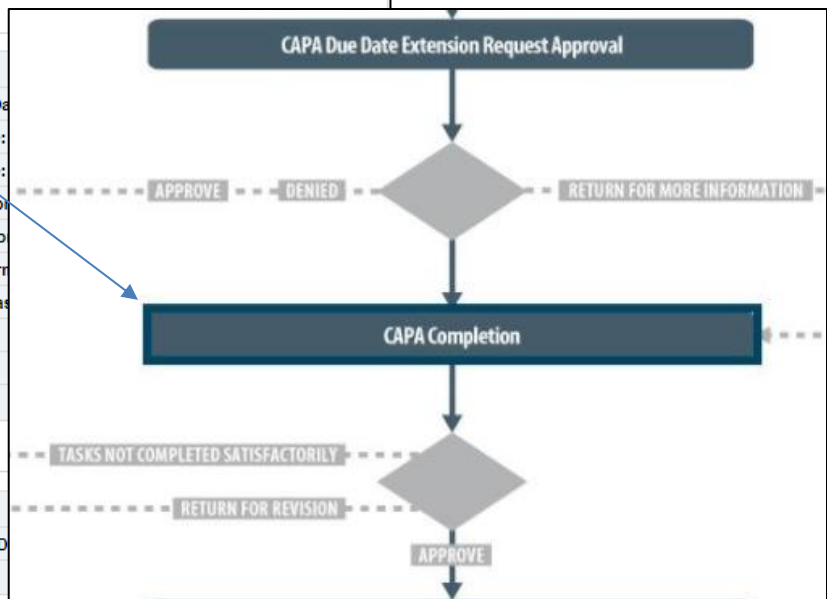
Name: Create a Centerlinin[...] Unique ID: PRE-00000009 D

Related Processes

Unique ID	Date Initiated	Status	View
DEV-000028	14-Jul-2017	Completed	View

Current Process Task: N/A

Expand all



Step 7: CAPA Completion

At this step in the CAPA Process, each of the **Reviewers** chosen at Step 1, and who reviewed the CAPA at Step 2, will receive an email Notification and will see the **CAPA Completion** task listed in the Process section of their SOLABS QM10 HOME Page.

October 2022

Brandy Schenck

Home > Views

PROCESSES

Received this week / last week

Unique ID	Date Initiated	Status	View	Act on
CAPA-000047	11-Aug-2017	In Process	View	Act on

Current Process Task: CAPA Completion_1

Acting on the CAPA Completion Task

Each **Reviewer** can choose to **View** the CAPA Process, and then choose **CAPA Completion** from the right-hand **Act on** Menu, or they can choose **Act on** from their HOME Page.

At this point, with the **CAPA Owner** having communicated **CAPA Completion**, they are getting this task in order to make their **CAPA Completion Decision**.

If a Reviewer chooses **Tasks Not Completed Satisfactorily**, they will be required to enter a **Rationale**. The CAPA Process will then return to **Step 4 - With Owner for CAPA Completion**.

If a Reviewer chooses **Return for Revision**, they will be required to enter a **Comment**. The CAPA Process will then return to **CAPA Initiator**.

NOTE: If only one Reviewer chooses the Tasks Not Completed Satisfactorily or the Return for Revision option, the other Reviewers must still make their **CAPA Completion Decision** before the process goes back to the CAPA Owner or the Initiator. Each Reviewer can see the decisions of the others in the Process Values table.

If all Reviewers choose **Approve**, the CAPA Process will progress to **Step 8 – CAPA Completion and VOE Plan – QA**.

The decision as to whether or not this CAPA should have a **Verification of Efficacy (VOE)** is the responsibility of the assigned **QA CAPA Approver** and happens in the next step.

Process > CAPA > CAPA Completion_1 > Act on Status: In Process

Process Details

Unique ID: CAPA-000047 Flowchart: Open

Current Process Tasks: CAPA Completion_1; CAPA Completion_2

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:56:35
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 15:40:06
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Completion_1	
Name: CAPA Completion_2	

[Expand all](#) [Print all](#)

Process Task Form - CAPA Completion_1

CAPA Completed within 1 extension(s)

CAPA Completion Decision:

- Approve
- Tasks Not Completed Satisfactorily
- Return for Revision

* Rationale:

Secondary Tasks

- Create a Centerlining Team
Due Date: 25-Aug-2017 Type
Originator: user1 (User 1)

Modify Remove

CAPA Completion Decision:

- Approve
- Tasks Not Completed Satisfactorily
- Return for Revision

* Rationale:

CAPA Completion Decision:

- Approve
- Tasks Not Completed Satisfactorily
- Return for Revision

* Comments:

Status: In Process

Process Details

Name: CAPA **Date Initiated:** 11-Aug-2017 13:17:41
Unique ID: CAPA-000047 **Initiated by:** user1 (User 1)
Day(s) opened: 0 **Date Closed :** <empty>
Secondary Tasks Completion (%): 100 (1/1) **Dependent Processes Completion (%):** 0 (0/0)

Current Process Tasks **Currently with**
 CAPA Completion and VOE Plan - QA jianuzzi (J)

Flowchart: Open

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017
Name: CAPA Completion_1	Last Confirmation Date: 11-Aug-2017
Name: CAPA Completion_2	Last Confirmation Date: 11-Aug-2017
Name: CAPA Completion and VOE Plan - QA	

Expand all Print all

Related Items

Secondary Tasks

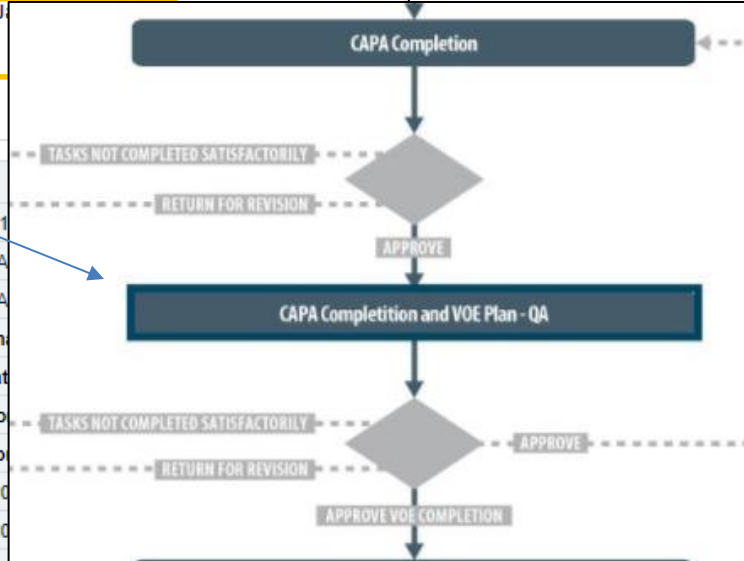
Name: Create a Centerin[...]	Unique ID: PRE-00000009	Due: 25-Aug-2017	Status: Completed	View
-------------------------------------	--------------------------------	-------------------------	--------------------------	----------------------

Expand all

Related Processes

Unique ID: DEV-000028	Date Initiated: 14-Jul-2017	Status: Completed	View
------------------------------	------------------------------------	--------------------------	----------------------

Expand all



Step 8: CAPA Completion and VOE Plan - QA

At this step in the CAPA Process, the **QA CAPA Approver** will receive a Notification and will see the **CAPA Completion and VOE Plan - QA** task listed in the Process section of their SOLABS QM10 HOME Page.

Home > Views Jacqueline Iannuzzi

PROCESSES

Received this week / last week
Unique ID: CAPA-000047 Date Initiated: 11-Aug-2017 Status: In Process Current Process Task: CAPA Completion and VOE Plan - QA View Act on

Acting on the CAPA Completion and VOE Plan – QA Task

At this step in the CAPA Process, the **QA CAPA Approver** has the *same options described at Step 7 above for the Reviewers*.

The **QA CAPA Approver** also has some *additional fields* to complete.

- QA Review CAPA Comments
- VOE Required?

The **QA Review CAPA Comments** field is optional.

The **VOE Required?** field is mandatory and is a single-select drop-down list:

A selection of **No** brings up a mandatory **Rationale** field. If the **CAPA Completion QA Decision** is then to **Approve**, the CAPA Process will then progress to **Step 12 - CAPA Closure**.

A selection of VOE Required is **Yes** brings up the mandatory fields for a **QA VOE Approver, VOE Plan and VOE Due Date**.

When the **VOE Due Date** is within 5 days of the current date, an email Notification will be sent to the CAPA Approver.

When they then choose a **CAPA Completion QA Decision** of **Approve** the CAPA Process will progress to **Step 9 – VOE Completion** but will stay with the original **QA CAPA Approver** since they are responsible for monitoring and then determining the final effectiveness of the CAPA.

Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed : <empty>
Secondary Tasks Completion (%): 100 (1/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks	Currently with
VOE Completion	jiannuzzi (Jacqueline Iannuzzi)

Flowchart: Open

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017
Name: CAPA Completion_1	Last Confirmation Date: 11-Aug-2017
Name: CAPA Completion_2	Last Confirmation Date: 11-Aug-2017
Name: CAPA Completion and VOE Plan - QA	Last Confirmation Date: 11-Aug-2017 16:17:38
Name: VOE Completion	

[Expand all](#) [Print all](#)

Related Items

Secondary Tasks

Name: Create a Centerlinin[...]	Unique ID: PRE-00000009	Due: 25-Aug-2017	Status: Completed	View
--	--------------------------------	-------------------------	--------------------------	----------------------

[Expand all](#)

Related Processes

Unique ID: DEV-000028	Date Initiated: 14-Jul-2017	Status: Completed	View
------------------------------	------------------------------------	--------------------------	----------------------

Current Process Task: N/A

[Expand all](#)

Step 9 – VOE Completion

At this step, even though the CAPA Process stays with the same person – the **QA CAPA Approver** – they will receive a Notification for the new **VOE Completion** task.

Jacqueline Iannuzzi

Home > Views

PROCESSES

Received this week / last week

Unique ID: CAPA-000047	Date Initiated: 11-Aug-2017	Status: In Process	View Act on
-------------------------------	------------------------------------	---------------------------	---

Current Process Task: VOE Completion

Acting on the VOE Completion Task

This **VOE Completion** task will stay with the **QA CAPA Approver** until such time as they are ready to make the **VOE Verification Decision**.

If the VOE Plan takes longer than may have been anticipated, they will have the option to submit a **VOE Due Date Extension Request** and to get **VOE Due Date Extension Request Approval**. These will be formally captured within the CAPA Process as **Steps 10 and 11**.

If **Request Extension** is chosen, the **Results of VOE** field is still mandatory but can be used to provide an update on the status of the VOE to date.

Process Task Form - VOE Co

* Results of VOE:

Need more time to assess.

VOE Verification Decision:

VOE Successfully completed
 Request Extension

Process > CAPA > **VOE Completion > Act on**

Status: In Process

Process Details

Unique ID: CAPA-000047 Flowchart: Open

Current Process Tasks: VOE Completion

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:56:35
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 15:40:06
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Completion_1	Last Confirmation Date: 11-Aug-2017 16:07:29
Name: CAPA Completion_2	Last Confirmation Date: 11-Aug-2017 16:07:59
Name: CAPA Completion and VOE Plan - QA	Last Confirmation Date: 11-Aug-2017 16:17:38
Name: VOE Completion	

Expand all Print all

Process Task Form - VOE Completion

* Results of VOE:

|

VOE Verification Decision:

VOE Successfully completed
 Request Extension

Secondary Tasks

Create a Centerlining Team

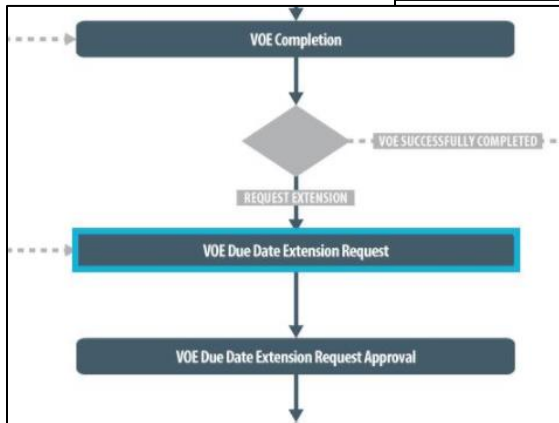
Due Date: 25-Aug-2017 Type: Pre-Implementation

Originator: user1 (User 1)

Modify Remove

Step 10: VOE Due Date Extension Request

This CAPA Process Step will also stay with the **QA CAPA Approver** but they will get another Notification and an **Act on the VOE Due Date Extension Request** task in order to choose a date and to formally capture the information as part of the CAPA Process.



[Home](#) > [VOE Due Date Extension Request \(1\)](#) > [Act on](#) Status: In Process

000047 Flowchart: Open

Tasks: VOE Due Date Extension Request (1)

and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:56:35
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 15:40:06
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Completion_1	Last Confirmation Date: 11-Aug-2017 16:07:29
Name: CAPA Completion_2	Last Confirmation Date: 11-Aug-2017 16:07:59
Name: CAPA Completion and VOE Plan - QA	Last Confirmation Date: 11-Aug-2017 16:17:38
Name: VOE Completion	Last Confirmation Date: 11-Aug-2017 16:24:55
Name: VOE Due Date Extension Request (1)	

Expand all Print all

Acting on the VOE Due Date Extension Request

At this point the CAPA Approver must enter a **Proposed VOE Extension Date** and a **Reason for the Extension Request**.

At this point the CAPA Process will move to **Step 11 – VOE Due Date Extension Request Approval** and will be assigned to the **QA VOE Approver** who was selected at Step 8.

Process Task Form - VOE Due Date Extension Request (1)

* Proposed VOE Extension Date:

* Reason for the Extension Request:

Secondary Tasks

- Create a Centerlining Team
 Due Date: 25-Aug-2017 Type: Pre-Implementation
 Originator: user1 (User 1)


Modify Remove

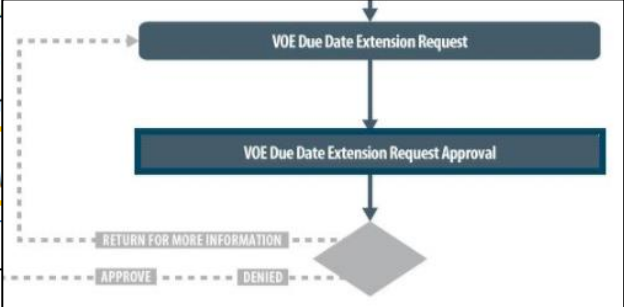
Process > CAPA > View

Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: u
Day(s) opened: 0	Date Closed:
Secondary Tasks Completion (%): 100 (1/1)	Dependent Pr
Current Process Tasks	Currently with
VOE Due Date Extension Request Approval (1)	mmoulaison (M

Flowchart: Open 



Step 11: VOE Due Date Extension Request Approval

The **QA VOE Approver**, chosen by the **QA CAPA Approver** at Step 8, will now receive a Notification to formally approve this **VOE Due Date Extension Request**.

Marcel Moulaison

Home > Views

PROCESSES

Received this week / last week

Unique ID: CAPA-000047	Date Initiated: 11-Aug-2017	Status: In Process	View Act on
Current Process Task: VOE Due Date Extension Request Approval (1)			

Acting on the VOE Due Date Extension Request Approval

A choice to **Return for more information** will require a mandatory **Comment** and send the Extension Request back to the Requester.

A choice of **Denied** will require a mandatory **Rationale** and send the CAPA Process back to the Requester.

A **VOE Due Date Extension Request Approval Decision** of **Approve** will extend the due date and send the CAPA Process back to **Step 9 – VOE Completion**, with the **QA CAPA Approver**.


When the CAPA Process originally reached **Step 9**, if the **QA CAPA Approver** had not chosen to request an extension, the other **VOE Verification Decision** was **VOE Successfully completed**.

Process Task Form - VOE Due Date Extension Request Approval (1)

VOE Due Date Extension Request Approval Decision:

Approve
 Return for more information
 Denied

VOE Due Date is to be updated to the following date:

31-Jan-2018 

At whatever point the **QA CAPA Approver** chooses the decision of **VOE Successfully completed** – either without needing an extension or after an extension – the CAPA Process will then move to **Step 12 – CAPA Closure**.

Expand all Print all

Process Task Form - VOE Completion

* Results of VOE:
 Completed successfully!

VOE Verification Decision:
 VOE Successfully completed
 Request Extension

Step 12: CAPA Closure

At this final Step in the CAPA Process, the **QA CAPA Approver** receives a **CAPA Closure** Notification, and will have the option to **View** the **Process Values** and any **Related Items**.

Status: In Process

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed: <empty>
Secondary Tasks Completion (%): 100 (1/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks CAPA Closure	Currently with jiannuzzi (Ja

Flowchart: Open

Process Values

Process Tasks
Name: Initiation and CAPA Definition Last Confirmation Date: 11-Aug-2017 16:07:29
Name: CAPA Plan Acceptance_1 Last Confirmation Date: 11-Aug-2017 16:07:59
Name: CAPA Plan Acceptance_2 Last Confirmation Date: 11-Aug-2017 16:17:38
Name: CAPA Plan QA Evaluation and Acceptance Last Confirmation Date: 11-Aug-2017 16:41:22
Name: With Owner for CAPA Completion Last Confirmation Date: 11-Aug-2017 16:29:01
Name: CAPA Due Date Extension Request (1) Last Confirmation Date: 11-Aug-2017 16:32:44
Name: CAPA Due Date Extension Request Approval (1) Last Confirmation Date: 11-Aug-2017 16:07:29
Name: CAPA Completion_1 Last Confirmation Date: 11-Aug-2017 16:07:29
Name: CAPA Completion_2 Last Confirmation Date: 11-Aug-2017 16:07:59
Name: CAPA Completion and VOE Plan - QA Last Confirmation Date: 11-Aug-2017 16:17:38
Name: VOE Completion Last Confirmation Date: 11-Aug-2017 16:41:22
Name: VOE Due Date Extension Request (1) Last Confirmation Date: 11-Aug-2017 16:29:01
Name: VOE Due Date Extension Request Approval (1) Last Confirmation Date: 11-Aug-2017 16:32:44
Name: CAPA Closure

Expand all Print all

Related Items

Secondary Tasks				
Name: Create a Centerlinin[...]	Unique ID: PRE-00000009	Due: 25-Aug-2017	Status: Completed	View
Expand all				
Related Processes				
Unique ID: DEV-000028	Date Initiated: 14-Jul-2017	Status: Completed	View	
Current Process Task: N/A				
Expand all				

CAPA Closure

```

graph TD
    A[CAPA Closure] --> B{ }
    B --> C[APPROVE]
    B --> D[RETURN FOR REVISION]
    C --> E((END))
    D --> E
    
```

At this step in the process, the **QA CAPA Approver** will make the decision as to whether the CAPA actions were successful in solving the problem/issue, make any final QA comments, and either return it for any necessary revisions or approve it.

Acting on the CAPA Closure Step

Process Task Form - CAPA Closure

* Were the corrective/preventative actions successful in solving the problem/issue?:

QA Close-Out Comments:

Close Decision:
 Approve
 Return for Revision

* Comments:

Process Task Form - CAPA Closure

* Were the corrective/preventative actions successful in solving the problem/issue?:

* Explain:

* Is a New CAPA Plan Required?:

* Is a New CAPA Plan Required?:

Initiate a CAPA process after confirming this step

If **Yes** is selected from the drop-down list, the **QA CAPA Approver** can make their **Close Decision** as either **Approve** or **Return for Revision**.

If **Return for Revision** is chosen, a **Comment** is mandatory and the process will return to Step 1 with the **CAPA Initiator**.

If **No** is selected from the drop-down list, additional mandatory fields will need to be completed.

In this case the **QA CAPA Approver** must **Explain** why they feel the corrective/preventative actions did not solve the problem/issue. They must also decide **Is a New CAPA Plan Required?**

If **Yes** is selected, a reminder will appear to initiate another CAPA after closing this one. It is also possible to initiate another CAPA from within the current CAPA Process using the **Related Processes** section. The two CAPA Processes will then be Related Items of each other. If **No** is selected, a **Rationale** is mandatory.

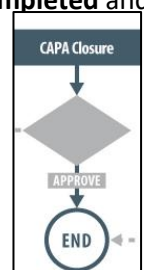
Related Processes

* Available Processes:

* Is a New CAPA Plan Required?:

* Rationale:

If the CAPA Actions are successful, and a **Close Decision of Approve** is **Submitted** and **Confirmed** by the CAPA Approver, the CAPA Process goes to a status of **Completed** and is at the **END**.



Viewing Details for a Completed CAPA Process

Users are able to search for and view processes at any stage, using the Navigation tab in the **PROCESS Section** of SOLABS QM10.

Using the Process Values Table

Process Tasks can be viewed by using the **Expand all** or **Print all** options at the bottom of the **Process Values** table. An individual Process Task can be expanded by clicking on it within the **Process Values** table.

Using the Related Items Table

Information on any **Secondary Tasks, Related Processes or Related Documents** can be accessed by clicking on the **View** option beside the listing in the **Related Items** section of the screen. From any of those Detail screens, the Process will be listed under Related Items – you can quickly toggle back to the Main Process by clicking **View** next to it.

Process > CAPA > View Status: Completed

Process Details

Name: CAPA	Date Initiated: 11-Aug-2017 13:17:41
Unique ID: CAPA-000047	Initiated by: user1 (User 1)
Day(s) opened: 0	Date Closed : 11-Aug-2017 16:50:59
Secondary Tasks Completion (%): 100 (1/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks N/A	Currently with N/A

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and CAPA Definition	Last Confirmation Date: 11-Aug-2017 13:32:34
Name: CAPA Plan Acceptance_1	Last Confirmation Date: 11-Aug-2017 13:35:07
Name: CAPA Plan Acceptance_2	Last Confirmation Date: 11-Aug-2017 13:50:32
Name: CAPA Plan QA Evaluation and Acceptance	Last Confirmation Date: 11-Aug-2017 15:08:29
Name: With Owner for CAPA Completion	Last Confirmation Date: 11-Aug-2017 15:56:35
Name: CAPA Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 15:40:06
Name: CAPA Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017 15:48:19
Name: CAPA Completion_1	Last Confirmation Date: 11-Aug-2017 16:07:29
Name: CAPA Completion_2	Last Confirmation Date: 11-Aug-2017 16:07:59
Name: CAPA Completion and VOE Plan - QA	Last Confirmation Date: 11-Aug-2017 16:17:38
Name: VOE Completion	Last Confirmation Date: 11-Aug-2017 16:41:22
Name: VOE Due Date Extension Request (1)	Last Confirmation Date: 11-Aug-2017 16:29:01
Name: VOE Due Date Extension Request Approval (1)	Last Confirmation Date: 11-Aug-2017 16:32:44
Name: CAPA Closure	Last Confirmation Date: 11-Aug-2017 16:50:59

[Expand all](#) [Print all](#)

Related Items

Secondary Tasks	
Name: Create a Centerlinin[...]	Unique ID: PRE-00000009 Due: 25-Aug-2017 Status: Completed View

[Expand all](#)

Related Processes	
Unique ID: DEV-000028 Date Initiated: 14-Jul-2017 Status: Completed View	Current Process Task: N/A

[Expand all](#)

Using the Audit Trail

Under the right-hand **Related Information** menu, click on the **Audit Trail** option.

There you will find all the details for every step of the CAPA Process, from **Process Completed** all the way down to **Process Started**, with options to expand or print the entire process or any individual steps.

Process > CAPA-000047 > Audit Trail	
Process Name: CAPA-000047	
Action Details: Process Completed Process Task Name: N/A Date: 11-Aug-2017 16:50:59 Role: FCT_a_D_QA_Systems Username (Full Name): jiannuzzi (Jacqueline Iannuzzi) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: CAPA Closure Date: 11-Aug-2017 16:50:59 Role: FCT_a_D_QA_Systems Username (Full Name): jiannuzzi (Jacqueline Iannuzzi) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: VOE Completion Date: 11-Aug-2017 16:41:22 Role: FCT_a_D_QA_Systems Username (Full Name): jiannuzzi (Jacqueline Iannuzzi) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: VOE Due Date Extension Request Approval (1) Date: 11-Aug-2017 16:32:44 Role: FCT_a_VP_Quality (QA) Username (Full Name): mmoulaison (Marcel) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: VOE Due Date Extension Request (1) Date: 11-Aug-2017 16:29:01 Role: FCT_a_D_QA_Systems Username (Full Name): jiannuzzi (Jacqueline Iannuzzi) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: VOE Completion Date: 11-Aug-2017 16:24:55 Role: FCT_a_D_QA_Systems Username (Full Name): jiannuzzi (Jacqueline Iannuzzi) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: CAPA Completion and V Date: 11-Aug-2017 16:17:38 Role: FCT_a_D_QA_Systems Username (Full Name): jiannuzzi (Jacqueline Iannuzzi) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: CAPA Completion_2 Date: 11-Aug-2017 16:07:59 Role: FCT_a_M_QA_Systems Username (Full Name): Ihussey (Lisa Jazon) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: CAPA Completion_1 Date: 11-Aug-2017 16:07:29 Role: FCT_a_AD_QA_Ops Username (Full Name): bschenck (Brandy Schenck) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: CAPA Plan Acceptance_2 Date: 11-Aug-2017 13:50:32 Role: FCT_a_M_QA_Systems Username (Full Name): Ihussey (Lisa Jazon) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: CAPA Plan Acceptance_1 Date: 11-Aug-2017 13:35:07 Role: FCT_a_AD_QA_Ops Username (Full Name): bschenck (Brandy Schenck) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: Initiation and CAPA Definition Date: 11-Aug-2017 13:32:34 Role: FCT_Role 1 Username (Full Name): user1 (User 1) Reason for Change: N/A	Print
Action Details: Process Started Process Task Name: N/A Date: 11-Aug-2017 13:17:41 Role: N/A Username (Full Name): user1 (User 1) Reason for Change: N/A	Print
Expand all Print all View	

CAPA Process Notifications

The Notifications available with the Off-the-Shelf CAPA Process APP P0050 are identified in the Process Roles section of this User Guide and at the related Process Steps. The content of these email Notifications is described below.

General information on SOLABS QM10 Notifications available with the Core Software can be found in the SOLABS Knowledge Base in a document titled **SOLABS QM10: Notifications Guide**.

Included Notifications

The following two Notifications are associated with the off-the-shelf CAPA Process P0050 APP.

If **VOE Due Date** is \leq today + 5 days the following notification is sent (notification is sent only once i.e. the first time this condition is met)

To: QA CAPA Approver identified in Step 1

Subject: The VOE for CAPA-XXXXX is due on [VOE Due Date]

Body:

The VOE for CAPA-XXXXX is due on [VOE Due Date]

Where CAPA-XXXXX is an hyperlink to the process

This condition is reevaluated every time VOE Due Date is modified

If **CAPA Due Date** is \leq today + 5 days the following notification is sent (notification is sent only once i.e. the first time this condition is met)

To: all users in the role of PR_CAPA_Owner

Subject: CAPA-XXXXX is due on [CAPA Due Date]

Body:

The CAPA-XXXXX is due on [CAPA Due Date]

Where CAPA-XXXXX is an hyperlink to the process

This condition is reevaluated every time CAPA Due Date is modified

Available Options for CAPA Process P0050

Option 1A – option to change some of the field Labels at Step 1 in the CAPA Process:

Original Label	New label
Title	Problem Description
Description of CAPA	CAPA Investigation and Action Plan
Source Record Number	CAPA Source

Option 2 – this option removes the option “No impact” as a value for the **CAPA Classification** field at Step 1

Option 3 – this option changes the field type for **Source Record Number** at Step 1 from a text field to a text area, allowing for up to 4000 characters.

Option 4 – this option changes the field type for **Probable Root Cause** at Step 1 from a text field to a text area, allowing for up to 4000 characters.

Option 5 - this option changes the field type for **Title** at Step 1 from a text field to a text area, allowing for up to 4000 characters.

Option 6 – this option changes the values for the **Type** field at Step 1

From: Corrective Action, Preventative Action

To: Corrective and Preventative Action, Continuous Improvement

The Root Cause Categories will be displayed for the choice of Corrective and Preventative Action.

Option 7 – this option adds additional Secondary Task Types

Task Type Name	Prefix
Immediate Action	IMME
Corrective Action	CORR
Preventive Action	PREV