

SOLABS QM10: Deviation Process P0054 User Guide

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Introduction

This document provides instructions on the use of the **SOLABS QM10 Deviation Process APP P0054** – 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, are available in the Process User Functional Design Specification (PUFDS) document that comes with deployment of the Process in your instance of SOLABS QM10.

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 QM PROCESS Section**.

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

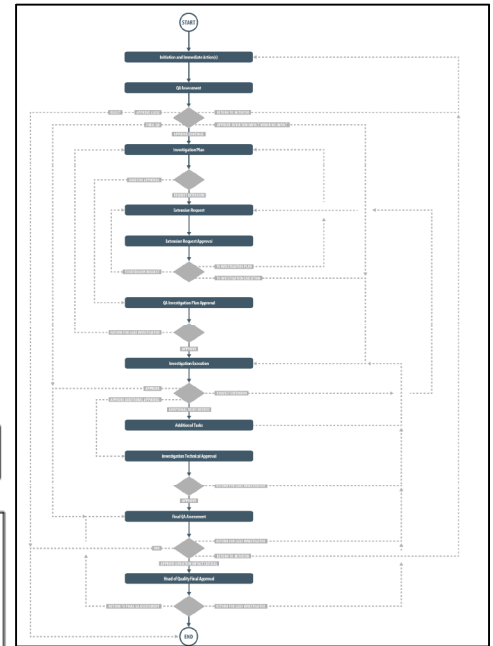
Different steps in a process are assigned to different roles and/or users in the system. You take action on the step assigned to you. For example, you may be assigned a **QA Assessment** step in a **Deviation** process. A manager can monitor the status of process tasks assigned to their employees by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

Deviation Process Flowcharts

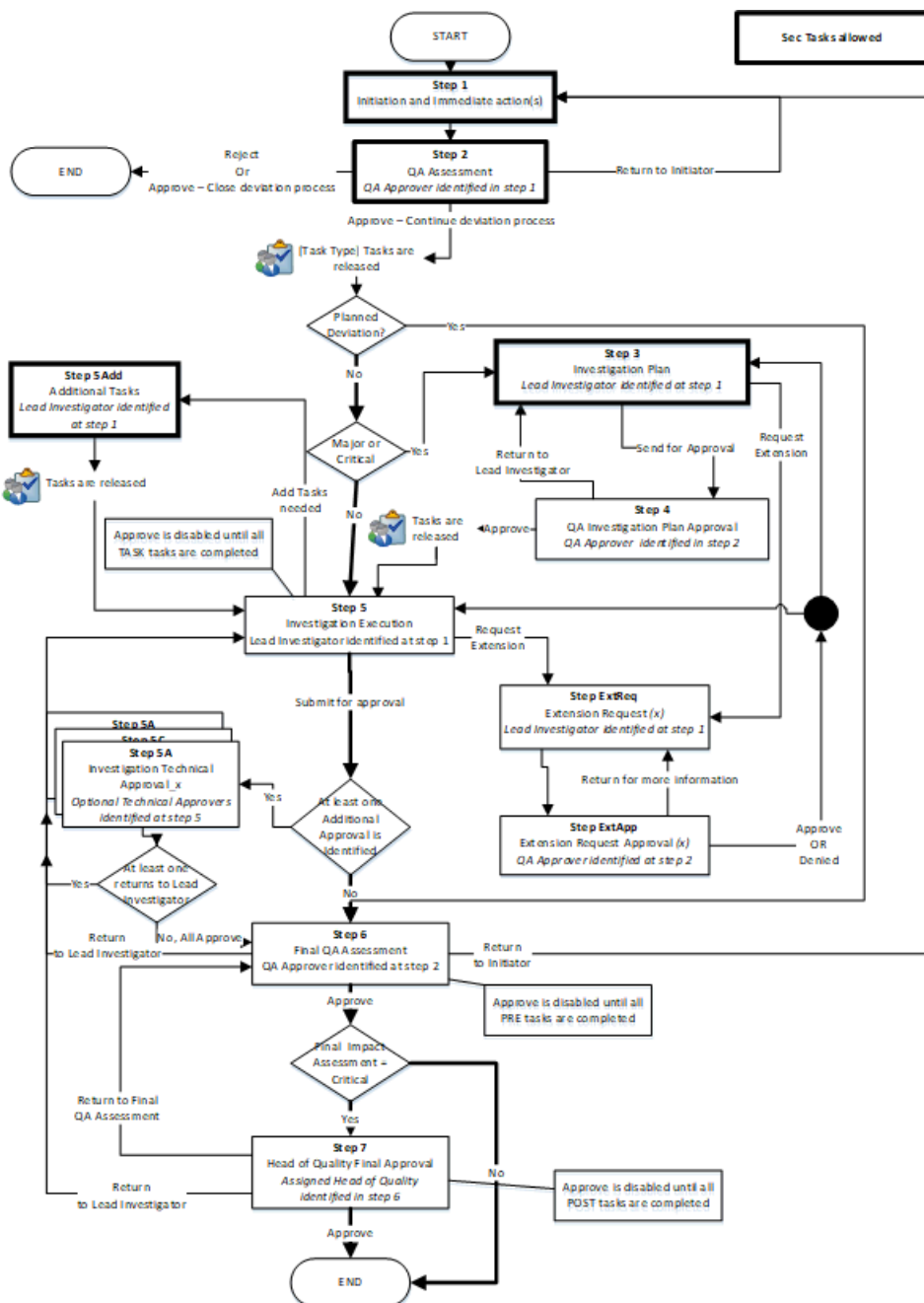
The Deviation Process Flowcharts are displayed on this page for informational purposes only - to show that it is a complex multi-step process with many related decision paths.

The Flowchart shown at the right is available within the Process App. As the process moves along, the active step in that Flowchart is highlighted.

The Flowchart shown below is available as part the User Functional Specification (UFDS) document that is provided with the Process App.



This User Guide is organized into sections for each of the Steps in the Deviation Process. The flowchart section for each of those steps will be displayed in larger, more readable format within those sections.



Deviation Process – Process Roles

The major steps in the process are displayed in the Process Flowchart by dark-shaded boxes. These major steps are considered Primary Tasks in the process. Decisions made by those involved in the process act to progress it to the next Step or return it to a prior Step.

The following **Deviation Process Roles** are associated with the **Deviation Process P0054** and need to 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 process step. They will see the task for that step in the Process Section of their SOLABS QM10 HOME Page and will also receive an email Notification. Contact your SOLABS System Administrator when any of these Deviation Process Roles need to be assigned to additional Users.

PR_DEV_Committee_Notification:

This Process Role must be assigned to those Users who should be notified at the following Steps in the Deviation Process. This is an optional Process Role. The related field can be selected as Yes, No or N/A.

- Step 2 - QA Assessment
- Step 6 – Final QA Assessment
- Step 7 – Head of Quality Final Approval

PR_DEV_Lead_Investigator:

This Process Role must be assigned to those Users who will be asked to perform the following Steps in the Deviation Process:

- Investigation Plan
- Extension Request
- Investigation Execution
- Additional Tasks

When all Secondary Tasks of type = TASK have a status of Completed or Cancelled, the chosen Lead Investigator will get an email Notification.

PR_DEV_QA_Approver:

This Process Role must be assigned to those Users from Quality who will be asked to perform the following Steps in the Deviation Process:

- QA Assessment
- Extension Request Approval
- QA Investigation Plan Approval
- Final QA Assessment

When Step 1 is confirmed with a choice of “Yes” for **Does this deviation impact distributed product?** Everyone with this role assignment will get an email Notification.

When all Secondary Tasks of type = Pre-Disposition have a status of Completed or Cancelled, the chosen QA Approver will get an email Notification.

PR_DEV_QA_Head:

This Process Role must be assigned to those Users from Quality who will be asked to perform the following Steps in the Deviation Process:

- Head of Quality Final Approval

When all Secondary Tasks of type = Post-Disposition have a status of Completed or Cancelled, the chosen QA Head will get an email Notification.

Starting the Deviation Process

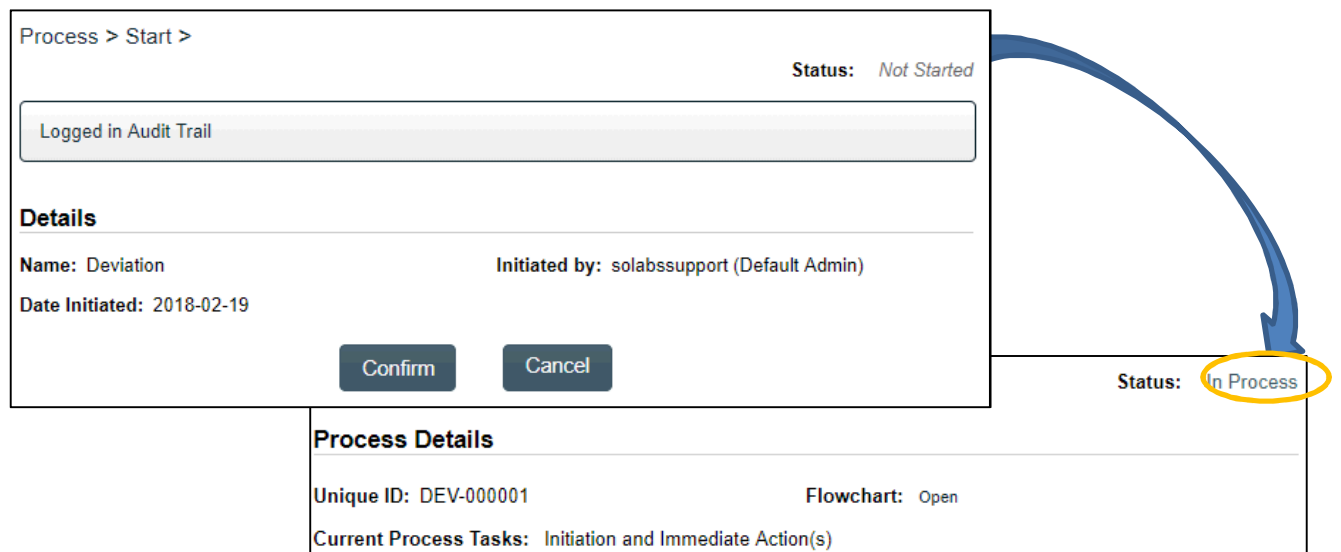
From the PROCESS Section in SOLABS QM10, choose Start Process from the Quick Access Process Menu.



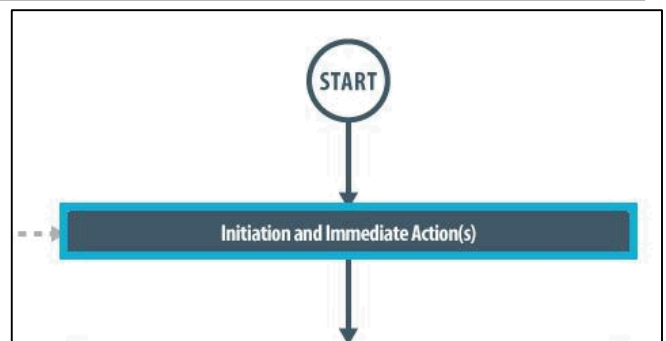
At the next screen, locate the listing for the Deviation Process and click the blue START button.



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 Deviation Process.



The first Step on the **Process Flowchart** will now be highlighted when the flowchart is opened.



Step 1: Initiation and Immediate Action(s)

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

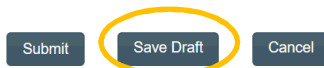
As seen on the screen shot to the right, there are many fields to be completed by the initiator at this step. This page provides some general information on the various types of fields.

Some of the fields on the **Process Task Form** are editable text fields or text areas. Others are single-item selection drop-down lists or multi-item selection fields. Fields with an asterisk (*) are mandatory.

The right-hand **Related Items** menu allows the initiator to **Link Documents** or **Link Processes**, if applicable. There are also sections under the Process Task Form section to initiate **Secondary Tasks** and to initiate new **Related Processes**. Initiation of a Document Control Process is not allowed at Step 1.

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 APPs.

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



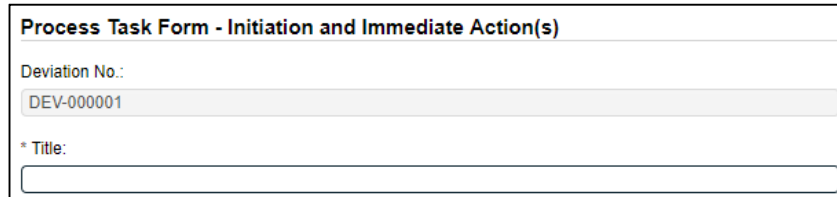
At the bottom of the screen there is a **Save Draft** option if all required fields cannot be completed at one time or before using the right-hand menus to **Link Documents** or **Link Processes**.

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

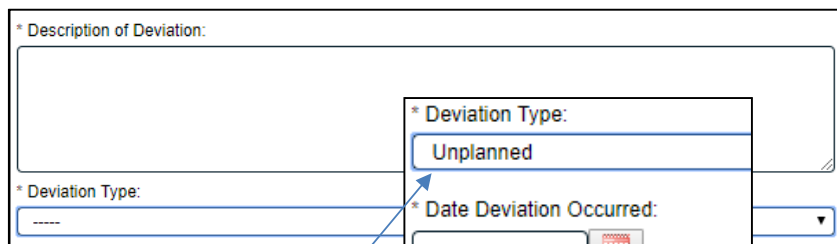
Completing the Process Task Form:

This sub-section covers the information required for each field in the **Process Task Form** at **Deviation Process Step 1**.

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

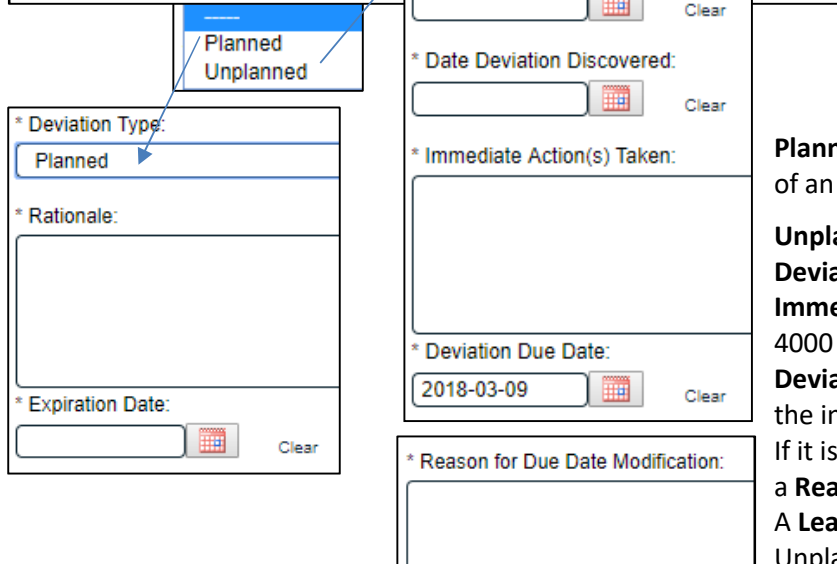


The **Title** field is mandatory. Choose a clear, concise and intuitive title for the Deviation that will quickly communicate the subject. Titles will appear in Deviation Reports.



The **Description of Deviation** field is a mandatory text area field (4000 characters) to provide information about the Deviation.

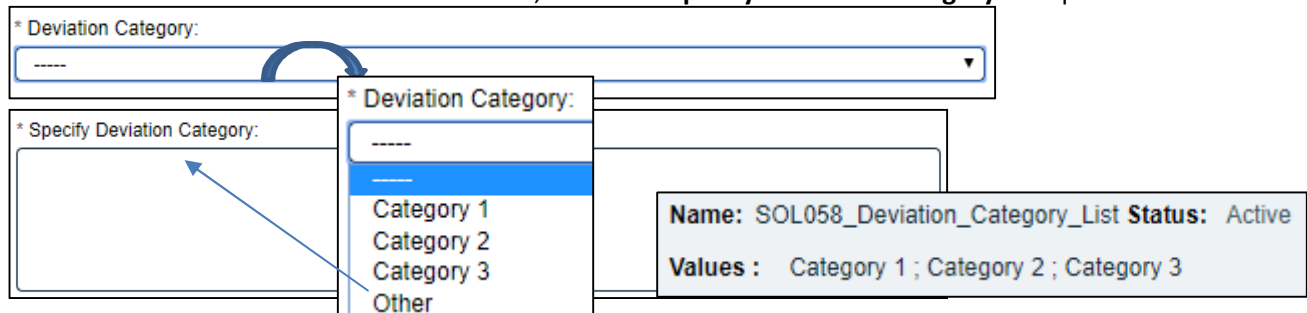
The **Deviation Type** field is a mandatory single-item selection field to choose the type of Deviation being initiated – either **Planned** or **Unplanned**. Depending on the section, additional mandatory fields will be displayed.



Planned deviations require a **Rationale** and entry of an **Expiration Date**.

Unplanned deviations require entry of **Date Deviation Occurred**, **Date Deviation Discovered**, **Immediate Action(s) Taken** (a text area allowing 4000 characters) and a **Deviation Due Date**. The **Deviation Due Date** will default to 30 days from the initiation of the Deviation but can be changed. If it is changed, a mandatory free-text field to enter a **Reason for Due Date Modification** is displayed. A **Lead Investigator** field will also be displayed for Unplanned Deviations.

The **Deviation Category** field is a mandatory field where the category of the Deviation can be selected. It is a single-item selection field populated by an **editable Custom List** of values maintained by the SOLABS System Administrator. If the value **Other** is selected, a field for **Specify Deviation Category** is required.



* GxP Classification:

- GCP (Good Clinical Practices)
- GDP (Good Distribution Practices)
- GLP (Good Laboratory Practices)
- GMP (Good Manufacturing Practices)
- PVG (Good Pharmacovigilance Practices)

Select all Deselect all

* Initiation Type:

* Site:

- Site 1
- Site 2

* Is Material Associated with Deviation? :

No

* Is Material Associated with Deviation? :

Yes

* Molecule #:

* Molecule Name:

* Formulation Description (Campaign Name):

* Material Type:

* Strength/Dose:

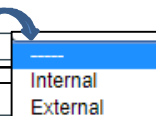
* Packaging Configuration:

Material Description (Excipients, Packaging Components):

[Quick Text]

* Lot Number(s):

Additional Information:



The **GxP Classification** field is a mandatory multi-item selection field allowing for up to five selections.

The **Initiation Type** field is a mandatory single-item selection field to choose either **Internal** or **External**.

The **Site** field is a mandatory multi-item selection field. It is populated by an **editable Custom List** maintained by the SOLABS System Administrator.

Name: SOL161_Site_List **Status:** Active
Values : Site 1 ; Site 2 ; Site 3

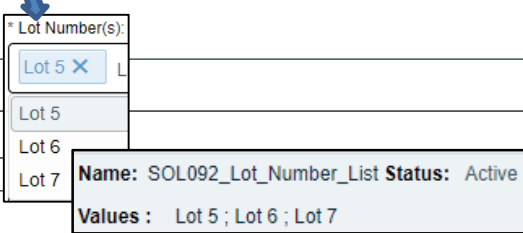
The **Is Material Associated with Deviation?** field is a single-item selection field allowing for **Yes** or **No**. If **Yes** is selected, additional single-item selection fields will be displayed for entry of information regarding the material. The values for those fields are populated from **editable Custom Lists**.

- The fields for **Molecule #** and **Molecule Name** initially appear to both be mandatory. However, when one is filled in, the other becomes non-mandatory.

- **Formulation Description (Campaign Name)** and **Material Type** are mandatory.

- When a **Material Type** is selected, the mandatory **Strength/Dose** and **Packaging Configuration** fields picklists will be populated with the appropriate values available for that Material Type, according to a client-specific EDI Table lists.

- **Material Description (Excipients, Packaging Components)** and **Additional Information** are non-mandatory text areas allowing 4000 and 8000 characters respectively.



- The **Lot Number(s)** field is mandatory. It is an Autocomplete, Multiple, Delimited Values based on an **editable Custom List**. Starting to type a number will bring up existing numbers that include those digits. When selected, each Lot Number will have an "X" after it, to allow removal.

* Does this deviation impact distributed product?:

The mandatory field for **Does this potentially impact distributed Product?** is a single-item selection field allowing for **Yes** or **No**.

Lead Investigator:

* QA Approver:

The **Lead Investigator** field is displayed when the **Deviation Type** of **Unplanned** is selected. It is not a mandatory field at **Step 1**. If it is not completed until **Step 2**, the name selected at **Step 2** will then populate the field at **Step 1**. It is a single-item selection field that allows selection of Users who are assigned the Process Role of **PR_DEV_Lead_Investigator**.

QA Approver is a mandatory field. It is a single-item selection field that allows selection of Users who are assigned the Process Role of **PR_DEV_QA_Approver**.

After the **Process Task Form** fields are completed, the sections for **Secondary Tasks** and **Related Processes** can be completed. The **Document Control / Impacted Documents** section is grayed out since it is not available at **Step 1**. The right-hand **Link Documents** and **Link Processes** option are available to link existing documents or processes as **Related Items**.

Creating Secondary Tasks

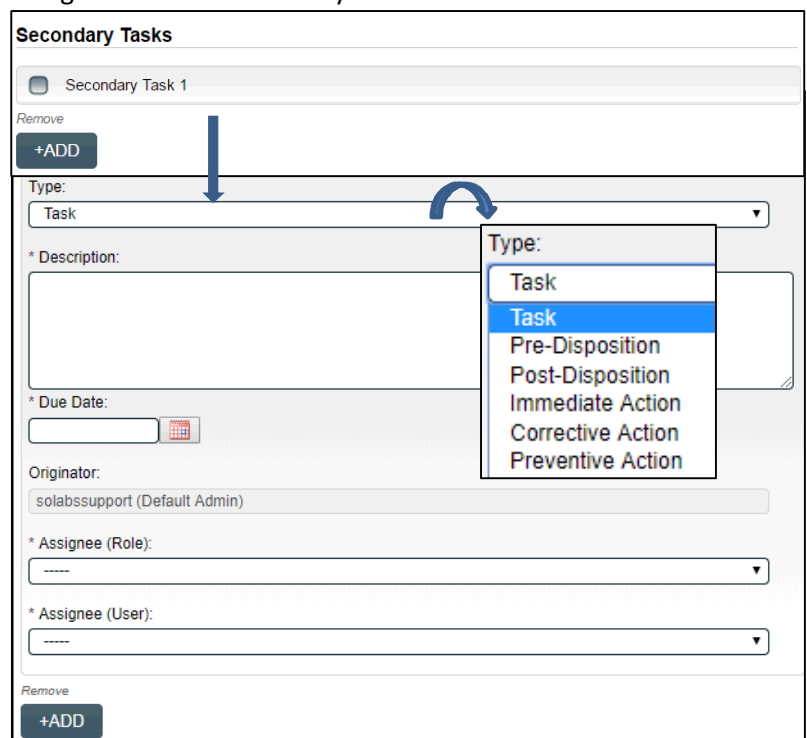
The initiator of the Deviation Process can create **Secondary Tasks** that will be associated with the Deviation. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the Deviation but that are not part of the Primary Tasks (process workflow steps).

The **Secondary Task** section is under the Process Task Form, but still on the Deviation Initiation and Immediate Action(s) screen. This section is available at various Steps of the Process, allowing others involved in the review, implementation and approval of the Deviation 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. Types **Task**, **Pre-Disposition** and **Post-Disposition** are used in the Deviation Process. The Step number listed beside each Task Type below indicates the Step by which it will need to be completed, in order for the process to progress.

- Task Prefix = TASK Step 4
- Pre-Disposition Prefix = PREDI Step 6
- Post-Disposition Prefix = POSTDI Step 7



The screenshot shows the 'Secondary Tasks' section of a form. At the top, there is a header 'Secondary Tasks' and a sub-header 'Secondary Task 1'. Below this is a 'Remove' button and a '+ADD' button. The main form area contains several fields: 'Type:' with a dropdown menu currently showing 'Task' and a list of options including 'Task', 'Pre-Disposition', 'Post-Disposition', 'Immediate Action', 'Corrective Action', and 'Preventive Action'; '* Description:' with a text input area; '* Due Date:' with a date picker; 'Originator:' with a text input showing 'solabssupport (Default Admin)'; '* Assignee (Role):' with a dropdown menu; and '* Assignee (User):' with a dropdown menu. At the bottom, there is another 'Remove' button and a '+ADD' button. Blue arrows and a curved arrow highlight the 'Type:' dropdown and its menu.

Enter a **Description** and a **Due Date** for the Task.

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

Both the **Assignee (Role)** and the **Assignee (User)** fields must be completed for the chosen User. The drop-down lists will bring up the Active Roles list and the Active Users list. It is a good practice to consult with the planned Assignee ahead of time to ensure they are able to complete the task in a timeframe that supports on time Deviation closure. There is an Available Option for this process to add a notification when Secondary Tasks are overdue. If this option is enabled, email notifications will go to the Assignee and their Department Head.

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 for **Task Type = Task** will receive email Notifications and see the View/Act On options for their Secondary Tasks only when they are released after confirmation of **Step 2 - QA Assessment**. Task Types of **Pre-Disposition** and **Post-Disposition** will be release at later steps in the process. All **Secondary Tasks** are listed under **Related Items** at the bottom of the screen at any Deviation Step. Until the Tasks are released, the status is listed as **Pending**.

Related Items			
Secondary Tasks			
Name:	Check Training Recor[...]	Unique ID:	Task-00000006
Due:	2018-02-28	Status:	Pending View

Initiating a Related Process

The screenshot shows the 'Related Processes' section of a software interface. It features a 'Related Processes' header, a 'Remove' button, and a '+ADD' button. Below this is a form with fields for '* Available Processes:', '* Initiator:', and 'Process Relation:'. The 'Process Relation:' section has two radio buttons: 'Dependent Process' (selected) and 'Related Process'. A blue arrow points from the 'Available Processes' field to a dropdown menu that is open, showing a list of process types: 'CAPA', 'Change Control', and 'Deviation'. Another blue arrow points from the 'Available Processes' field to the 'Available Processes' field in the dropdown menu.

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

The **Available Processes** field is a Single-item selection field populated with a list of the Process APPs deployed at your organization.

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

The mandatory **Initiator** field is a Single-item selection field populated by the list of all Active Users. The person chosen in this field will be the person who will be assigned **Step 1** of the process being initiated. There is also an option to choose **myself**, if you would like to initiate both processes concurrently as the initiator. The Deviation process will then be the **Parent Process** of the new process being initiated.

If a Related Process was already initiated, separately from this Deviation, it can be linked as a **Related Item** using the right-hand menu option under **Related Items**. In this case, do not select the Available Processes box and instead use the **Link Processes** option.

Related Items

[Link Documents](#)

[Link Processes](#)

Whether linking an existing process or initiating a new one, the **Related Processes** will be listed in the **Related Items** section, along with any **Secondary Tasks** and **Related Documents**, when Deviation **Step 1** is Submitted and Confirmed.

Related Items

Secondary Tasks

Name: Check Training Recor[...] Unique ID: Task-00000012 Due: 2018-03-15 Status: Pending View

Expand all

Related Documents

Name: Batch Record No.: <empty> Due: <empty> Status: Approved & Effective Open | View

Expand all

Related Processes

Unique ID: CCR-000005 Date Initiated: 2018-02-21 Status: In Process View

Current Process Task: Step 1 - Change Control Request

Expand all

Submit and Confirm

When all information has been entered into the **Process Task Form**, any **Linked Documents** or **Linked Processes** have been added, any **Secondary Tasks** have been created and any new **Related Processes** have been initiated, click **Submit** and then **Confirm** to progress the Deviation process to **Step 2 – QA Assessment**.

The Process Flowchart will highlight the next step of the process and the person chosen in **Step 1** as the **QA Approver** will be listed. The **QA Approver** will also receive an email Notification and will see the **QA Assessment** task listed on their SOLABS QM HOME Page.

Status: In Process

Process Details

Name: Deviation Date Initiated: 2018-02-07 18:29:42

Unique ID: DEV-000001 Initiated by: solabssupport (Default Admin)

Day(s) opened: 14 Date Closed: <empty>

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

Current Process Tasks

QA Assessment Currently with afavell (Amanda Favell)

Flowchart: Open

Process Values

Process Tasks

Name: Initiation and Immediate Action(s) Last Confirmation Date: 2018-02-21 13:16:04

Name: QA Assessment Expand all Print all

Related Items

Secondary Tasks

Check Training Recor[...] Unique ID: Task-00000006 Due: 2018-02-28 Status: Pending View

Expand all

Documents

Batch Record No.: <empty> Due: <empty> Status: Approved & Effective Open | View

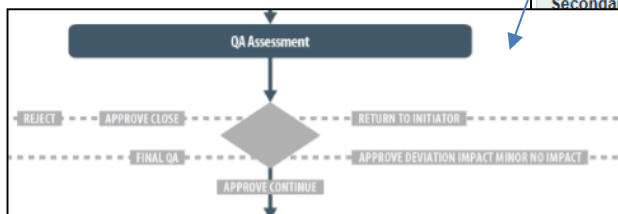
Expand all

Related Processes

Unique ID: CCR-000005 Date Initiated: 2018-02-21 Status: In Process View

Current Process Task: Step 1 - Change Control Request

Expand all



Upon Submission of Step 1, the following email Notifications will be sent by QM10:

- The Department Head of the Initiator will receive a Notification that a Deviation was initiated.
- If a choice of “Yes” for **Does this deviation impact distributed product?** was selected, everyone with with the process role of PR_DEV_QA_Approver will receive a Notification.

Step 2: QA Assessment

At this step in the Deviation Process, the **QA Approver** chosen at Step 1 will receive an email Notification and will see the **QA Assessment** task listed in the Process section of their SOLABS QM HOME Page.

Amanda Favell

Home > Views

PROCESSES

Received this week / last week

Unique ID: DEV-000010 Date Initiated: 2018-03-07 Status: In Process View | Act on

Current Process Task: QA Assessment

Viewing a QA Assessment Task

If the QA Approver clicks on the **View** option to the right of the Process Task, they can view the Process Details.

From the View screen, there are **Expand all** options for the **Process Values** table and the **Related Items** table (if any were included at Step 1), that can be used to see detailed information entered by the Initiator at Step 1.

Status: In Process

Process Details

Name: Deviation **Date Initiated:** 2018-03-07 14:49:16

Unique ID: DEV-000010 **Initiated by:** solabssupport (Default Admin)

Day(s) opened: 1 **Date Closed :** <empty>

Secondary Tasks Completion (%): 0 (0/1) **Dependent Processes Completion (%) :** 0 (0/0)

Current Process Tasks
QA Assessment **Currently with**
afavell (Amanda Favell)

Flowchart: Open

Process Values

Process Tasks

Name: Initiation and Immediate Action(s) **Last Confirmation Date:** 2018-03-08 12:34:44

Name: QA Assessment Expand all | Print all

Related Items

Secondary Tasks

Name: Check Training Recor[...] **Unique ID:** Task-00000012 **Due:** 2018-03-15 **Status:** Pending View

Expand all

Related Documents

Name: Batch Record **No.:** <empty> **Due:** <empty> **Status:** Approved & Effective Open | View

Expand all

Related Processes

Unique ID: CCR-000005 **Date Initiated:** 2018-02-21 **Status:** In Process View

Current Process Task: Step 1 - Change Control Request

Process Values

Process Tasks

Name: Initiation and Immediate Action(s) **Last Confirmation Date:** 2018-03-08 12:34:44

Deviation No.: DEV-000010

Title: Missed Checks for Fill Volume for Product XXX, Lot 5

Description of Deviation: Missed Checks for Fill Volume for Product XXX, Lot 5

Deviation Type: Unplanned

Date Deviation Occurred: 2018-03-07

Date Deviation Discovered: 2018-03-08

Immediate Action(s) Taken: Segregate sections of batch associated with missed checks

Deviation Due Date: 2018-04-06

Deviation Category: Category 1

GxP Classification: GMP (Good Manufacturing Practices)

Initiation Type: Internal

Site: Site 1

Is Material Associated with Deviation?: Yes

Molecule #: 1

Molecule Name: Adimantium

Formulation Description (Campaign Name): Campaign 1

Material Type: Type 1

Strength/Dose: Strength 1

Packaging Configuration: Package 1

Material Description (Excipients, Packaging Components): Desc 1

Lot Number(s): Lot 5

Additional Information: N/A

Does this deviation impact distributed product?: No

Lead Investigator:

QA Approver: afavell (Amanda Favell)

Sign-off by: solabssupport (Default Admin)

Name: QA Assessment

<empty> Collapse all | Print all

The **View** option to the right of any listed **Related Item** (Secondary Tasks, Related Documents, Related Processes) would bring up the **Task Details, Document Details** or **Process Details** screens associated with those **Related Items**. The parent Deviation Process will be listed as a Related Item on those screens, allowing easy access back to the Deviation Process. The QA Assessment section of the Expanded Process Values table is *<empty>* at this point because the QA Approver has not yet Acted on this step in the process.

Acting on the QA Assessment Task

When the **QA 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 **QA Assessment** task.

As described on the last page, the QA Approver can use the **Expand all** option under the Process Values table to see all information entered by the Initiator at Step 1.

The **Process Task Form** includes editable text fields, text areas, single-item selection fields or multi-item selection fields. Fields with an asterisk (*) are mandatory.

The right-hand **Related Items** menu allows the QA Approver to **Link Documents** or **Link Processes**, if applicable. There are also sections under the Process Task Form section to initiate more **Secondary Tasks** and to initiate new **Related Processes**. Initiation of a Document Control Process is not allowed at Step 2.

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 APPs.

There is a **Save Draft** option at the bottom if all the required fields cannot be completed at one time or when using the right-hand menu to **Link Documents** or **Link Processes**.

Submit Save Draft Cancel

CAUTION: Navigating away from this page without clicking on either **Submit** or **Save Draft**, will result in all entries being lost.

Process > Deviation > QA Assessment > Act on

status: In Process

Process Details

Unique ID: DEV-000010 Flowchart: Open

Current Process Task: QA Assessment

Process Values

Process Tasks

Name: Initiation and Immediate Action(s) Last Confirmation Date: 2018-03-08 12:34:44

Name: QA Assessment

Expand all Print all

Process Task Form - QA Assessment

* Lot Number(s):

Lot 5 X

Is Assessment Required?:

Yes

No

* Type of Assessment:

* Description of the Assessment:

[Quick Text] Remove

+ADD

* Deviation Classification:

* Is this a Recurring Deviation?:

* Does this deviation impact distributed product?:

No

* Assigned QA Approver:

afavell (Amanda Favell)

* Lead Investigator:

Is committee notification required?:

Yes

No

N/A

* Committee Notification:

afavell (Amanda Favell)

dvaquilar (Delfin Vaquilar)

Expand

QA Assessment Decision:

Approve - continue deviation process

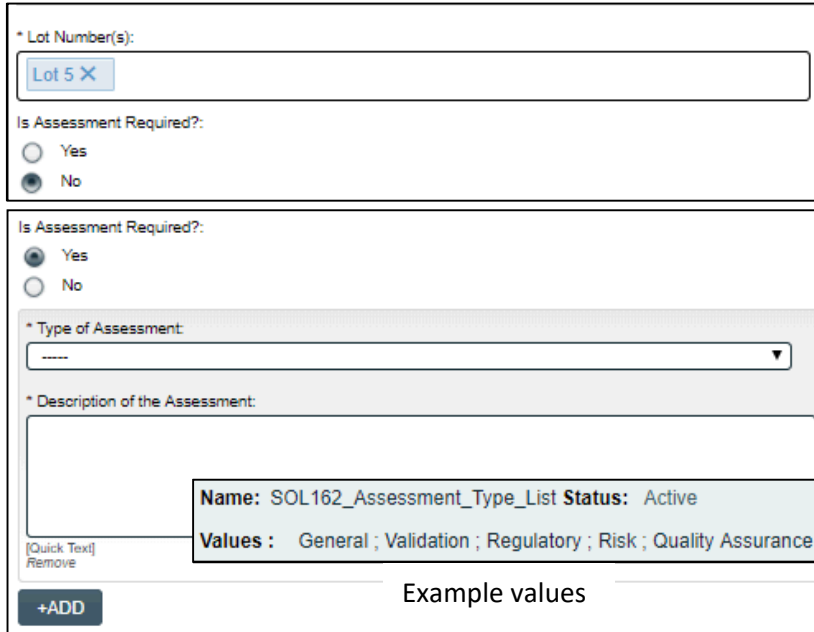
Approve - close deviation process

Return to initiator

Reject

Comments:

To complete the information after the Save Draft option, choose either the Act On option from the Process section of your HOME Page, or search for the Deviation Process and then use the right-hand Act on Menu to open the Process Task Form fields.

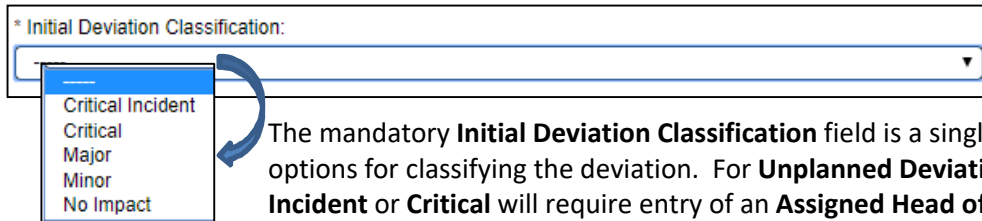


The **Lot Number(s)** field will be displayed if the **Is Material Associated with Deviation?** section was **Yes** at Step 1. It will be pre-populated with any lot numbers added at that time. Additional lot numbers can be added. Starting to type a number will bring up existing numbers that include those digits.

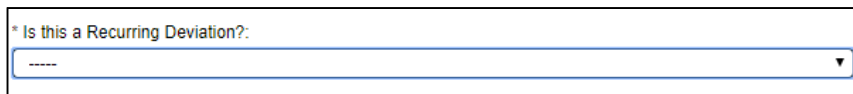
Is Assessment Required? must be selected as either **Yes** or **No**. If **Yes** is selected, a group of mandatory fields for **Type of Assessment** and **Description of the Assessment** will be displayed. If there is more than one Type of Assessment required, the **+ADD** button will bring up another set of fields.

Type of Assessment is a single-item selection field populated by values from an **editable Custom List** maintained by the SOLABS System Administrator.

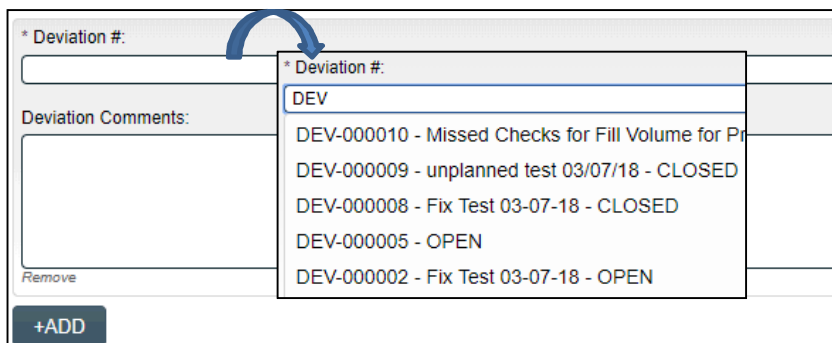
The **Description of the Assessment** field can be completed with free text (up to 8000 characters) or by using **Quick Text** options populated from an **editable Custom List** maintained by the SOLABS System Administrator.



The mandatory **Initial Deviation Classification** field is a single-item selection field with 5 options for classifying the deviation. For **Unplanned Deviations**, a selection of **Critical Incident** or **Critical** will require entry of an **Assigned Head of Quality** at Step 6 and will include an additional approval **Step 7: Head of Quality Final Approval**.



The mandatory **Is this a Recurring Deviation?** field is a single-item selection field with **Yes** or **No** options. If **Yes** is selected, a group of additional fields will appear to enter the **Deviation #** and any optional **Deviation Comments** (up to 8000 characters). Starting to type either a Deviation Number or Title will bring up the list of existing Deviation Processes to choose from.



The chosen Deviation will then be listed under **Related Processes**, in the **Related Items** section. If there is more than one recurring deviation, the **+ADD** button can be used to bring up another group of fields.

* Does this deviation impact distributed product?:

Does this deviation impact distributed product? is a **Yes** or **No** choice.

* Assigned QA Approver:

The mandatory **Assigned QA Approver** field will be pre-populated with the **QA Approver** chosen at Step 1 but is editable.

* Lead Investigator:

The **Lead Investigator** field is mandatory at Step 2.

This field is a single-item selection field, populated with the names of Users who are assigned the process role **PR_DEV_Lead_Investigator**. This field was available at Step 1 but was not mandatory. If a **Lead Investigator** was chosen at Step 1, the field will be pre-populated with that person, but can be edited.

If no Lead Investigator was chosen at Step 1, a choice must be made at Step 2. The choice at Step 2 will then auto-populate the value at Step 1, since this is a Shared field.

Is committee notification required?:
 Yes
 No
 N/A

* Committee Notification:

- afavell (Amanda Favell)
- dvaquilar (Delfin Vaquilar)
- jdavid (Jeff David)
- kheather (Kevin Heather)
- lorcullo (Leovy Orcullo)
- rsamuel (Roger Samuel)

Select all Deselect all

The section for **Is committee notification required?** and the related mandatory, multi-item selection **Committee Notification** field is displayed, and defaults to a selection of **Yes**, if at least one User is assigned the process role **PR_DEV_Committee_Notification**.

The Users listed in the **Committee Notification** section are all Users who have the process role **PR_DEV_Committee_Notification** assigned to them. One or more can be selected and will receive an email Notification when Steps 2, 6 and 7 are confirmed. The selection can be changed to **No**, if no notifications are required.

If no Users are assigned the process role of **PR_DEV_Committee_Notification**, this section defaults to a selection of **N/A**.

Before the final **QA Assessment Decision** is made, the QA approver can create any additional **Secondary Tasks** that may be required, can **Link Documents**, **Link Processes** or initiate a **Related Process**.

Caution: Use the **Save Draft** option prior to using the right-hand menus to link a document or process, or data entered so far will be lost and have to be entered again.

QA Assessment Decision – Submit and Confirm

When all information has been entered in the **Process Task Form**, and any **Secondary Tasks**, **Linked Documents**, **Linked Processes** or new **Related Processes** have been added, the **QA Assessment Decision** is made by the QA Approver. There are four available choices for the **QA Assessment Decision**, some of which may not be enabled in certain situations.

QA Assessment Decision:

- Approve - continue deviation process
- Approve - close deviation process
- Return to initiator
- Reject

Comments:

The option of **Approve – close deviation process** is greyed out if **Deviation Type = Unplanned** was selected at Step 1. It will be the default option when **Deviation Type = Planned** was selected with no Secondary Tasks.

With a decision of **Approve – close deviation process**, the Deviation Process will move to the end and be at a status of **Completed**. If there are still outstanding Secondary Tasks, the following warning message will be displayed below the decision field: **Some secondary tasks have been initiated and won't be monitored and/or released to their assignee.**

The decisions of **Return to initiator** and **Reject** will both change the **Comments** field to a mandatory field. **Return to initiator** will move Deviation Process back to **Step 1** when submitted. **Reject** will close the Deviation Process, to a status of **Completed** when submitted.

A **QA Assessment Decision of Approve – continue deviation process** will progress the Deviation Process as follows, depending on the selections made for **Deviation Type** and for **Deviation Classification**:

- If **Deviation Type = Unplanned** and **Deviation Classification = Major, Critical or Critical incident**, the process moves to **Step 3 – Investigation Plan** on confirmation.
- If **Deviation Type = Unplanned** and **Deviation Classification = Minor or No Impact**, the process moves to **Step 5 – Investigation Execution** on confirmation.
- If **Deviation Type = Planned**, the process moves to **Step 6 – Final QA Assessment** on confirmation.

The decision of **Approve – continue deviation process** will also result in the following:

- All **Secondary Tasks** will be released to the Assignees. They will receive email Notifications and will see the Tasks listed in the Task Section of their SOLABS QM Home Page.
- Any new **Related Processes** that were initiated as **Dependent Processes** and were at a status of **Awaiting Confirmation from Parent Process**, are now available to the Assignees to Act on.

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**. The assigned Secondary Tasks, Linked Documents and Linked Processes will be listed in the **Related Items** section.

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 7	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks Investigation Plan	Currently with j david (Jeff David)

Flowchart: Open

Process Values

Process Tasks
Name: Initiation and Immediate Action(s) Last Confir
Name: QA Assessment Last Confirmation Date: 20
Name: Investigation Plan

Related Items

Secondary Tasks	
Name: Check Training Recor[...] Unique ID: Task-00000012 Due: 2018-03-15 Status: Not Started	View
Expand all	
Related Documents	
Name: Batch Record No.: <empty> Due: <empty> Status: Approved & Effective	Open View
Name: InProcess Controls for Checkwe[...] No.: <empty> Due: <empty> Status: Approved & Effective	Open View
Expand all	
Related Processes	
Unique ID: CCR-000005 Date Initiated: 2018-02-21 Status: In Process	View
Current Process Task: Step 1 - Change Control Request	

Secondary Task Assignments – Assignee Actions

If there were any **Secondary Tasks** assigned at Step 1 or 2, they are now released to Act on since the QA Assessment step has been completed by the QA Approver.

Assignees of Secondary Tasks will receive an email Notification and will also see the tasks listed in the TASKS section of their SOLABS QM HOME Page.

TASKS	
Due this week / last week	
Name: Check Training Recor[...] Unique ID: Task-00000012 Due: 2018-03-15 Status: Not Started	View Act on

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 **Deviation 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 Deviation Process if they choose to View a Secondary Task.

James McDowall

Task > View

Task Details

Name: Check Training Records for Operators Involved

Type: Task **Unique ID:** Task-00000012

Description: Check Training Records for operators involved in filling of Product XXX, Lot 5, 6

Reference Date: 2018-03-14

Location: Root\DEV-000010 Process Task Group\Initiation and Immediate Action(s) Task Group

Estimated Start Day Offset: 0 **Estimated End Day Offset:** 1

Estimated Start Date: 2018-03-14 **Estimated End Date:** 2018-03-15

Start Date: N/A **End Date:** N/A

Status: Not Started

Comments:

Task Ownership

Originator: solabssupport (Default Admin)

Assignee (Role): any

Assignee (User): jmcdownall (James McDowall)

Related Items

Main Related Process

Unique ID: DEV-000010 **Date Initiated:** 2018-03-07 **Status:** In Process [View](#)

Current Process Task: Investigation Plan

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.

James McDowall

Task > Act on

Task Details

Name:

Type: Unique ID:

Description:

Reference Date:

Location:
Available Task Groups

Estimated Start Date Offset: Estimated End Date offset:

Estimated Start Date: Estimated End Date:

Start Date: Clear End Date: Clear

Status:

Not Started

In Progress

Pending

Completed

Return to Originator

Comments:

Task Ownership

Originator:

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](#)

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

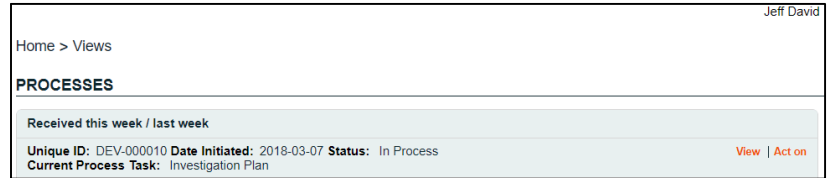
If a status of **Completed** is selected, the **End Date** field will be populated with the current date. If an **End Date** is entered, the Status will automatically move to **Completed**.

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.

Step 3: Investigation Plan

The **Lead Investigator** chosen by the Initiator at Step 1 or Step 2 for an unplanned Deviation classified as Major, Critical or Critical Incident will receive an email Notification and see the **Investigation Plan** task listed on their SOLABS QM10 HOME Page.



Home > Views

PROCESSES

Received this week / last week

Unique ID: DEV-000010 Date Initiated: 2018-03-07 Status: In Process [View](#) | [Act on](#)

Current Process Task: Investigation Plan

Acting on the Investigation Plan Task

When the **Lead Investigator** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Investigation Plan** task.

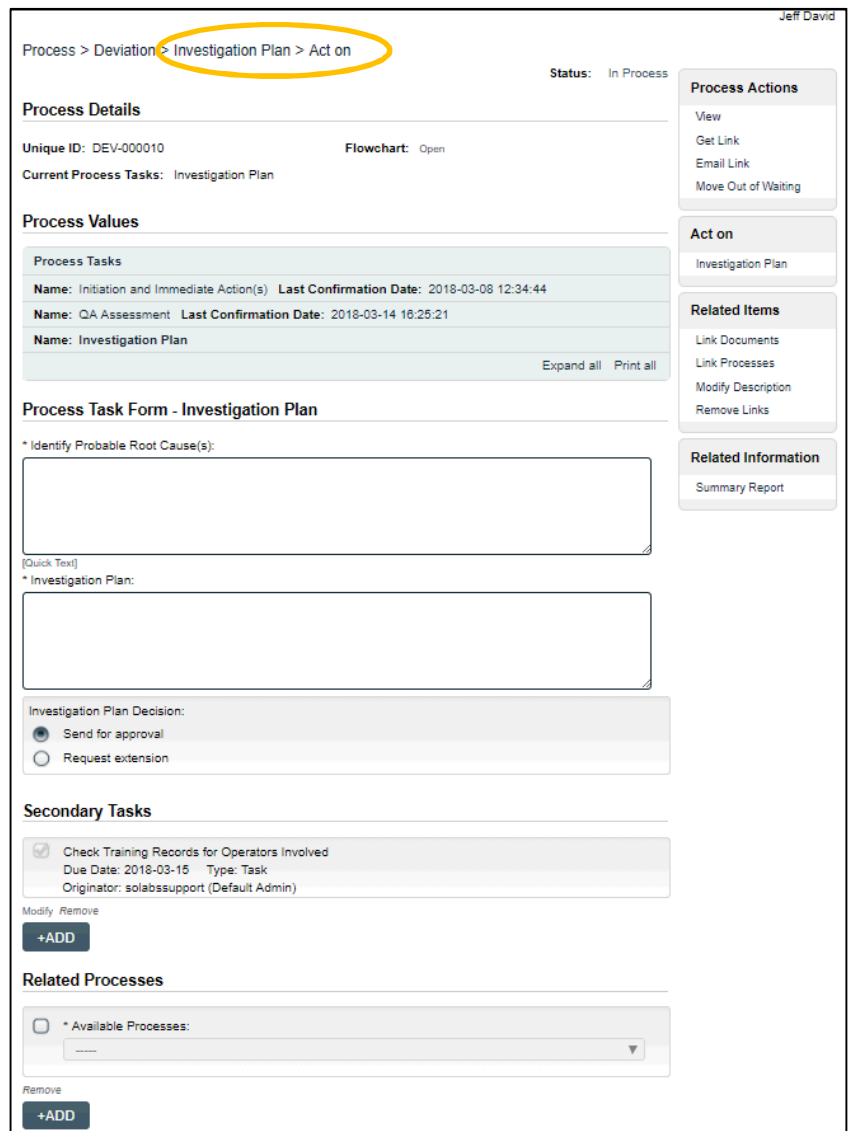
As described for the previous sections, the Lead Investigator can use the **Expand all** option under the Process Values table to see all information entered at Steps 1 and 2.

The **Process Task Form** includes mandatory text fields or text areas, one of which can be set to be populated by Quick Text (Custom List) options. These will be used to **Identify Probable Root Causes(s)** and to describe the **Investigation Plan**.

The right-hand **Related Items** menu allows the Lead Investigator to **Link Documents** or **Link Processes**, if applicable. There are also sections under the Process Task Form section to initiate more **Secondary Tasks** or **Related Processes**. Initiation of a Document Control Process is not allowed at Step 3.

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 APPs.

There is a **Save Draft** option at the bottom if all the required fields cannot be completed at one time or when using the right-hand menus to **Link Documents** or to **Link Processes**.



Process > Deviation > Investigation Plan > Act on

Status: In Process

Process Details

Unique ID: DEV-000010 Flowchart: Open

Current Process Tasks: Investigation Plan

Process Values

Process Tasks

Name: Initiation and Immediate Action(s)	Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment	Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan	

Expand all Print all

Process Task Form - Investigation Plan

* Identify Probable Root Cause(s):

[Quick Text]

* Investigation Plan:

Investigation Plan Decision:

Send for approval

Request extension

Secondary Tasks

Check Training Records for Operators Involved

Due Date: 2018-03-15 Type: Task

Originator: solabssupport (Default Admin)

Modify Remove

+ADD

Related Processes

* Available Processes:

Remove

+ADD

Process Actions

- View
- Get Link
- Email Link
- Move Out of Waiting

Act on

Investigation Plan

Related Items

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

Related Information

- Summary Report

CAUTION: Navigating away from this page without clicking on either **Submit** or **Save Draft**, will result in all entries being lost. To complete the information after the Save Draft option, choose either the Act On option from the Process section of your HOME Page, or search for the Deviation Process and then use the right-hand Act on Menu to open the Process Task Form fields.



The **Investigation Plan Decision** section includes two choices: **Send for Approval** or **Request extension**. If any **Secondary Tasks** of **Task Type = Task** are not yet completed, the **Send for Approval** option will be grayed out.

- When a choice of **Request extension** is Submitted and Confirmed, the Deviation Process will move to the **Extension Request Step**.
- When a choice of **Send for Approval** is Submitted and confirmed, the Deviation Process will move to **Step 4: QA Investigation Plan Approval**.

The **Process Flowchart** will highlight the next step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**:

- the **QA Approver** if **Send for Approval** was Submitted and Confirmed
- the **Lead Investigator** again, if **Request extension** was Submitted and Confirmed

Process > Deviation > View Status: In Process

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 9	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks Currently with

Extension Request (1) jdavid

Flowchart: Open →

Process Values

Process Tasks	
Name: Initiation and Immediate Action(s)	Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment	Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan	Last Confirmation Date: 2018-03-16 15:48:42
Name: Extension Request (1)	
Expand all Print all	

Related Items

Secondary Tasks	
Name: Check Training Recor[...]	Unique ID: Task-00000012 Due: 2018-03-15 Status: Not Started View
Expand all	

REQUEST EXTENSION

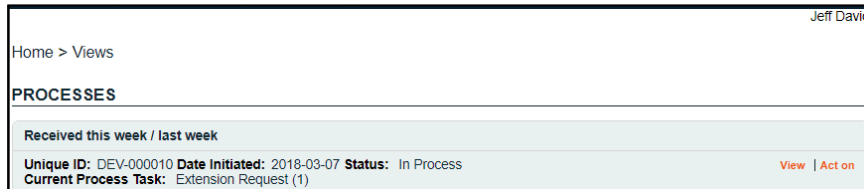
↓

Extension Request

↓

Extension Request Step

At this step in the Deviation Process, the **Lead Investigator** will receive an email Notification and will see the **Request Extension** task listed in the Process section of their SOLABS QM HOME Page. Extension Requests are formally captured as a separate Step, 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 **Lead Investigator**. If another one should be necessary, it would show **(2)**.



Acting on the Extension Request Task

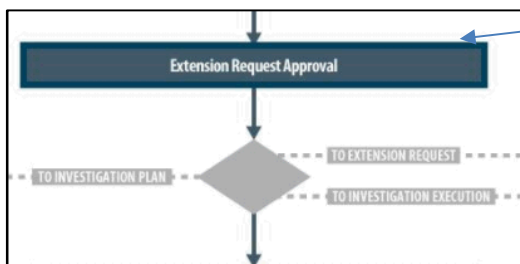
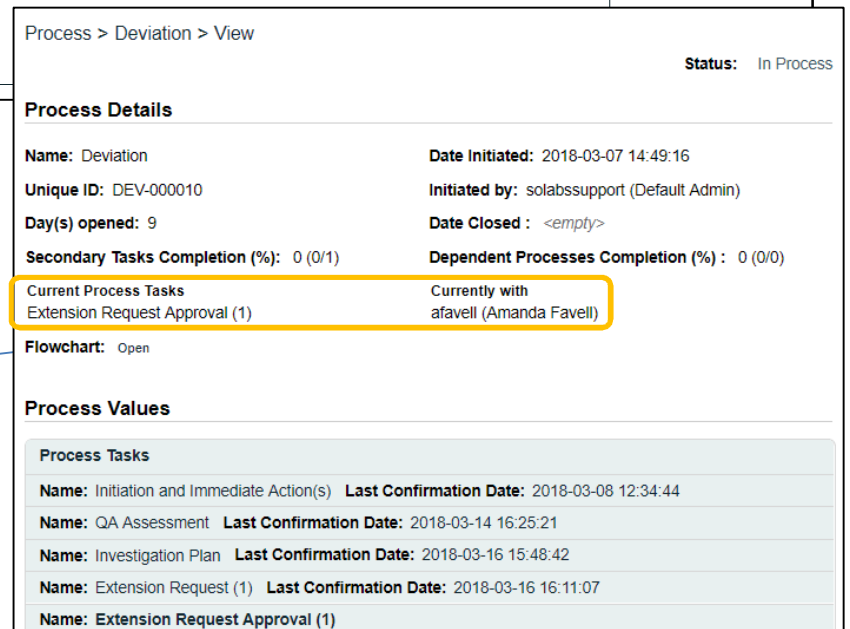
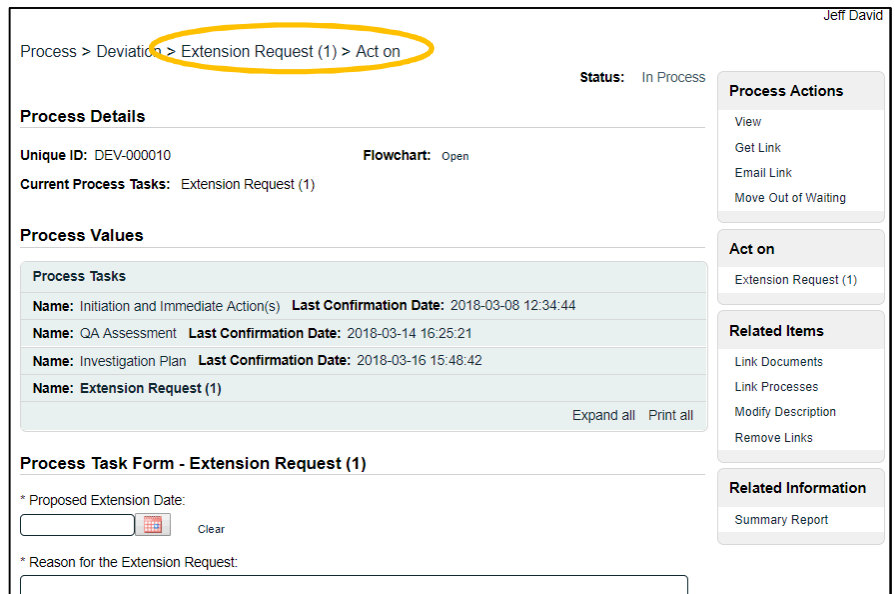
When the **Lead Investigator** clicks on the **Act on** option to the right of the **Extension Request** task, they will go immediately to the **Act on** screen for their **Extension Request** task.

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

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out.

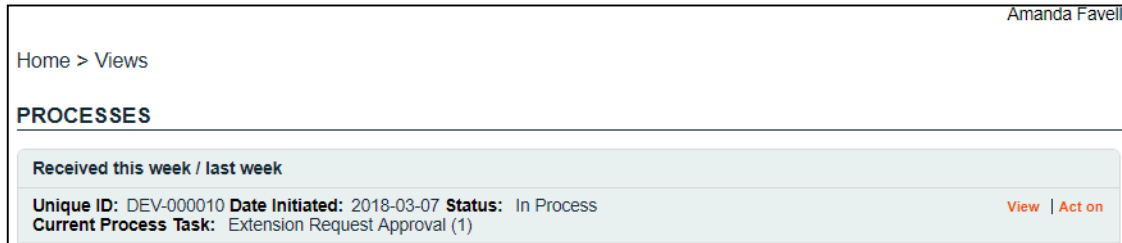
When this step is Submitted and Confirmed, the process will progress to the **Extension Request Approval Step**.

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with: QA Approver**.



Extension Request Approval Step

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



Home > Views Amanda Favell

PROCESSES

Received this week / last week

Unique ID: DEV-000010 Date Initiated: 2018-03-07 Status: In Process Current Process Task: Extension Request Approval (1)	View Act on
---	---

Acting on the Extension Request Approval Task

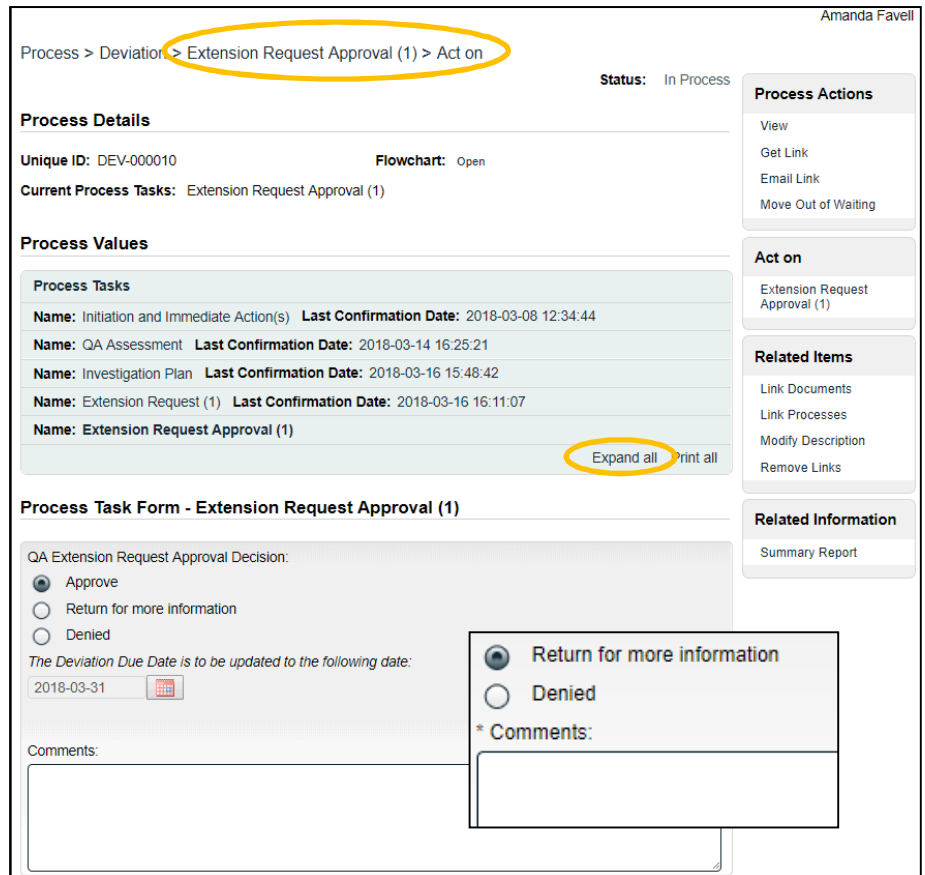
When the **QA Approver** clicks on the **Act on** option to the right of the **Extension Request Approval** task, they will go immediately to the **Act on** screen for their **Extension Request Approval** task.

At the **Act on** screen for the **Extension Request Approval** task, the **QA Approver** can view information entered at all 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.

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out.

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

A choice of either **Return for more information** or **Denied**, will result in the **Comment** field being mandatory. The process will then go back to the previous Step so that the **Lead Investigator** can address the comment.



Process > Deviation > Extension Request Approval (1) > Act on Amanda Favell

Status: In Process

Process Details

Unique ID: DEV-000010 Flowchart: Open
 Current Process Tasks: Extension Request Approval (1)

Process Values


Process Tasks
Name: Initiation and Immediate Action(s) Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan Last Confirmation Date: 2018-03-16 15:48:42
Name: Extension Request (1) Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1)

Expand all Print all

Process Task Form - Extension Request Approval (1)

QA Extension Request Approval Decision:

Approve
 Return for more information
 Denied

The Deviation Due Date is to be updated to the following date:
 2018-03-31 

Comments:

Return for more information
 Denied
 * Comments:

A **QA Extension Request Approval Decision** of **Approve**, will send the Deviation Process back to **Step 3 – Investigation Plan** with a new Deviation Due Date.

At this point the **Lead Investigator** can continue to monitor for completion of activities related to the plan, incorporating the revised Deviation due date.

Process > Deviation > View Amanda Favell

Status: In Process

Process Actions

View

Get Link

Email Link

Move Out of Waiting

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 9	Date Closed: <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks Currently with jdavid

Investigation Plan

Flowchart: Open

Process Values

Process Tasks	
Name: Initiation and Immediate Action(s)	Last Confirmation
Name: QA Assessment	Last Confirmation Date: 2018-03-
Name: Investigation Plan	
Name: Extension Request (1)	Last Confirmation Date: 201
Name: Extension Request Approval (1)	Last Confirmation Date: 2018-03-16 16:55:31

Expand all Print all

Related Items

Secondary Tasks			
Name: Check Training Recor[...]	Unique ID: Task-00000012	Due: 2018-03-15	Status: Not Started View
Expand all			

From the **Process Values** table, we can see that the **Lead Investigator** had requested an extension and that it was approved. At that point, the Deviation Process went back to **Step 3 – Investigation Plan**.

The **Lead Investigator** will now receive another Notification – just like they did prior to requesting the extension and will see the **Investigation Plan** task listed in the Process section of their SOLABS QM HOME Page.

Jeff David

Home > Views

PROCESSES

Received this week / last week

Unique ID: DEV-000010 **Date Initiated:** 2018-03-07 **Status:** In Process View | Act on

Current Process Task: Investigation Plan

The Deviation Process they own is now accepted for an extension. They can choose the **View** option to access all information previously entered. When the **Lead Investigator** is ready to choose an **Investigation Plan Decision** of **Send for Approval** the Deviation Process will progress to **Step 4 – QA Investigation Plan Approval**.

Investigation Plan Decision:

Send for Approval

Request Extension

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with: QA Approver**.

Process > Deviation > View Status: In Process

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 9	Date Closed: <empty>
Secondary Tasks Completion (%): 0 (0/3)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks Currently with
 QA Investigation Plan Approval afavell

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and Immediate Action(s)	Last Confirmation
Name: QA Assessment	Last Confirmation Date: 2018-03-1
Name: Investigation Plan	Last Confirmation Date: 2018-03-
Name: Extension Request (1)	Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1)	Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval	

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

Related Items

Secondary Tasks				
Name: Check Training Recor[...]	Unique ID: Task-00000012	Due: 2018-03-15	Status: Not Started	View
Name: Check Filler PM Reco[...]	Unique ID: PREDI-00000014	Due: 2018-03-22	Status: Pending	View
Name: Update Filler PM Sch[...]	Unique ID: POSTDI-00000011	Due: 2018-03-30	Status: Pending	View

Step 4: QA Investigation Plan Approval

At this step in the Deviation Process, the **QA Approver** will receive an email Notification and will see the **QA Investigation Plan Approval** task listed in the Process section of their SOLABS QM HOME Page.

Amanda Fav

Home > Views

PROCESSES

Outstanding

Unique ID: DEV-000010	Date Initiated: 2018-03-07	Status: In Process	View Act on
Current Process Task: QA Investigation Plan Approval			

Acting on the QA Investigation Plan Approval Task

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

At the **Act on** screen for the **QA Investigation Plan Approval** task, the **QA Approver** can view information entered at all 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.

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out. **Linked Documents, Linked Processes** or new **Related Processes** could be added if appropriate.

At this point, they need to enter the **QA Investigation Plan Approval Decision**.

- If they choose **Return to lead investigator**, the **Comment** field is mandatory. The process will then go back to the **Step 3: Investigation Plan** so the **Lead Investigator** can address the comment.
- If they choose **Approve**, the Deviation Process will progress to **Step 5 – Investigation Execution** and all **Secondary Tasks** will be released to the assignees. The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with: Lead Investigator**.

Process > Deviation > QA Investigation Plan Approval > Act on

Status: In Process

Process Details

Unique ID: DEV-000010 Flowchart: Open

Current Process Tasks: QA Investigation Plan Approval

Process Values

Process Tasks

Name: Initiation and Immediate Action(s)	Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment	Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan	Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1)	Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1)	Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval	

Expand all Print all

Process Task Form - QA Investigation Plan Approval

QA Investigation Plan Approval Decision:

Approve

Return to lead investigator

Comments:

QA Investigation Plan Approval Decision:

Approve

Return to lead investigator

* Comments:

Secondary Tasks

Check Filler PM Records
Due Date: 2018-03-22 Type: Pre-Disposition
Originator: jdavid (Jeff David)

Update Filler PM Schedule as Needed



Process Details

Name: Deviation Date Initiated: 2018-03-07 14:49:16

Unique ID: DEV-000010 Initiated by: solabssupport (Default Admin)

Day(s) opened: 12 Date Closed: <empty>

Secondary Tasks Completion (%): 0 (0/3) Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks

Investigation Execution Currently with: jdavid (Jeff David)

Flowchart: Open

Process Values

Process Tasks

Name: Initiation and Immediate Action(s)	Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment	Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan	Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1)	Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1)	Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval	Last Confirmation Date: 2018-03-19 16:12:56
Name: Investigation Execution	

Expand all Print all

Related Items

Secondary Tasks

Name: Check Training Reco[...]	Unique ID: Task-00000012	Due: 2018-03-15	Status: Not Started	View
Name: Check Filler PM Reco[...]	Unique ID: PREDI-00000014	Due: 2018-03-22	Status: Not Started	View
Name: Update Filler PM Sch[...]	Unique ID: POSTDI-00000011	Due: 2018-03-30	Status: Not Started	View

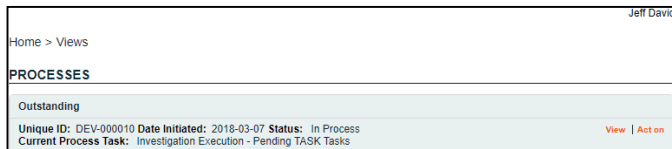
Expand all

Related Documents

Name: Batch Record No.:	<empty>	Due: <empty>	Status: Approved & Effective	Open View
-------------------------	---------	--------------	------------------------------	-------------

Step 5: Investigation Execution

At this step in the Deviation Process, the **Lead Investigator** will receive an email Notification and will see the **Investigation Execution** task listed in the Process section of their SOLABS QM HOME Page. If there is at least one Secondary Task of Task Type = TASK, the name of this step will be **Investigation Execution – Pending TASK Tasks**. Note – due to QM10 system timers, “- Pending TASK Tasks” will not be visible for at least 5 minutes after submission of the previous step.



Acting on the Investigation Execution Task

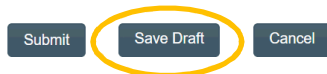
When the **Lead Investigator** clicks on the **Act on** option to the right of the **Investigation Execution** task, they will go immediately to the **Act on** screen for that task.

The **Process Task Form** includes free-text fields, single-item selection fields and multi-item selection fields. Those with an asterisk (*) are mandatory. **Each field in the Process Task Form will be described starting on the next page.**

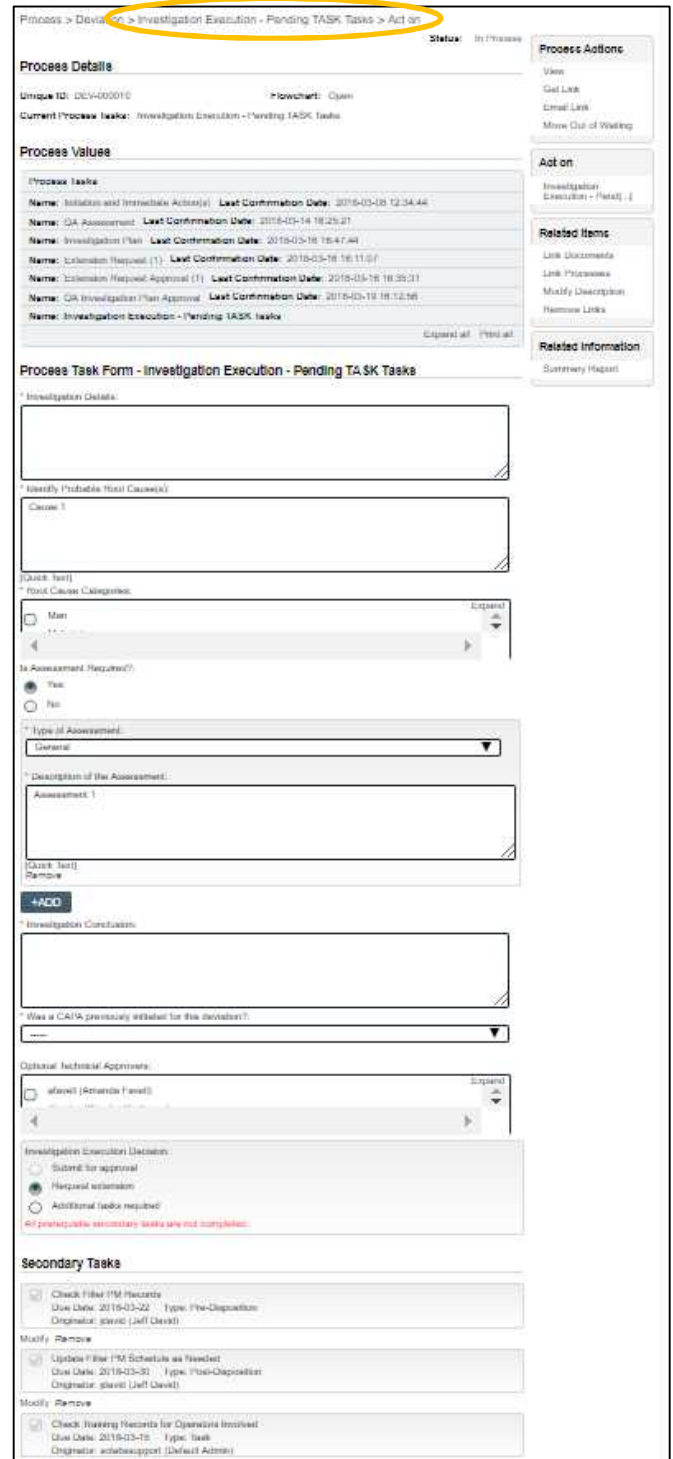
The right-hand **Related Items** menu allows the Lead Investigator to **Link Documents** or **Link Processes**, if applicable. New **Related Processes** can also be added if needed. Refer to the separate document SOLABS QM10: Introduction to PROCESS Section for information on use of the right-hand menus since they are common to all SOLABS QM Process APP screens.

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out, but the **Investigation Execution Decision** includes an option for **Additional tasks required**, which will formally capture that need as a Process Step called **Additional Tasks**.

Use the **Save Draft** option if all required fields cannot be completed at one time.



CAUTION: As mentioned for previous steps, if you navigate away from this page or use the right-hand menus without clicking on either **Submit** or **Save Draft**, all entries will be lost.



Process Task Form - Investigation Execution

* Investigation Details:

* Identify Probable Root Cause(s):

[Quick Text]

* Root Cause Categories:

- Man SOL102_Method_Category_List Status: Active
- Material SOL094_Machine_Category_List Status: Active
- Method SOL095_Man_Category_List Status: Active
- Machine SOL099_Material_Category_List Status: Active
- Environment SOL066_Environment_Category_List Status: Active

Select all Deselect all

The mandatory **Investigation Details** field is a free-text area allowing up to 4000 characters.

The mandatory **Identify Probable Root Cause(s)** field is a free-text area allowing up to 4000 characters that can also be populated using a **Quick Text** Custom List maintained by the SOLABS System Administrator.

The mandatory **Root Cause Categories** field is a multi-select list of options. For each option chosen, an additional single-item selection field will appear to choose the next level **Category**. These lists are populated from **editable Custom Lists** maintained by the SOLABS System Administrator.



* Man Category:

- Learning
- Omission
- Application
- Inconsistency
- Decision

* Material Category:

- Vendor Quality
- Stability

Example Values

* Method Category:

- Validation/Qualification
- Incorrect Master Document
- No Master Document
- Planned Deviation

* Machine Category:

- Equipment Malfunction
- Validation/Qualification

* Environment Category:

- PW
- HVAC
- HEPA
- Compressed Air
- Power
- Roof Leak

Is Assessment Required?:

Yes

No

The **Is Assessment Required?** field is a **Yes** or **No** selection. If **Yes** is selected, a group of mandatory fields for **Type of Assessment** and **Description of the Assessment** will be displayed. If there is more than one Type of Assessment required, the **+ADD** button will bring up another set of fields. These fields are also available at Step 2 – QA Assessment. See Page 14 for more information on setting up the values, since this field shares an editable Custom List with that Step.



* Type of Assessment:

General

* Description of the Assessment:

Assessment 1

[Quick Text]
Remove

+ADD

* Investigation Conclusion:

* Was a CAPA previously initiated for this deviation?:

Yes

No

* CAPA #:

* Describe CAPA Effectiveness:

Remove

+ADD

CAPA

CAPA-000005 - OPEN

CAPA-000004 - OPEN

CAPA-000003 - OPEN

CAPA-000001 - CLOSED

CAPA-000002 - OPEN

Optional Technical Approvers:

afavell (Amanda Favell)

director (Director Packager)

dvaquilar (Delfin Vaquilar)

divilayla (Dee Vilaylack)

eharinov (Elena Harinov)

jdavid (Jeff David)

Select all Deselect all

The mandatory **Investigation Conclusion** field is a free-text area allowing up to 4000 characters.

The mandatory **Was a CAPA previously initiated for this deviation?** field is a single-item selection **Yes** or **No** field. If **Yes** is selected, a group of mandatory fields for **CAPA #** and **Describe CAPA Effectiveness** will be displayed. If there is more than one previous CAPA, the **+ADD** button will bring up another set of fields.

Starting to type CAPA into the **CAPA #** field will bring up a list of existing CAPA Processes in SOLABS QM.

The **Optional Technical Approvers** field is not mandatory. It is a multi-item selection field populated with the list of all active SOLABS QM Users.

If **Optional Technical Approvers** are selected, the process will formally capture those approvals by progressing to a Process Step called **Investigation Technical Approval** when Step 5 is Submitted and Confirmed, unless the **Investigation Execution Decision** is either **Request extension** or **Additional tasks required**. In those cases, the **Investigation Technical Approvals** will be released when that information is provided.

Investigation Execution Decision

Investigation Execution Decision:

Submit for approval

Request extension

Additional tasks required

All prerequisite secondary tasks are not completed.

The **Submit for approval** option will be grayed out if there are any Secondary Tasks of Task Type = TASK that are not yet complete.

If **Request Extension** is selected, the process will go back to the **Extension Request** step (see Page 21) and be assigned to the Lead Investigator to formally document the new Extension Request.

As when an extension was requested for the Investigation Plan, the process will then move to the **Extension Request Approval** step (see Page 22) and be assigned to the QA Approver to approve the new Due Date.

If **Additional tasks required** is selected, the process will go to the **Additional Tasks** step, and be assigned to the **Lead Investigator** to define those tasks. The Submit for Approval option will stay as grayed out in that case.

If the Secondary Tasks of Task Type = Task are complete, there are no Additional Tasks Required and there is no need to Request Extension, then a choice of **Submit for approval** will progress the process as follows:

- If any **Optional Technical Approvers** were selected, it will move to **Investigation Technical Approval**.
- If no Optional Technical Approvers are required, it will move to **Step 6: Final QA Assessment**.

In any case, the **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**:

- **Lead Investigator** if the process goes back to either **Extension Request** or **Additional Tasks**
- **Technical Approver(s)** if any were selected for **Investigation Technical Approval**
- **QA Approver** if the process progresses to **Step 6: Final QA Assessment**

In this example, the Investigation Execution Decision is Additional tasks required.

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 12	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/3)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks	Currently with
Additional Tasks	jdavid (

Flowchart: Open →

ADDITIONAL TASKS NEEDED

Additional Tasks

Process Values

Process Tasks	
Name: Initiation and Immediate Action(s)	Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment	Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan	Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1)	Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1)	Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval	Last Confirmation Date: 2018-03-19 16:12:56
Name: Investigation Execution	Last Confirmation Date: 2018-03-19 17:48:59
Name: Additional Tasks	

Expand all Print all

Additional Tasks

At this step in the Deviation Process, the **Lead Investigator** will receive an email Notification and will see the **Additional Tasks** task listed in the Process section of their SOLABS QM HOME Page. This allows the decision to create additional Secondary Tasks at this point in the process to be formally captured.

Jeff David

Home > Views

PROCESSES

Outstanding

Unique ID: DEV-000010 Date Initiated: 2018-03-07 Status: In Process View | Act on

Current Process Task: Additional Tasks

Acting on the Additional Tasks Task

When the **Lead Investigator** clicks on the **Act on** option to the right of the **Additional Tasks** task, they will go immediately to the **Act on** screen for that task.

From this screen, they can use the **+ADD** button in the **Secondary Tasks** section to add additional Secondary Tasks.

Process > Deviation > **Additional Tasks > Act on** Status: In Process

Process Details

Unique ID: DEV-000010 Flowchart: Open

Current Process Tasks: Additional Tasks

Process Values

Process Tasks
Name: Initiation and Immediate Action(s) Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1) Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1) Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval Last Confirmation Date: 2018-03-19 16:12:56
Name: Investigation Execution Last Confirmation Date: 2018-03-19 17:48:59
Name: Additional Tasks Expand all Print all

Process Task Form - Additional Tasks

Secondary Tasks

<input checked="" type="checkbox"/> Check Filler PM Records Due Date: 2018-03-22 Type: Pre-Disposition Originator: jdavid (Jeff David) <small>Modify Remove</small>
<input checked="" type="checkbox"/> Update Filler PM Schedule as Needed Due Date: 2018-03-30 Type: Post-Disposition Originator: jdavid (Jeff David) <small>Modify Remove</small>
<input checked="" type="checkbox"/> Check Training Records for Operators Involved Due Date: 2018-03-15 Type: Task Originator: solabssupport (Default Admin) <small>Modify Remove</small>

+ADD

Refer to Page 9 of this document for instructions on Creating Secondary Tasks.

After Submitting and Confirming the **Additional Tasks** step, the **Secondary Tasks** will be immediately released to the assignees and the Deviation process will return to **Step 5: Investigation Execution**.

Process Details

Name: Deviation Date Initiated: 2018-03-07 14:49:16
 Unique ID: DEV-000010 Initiated by: solabssupport (Default Admin)
 Day(s) opened: 13 Date Closed : <empty>
 Secondary Tasks Completion (%): 0 (0/4) Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks
 Investigation Execution Currently with jdavid (Jeff David)

Flowchart: Open

Process Values

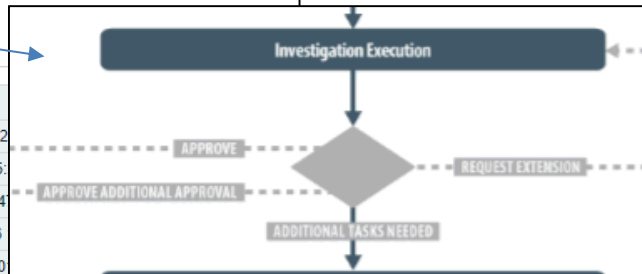
Process Tasks	Last Confirmation Date
Name: Initiation and Immediate Action(s)	2018-03-14 16:25
Name: QA Assessment	2018-03-14 16:25
Name: Investigation Plan	2018-03-16 16:4
Name: Extension Request (1)	2018-03-16
Name: Extension Request Approval (1)	2018-03-16
Name: QA Investigation Plan Approval	2018-03-19 16:12:56
Name: Investigation Execution	
Name: Additional Tasks	2018-03-20 09:38:07

Expand all Print all

Related Items

Secondary Tasks	Unique ID	Due	Status	View
Name: Check Training Recor[...]	Task-00000012	2018-03-15	Not Started	View
Name: Check Filler PM Reco[...]	PREDI-00000014	2018-03-22	Not Started	View
Name: Update Filler PM Sch[...]	POSTDI-00000011	2018-03-30	Not Started	View
Name: Update SOP for Fill[...]	POSTDI-00000012	2018-04-27	Not Started	View

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**: still the **Lead Investigator**. The additional **Secondary Tasks** will be listed under **Related Items**.



The Lead Investigator will continue to monitor the process until they are ready to make the **Investigation Execution Decision of Submit for Approval**. As mentioned on Page 28 of this document, that decision will not be possible until all **Secondary Tasks of Task Type = Task** are completed.

When a choice of **Submit for Approval** is able to be selected, the process will progress as follows:

- If any **Optional Technical Approvers** were selected, it will move to **Investigation Technical Approval**.
- If no **Optional Technical Approvers** are required, it will move to **Step 6: Final QA Assessment**.

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**: in this case the **Technical Approver(s)** selected at Step 7.

The number listed after the **Investigation Technical Approval** Process Task represents the number of Technical Approvers chosen – in this example there was just one chosen. If multiple were chosen, they would all be listed.

Process Details

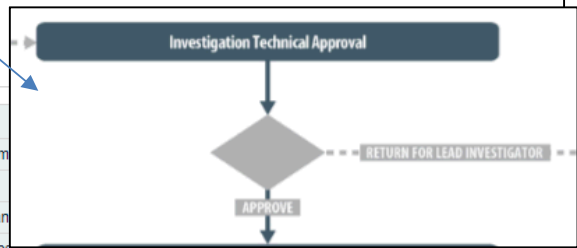
Name: Deviation Date Initiated: 2018-03-07 14:49:16
 Unique ID: DEV-000010 Initiated by: solabssupport (Default Admin)
 Day(s) opened: 13 Date Closed : <empty>
 Secondary Tasks Completion (%): 25 (1/4) Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks
 Investigation Technical Approval_1 Currently with eharinov (Elena Harinov)

Flowchart: Open

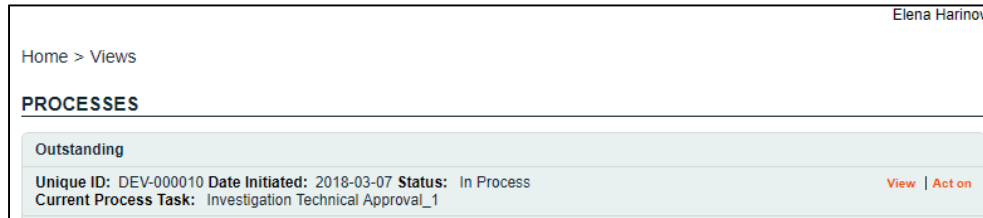
Process Values

Process Tasks	Last Confirmation Date
Name: Initiation and Immediate Action(s)	2018-03-14 16:25
Name: QA Assessment	2018-03-14 16:25
Name: Investigation Plan	2018-03-16 16:4
Name: Extension Request (1)	2018-03-16 16:4
Name: Extension Request Approval (1)	2018-03-16 16:35:31
Name: QA Investigation Plan Approval	2018-03-19 16:12:56
Name: Investigation Execution	2018-03-20 10:02:48
Name: Additional Tasks	2018-03-20 09:38:07
Name: Investigation Technical Approval_1	



Investigation Technical Approval

At this step in the Deviation Process, the **Technical Approver(s)** will receive an email Notification and will see the **Investigation Technical Approval** task listed in the Process section of their SOLABS QM HOME Page. Each person selected will need to Act on that task. In this example there was just one person assigned the task, so the numbers **_1** appears beside the task. If there were others, they would see **_2, _3**, etc. to differentiate the separate reviews.



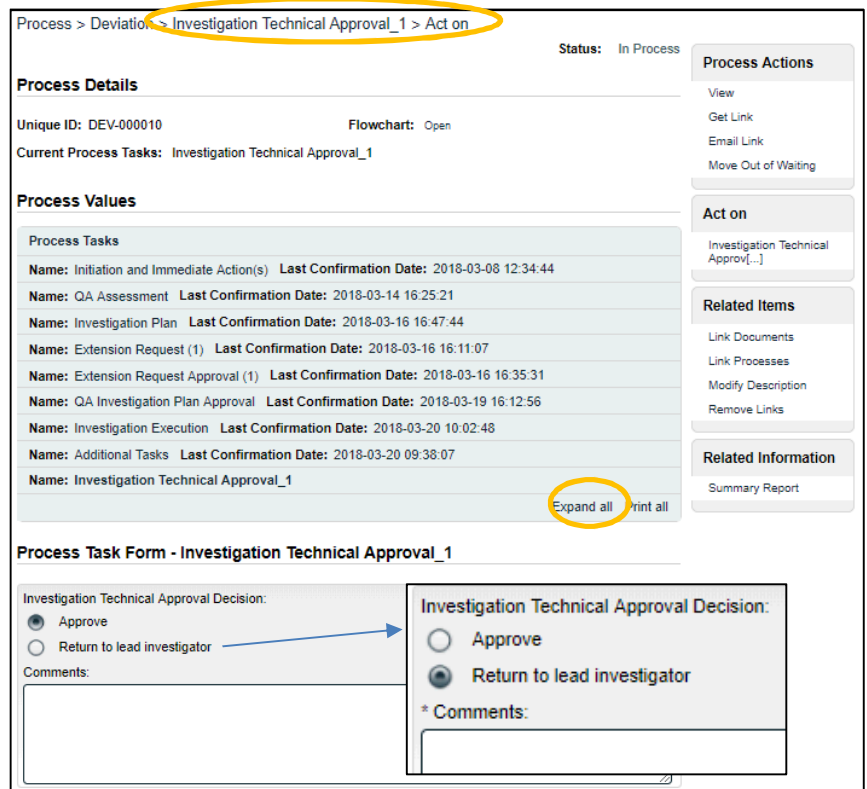
Acting on the Investigation Technical Approval Task

When the **Technical Approver** clicks on the **Act on** option to the right of the **Investigation Technical Approval** task, they will go immediately to the **Act on** screen for that task.

They can use the **Expand all** option under the **Process Values** table to view all information entered for the Deviation Process up to this point. If they go to the **Process Actions >View** option, they can see all **Related Items** at the bottom of the screen as well.

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out. The **Related Processes**, **Link Documents** and **Link Processes** options are available.

The Technical Approvers have an optional free-text area for **Comments** that allows up to 8000 characters.



The **Investigation Technical Approval Decision** has two options: **Approve** or **Return to lead investigator**. A decision of **Return to lead investigator** makes the **Comments** field become mandatory. When this decision is Submitted and Confirmed, the process will go back to **Step 5: Investigation Execution** and be assigned to the **Lead Investigator** to address the comments.

An **Investigation Technical Approval Decision** of **Approve** will progress the Deviation Process to **Step 6: Final QA Assessment**.

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**: in this case the **QA Approver**.

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 13	Date Closed : <empty>
Secondary Tasks Completion (%): 25 (1/4)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks	Currently with
Final QA Assessment	afavell (

Flowchart: Open →

Process Values

Process Tasks
Name: Initiation and Immediate Action(s) Last Confirmation
Name: QA Assessment Last Confirmation Date: 2018-03-14
Name: Investigation Plan Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1) Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1) Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval Last Confirmation Date: 2018-03-19 16:12:56
Name: Investigation Execution Last Confirmation Date: 2018-03-20 10:02:48
Name: Additional Tasks Last Confirmation Date: 2018-03-20 09:38:07
Name: Investigation Technical Approval_1 Last Confirmation Date: 2018-03-20 17:33:45
Name: Final QA Assessment

Expand all Print all

Step 6: Final QA Assessment

At this step in the Deviation Process, the **QA Approver** will receive an email Notification and will see the **Final QA Assessment** task listed in the Process section of their SOLABS QM HOME Page. If there are any pending Secondary Tasks of Task Type = Pre-Disposition, the name of this step will be **Final QA Assessment – Pending Pre-Disposition Tasks**, since the QA Approver will not be able to Approve this step until those are complete. (Note: due to QM10 system timers, “- Pending Pre-Disposition Tasks” will not be visible for at least 5 minutes after submission of the previous step. There is also a statement highlighted in red on the Act on screen if there are any pending Secondary Tasks of Task Type = Pre-Disposition.

Amanda Favell

Home > Views

PROCESSES

Outstanding
Unique ID: DEV-000010 Date Initiated: 2018-03-07 Status: In Process View Act on Current Process Task: Final QA Assessment - Pending Pre-Disposition Tasks

Acting on the Final QA Assessment Task

When the **QA Approver** clicks on the **Act on** option to the right of the **Final QA Assessment** task, they will go immediately to the **Act on** screen for that task.

They can use the **Expand all** option under the **Process Values** table to view all information entered for the Deviation Process up to this point. If they go to the **Process Actions** >**View** option, they can see all **Related Items** and can then **View** them as well.

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out. The **Related Processes**, **Link Documents** and **Link Processes** options are available.

The QA Approver can use the **Is Assessment Required?** selection to add additional **Assessment Types** as needed. See page 14 of this document for the fields associated with a **Yes** selection.

The mandatory **Deviation Classification** field will be pre-populated with the Initial Deviation Classification entered by the QA Approver at Step 2. The **QA Approver** can change the Classification at this point if warranted.

As mentioned at Step 2, if the classification was entered as either **Critical** or **Critical Incident**, then an **Assigned Head of Quality** field will be mandatory and will be displayed at this step. It is a single-item selection drop-down list populated with the list of users who have the process role **PR_DEV_QA_Head** assignment.

Process > Deviation > **Final QA Assessment - Pending Pre-Disposition Tasks > Act on** Status: In Process

Process Details

Unique ID: DEV-000010 Flowchart: Open

Current Process Tasks: Final QA Assessment - Pending Pre-Disposition Tasks

Process Values

Process Tasks
Name: Initiation and Immediate Action(s) Last Confirmation Date: 2018-03-08 12:34:44
Name: QA Assessment Last Confirmation Date: 2018-03-14 16:25:21
Name: Investigation Plan Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1) Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1) Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval Last Confirmation Date: 2018-03-19 16:12:56
Name: Investigation Execution Last Confirmation Date: 2018-03-20 10:02:48
Name: Additional Tasks Last Confirmation Date: 2018-03-20 09:38:07
Name: Investigation Technical Approval_1 Last Confirmation Date: 2018-03-20 17:33:45
Name: Final QA Assessment - Pending Pre-Disposition Tasks

Expand all Print all

Process Task Form - Final QA Assessment - Pending Pre-Disposition Tasks

Is Assessment Required?:
 Yes
 No

* Deviation Classification:
 Critical

* Assigned Head of Quality:
 afavell (Amanda Favell)

Final Assessment Decision:
 Approve
 Return to lead investigator
 Return to initiator

All prerequisite secondary tasks are not completed.

* Comments:
 [Text Area]

Secondary Tasks

<input checked="" type="checkbox"/> Check Filler PM Records Due Date: 2018-03-22 Type: Pre-Disposition Originator: jdavid (Jeff David)
<input checked="" type="checkbox"/> Update Filler PM Schedule as Needed Due Date: 2018-03-30 Type: Post-Disposition

Modify Remove

At this point the QA Approver will make the **Final Assessment Decision**.

A decision of **Return to lead investigator** will make the **Comments** field mandatory. When this decision is Submitted and Confirmed, the Deviation Process will go back to **Step 5: Investigation Execution** and be assigned to the **Lead Investigator** to address the comments.

A decision of **Return to initiator** will also make the **Comments** field mandatory. When this decision is Submitted and Confirmed, the Deviation Process will go back to **Step 1: Initiation and Immediate Action(s)** and be assigned to the **Initiator** to address the comments. If Deviation Type is **Planned**, the decision **Return to initiator** is greyed out.

The decision of **Approve** is grayed out if any Secondary Tasks of Task Type = Pre-Disposition are not complete.

When a decision of **Approve** is able to be Submitted and Confirmed, the Deviation Process will progress as follows:

- If the Deviation was not classified as either Critical or Critical Incident, the process will be complete and go to **END**.
- If the Deviation was classified as either Critical or Critical Incident, the process will progress to **Step 7: Head of Quality Final Approval**.

The **Process Flowchart** will highlight that step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with**: in this case the **Head of Quality**.

Process Details

Name: Deviation	Date Initiated: 2018-03-07 14:49:16
Unique ID: DEV-000010	Initiated by: solabssupport (Default Admin)
Day(s) opened: 13	Date Closed : <empty>
Secondary Tasks Completion (%): 50 (2/4)	Dependent Processes Completion (%): 0 (0/0)


Current Process Tasks	Currently with
Head of Quality Final Approval	kheathe

Flowchart: [Open](#)

Process Values

Process Tasks	
Name: Initiation and Immediate Action(s)	Last Confirmation
Name: QA Assessment	Last Confirmation Date: 2018-03-14
Name: Investigation Plan	Last Confirmation Date: 2018-03-16 16:47:44
Name: Extension Request (1)	Last Confirmation Date: 2018-03-16 16:11:07
Name: Extension Request Approval (1)	Last Confirmation Date: 2018-03-16 16:35:31
Name: QA Investigation Plan Approval	Last Confirmation Date: 2018-03-19 16:12:56
Name: Investigation Execution	Last Confirmation Date: 2018-03-20 10:02:48
Name: Additional Tasks	Last Confirmation Date: 2018-03-20 09:38:07
Name: Investigation Technical Approval_1	Last Confirmation Date: 2018-03-20 17:33:45
Name: Final QA Assessment	Last Confirmation Date: 2018-03-20 18:43:58
Name: Head of Quality Final Approval	

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



```

graph TD
    Start([Head of Quality Final Approval]) --> Decision{ }
    Decision --> End((END))
    Decision -.->|RETURN TO FINAL QA ASSESSMENT| Start
    Decision -.->|RETURN FOR LEAD INVESTIGATOR| Start
    
```

Step 7: Head of Quality Final Approval

At this step in the Deviation Process, the **Head of Quality** will receive an email Notification and will see the **Head of Quality Final Approval** task listed in the Process section of their SOLABS QM HOME Page. If there are any pending Secondary Tasks of Task Type = Post-Disposition, the name of this step will be **Head of Quality Final Approval – Pending Post-Disposition Tasks**, since the Head of Quality will not be able to Approve this step until those are complete. (Note: due to QM10 system timers, “- Pending Post-Disposition Tasks” will not be visible for at least 5 minutes after submission of the previous step. There is also a statement highlighted in red on the Act on screen if there are any pending Secondary Tasks of Task Type = Post-Disposition.

Acting on the Head of Quality Final Approval Task

When the **Head of Quality** clicks on the **Act on** option to the right of the **Head of Quality Final Approval** task, they will go immediately to the **Act on** screen for that task.

They can use the **Expand all** option under the **Process Values** table to view all information entered for the Deviation Process up to this point. If they go to the **Process Actions** >**View** option, they can see all **Related Items** at the bottom of the screen and view them as well.

Secondary Tasks cannot be added at this Step so the **+ADD** option is grayed out. The **Related Processes**, **Link Documents** and **Link Processes** options are available if needed.

At this point the **Head of Quality** will make the **Head of Quality Decision**.

A decision of **Return to lead investigator** will make the **Comments** field mandatory. When this decision is Submitted and Confirmed, the Deviation Process will go back to **Step 5: Investigation Execution** and be assigned to the **Lead Investigator** to address the comments.

A decision of **Return to final QA assessment** also makes the **Comments** field mandatory. When this decision is Submitted and Confirmed, the Deviation Process will go back to **Step 6: Final QA Assessment**, and be assigned to the **QA Approver** to address the comments.

A decision of **Approve** will move the Deviation Process goes to a status of **Completed** and is at the **END**.

Viewing Details for a Completed Deviation Process

Users are able to search for and view processes at any stage, using the **Navigation** tab in the **PROCESS Section** of SOLABS QM. If the Process was recently worked on, it will also be available in the **Recent Items** section.

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 **Details** screens, the Process will be listed under Related Items – you can quickly toggle back to the Main Process by clicking **View** next to it.

Related Items

Secondary Tasks			
Name: Check Training Recor[...]	Unique ID: Task-00000012	Due: 2018-03-15	Status: Completed View
Name: Check Filler PM Reco[...]	Unique ID: PREDI-00000014	Due: 2018-03-22	Status: Completed View
Name: Update Filler PM Sch[...]	Unique ID: POSTDI-00000011	Due: 2018-03-30	Status: Completed View
Name: Update SOP for Filli[...]	Unique ID: POSTDI-00000012	Due: 2018-04-27	Status: Completed View

Task Details

Name: Check Training Records for Operators Involved
 Type: Task Unique ID: Task-00000012
 Description: Check Training Records for operators involved in filling of Product XXX, Lot 5, 6
 Reference Date: 2018-03-14
 Location: Root\DEV-000010 Process Task Group\Initiation and Immediate Action(s) Task Group
 Estimated Start Day Offset: 0 Estimated End Day Offset: 1
 Estimated Start Date: 2018-03-14 Estimated End Date: 2018-03-15
 Start Date: 2018-03-20 End Date: 2018-03-20
 Status: Completed
 Comments:

Task Ownership

Originator: solabssupport (Default Admin)
 Assignee (Role): any
 Assignee (User): jmcdownall (James McDowall)

Related Items

Main Related Process			
Unique ID: DEV-000010	Date Initiated: 2018-03-07	Status: Completed	View
Current Process Task: N/A			

Creating a Summary Report

Under the right-hand **Related Information** menu, click on the **Summary Report** option.

Related Information

- [Audit Trail](#)
- [Summary Report](#)

Select the desired **Print Out Options** and then click on **Generate Report**. A multi-page PDF Report will be generated, with any company header information set in System Configurations, and will include details on each step requested for the report.

Status: Completed

Process Details

Name: Deviation Date Initiated: 01-Oct-2018 12:20:52
 Unique ID: DEV-000012 Initiated by: gdxixon (Gretchen Dixon)
 Day(s) opened: 0 Date Closed: 10-Oct-2018 14:19:03
 Secondary Tasks Completion (%): 0 (0/0) Dependent Processes Completion (%): 100 (1/1)
 Current Process Tasks: N/A Currently with: N/A
 Flowchart: Open

Print Out Options

- Process Details
- Process Values Table – Step 1 Only
- Process Values Table – All Steps
- Process Secondary Tasks
- Dependent Processes
- Process Relationships (Other Related Items)

GD&P

1 GDP Boulevard
 Burlington, VT
 05401
 USA
 1-802-223-4567
 1-800-223-4567
 www.gdgp.com

DEV-000012

Name: Deviation Date Initiated: 01-Oct-2018 12:20:52
 Unique ID: DEV-000012 Initiated by: gdxixon (Gretchen Dixon)
 Days opened: 9 Date Closed: 10-Oct-2018 14:19:03
 Secondary Tasks Completion (%): 0 (0/0) Dependent Processes Completion (%): 100 (1/1)
 Current Process Tasks: N/A Currently with: N/A

Process Values

Name: Initiation and Immediate Action(s) Last Confirmation Date: 10-Oct-2018 13:45:56

Deviation No.: DEV-000012
 Title: Training not completed for all QA Specialists on SOP QAC-001, Internal Audit Program
 Description of Deviation: Some QA Specialists were not trained on the latest revision of SOP QAC-001, resulting in audit report requirements and timing not in alignment with the SOP.
 Deviation Type: Unplanned
 Date Deviation Occurred: 01-Oct-2018
 Date Deviation Discovered: 10-Oct-2018
 Immediate Action(s) Taken: Ensure all QA Specialists have completed training on SOP QAC-001 Revision 3.0.
 Deviation Due Date: 31-Oct-2018
 Deviation Category: Category 1
 GxP Classification: GMP (Good Manufacturing Practices)
 Stage: Other
 Specify Product Stage: Not product related
 Initiation Type: Internal
 Site: Manufacturing Site 1; Manufacturing Site 2; Quality Control Testing Lab
 Is Material Associated with Deviation?: No
 Does this potentially impact distributed Product?: No
 Lead Investigator: dbarnes (Donald Barnes)
 QA Approver: rnturner (Marilyn Turner)
 Sign-off by: gdxixon (Gretchen Dixon)

Name: QA Assessment Last Confirmation Date: 10-Oct-2018 13:49:10

Initial Impact Assessment: Noted during monthly QA Metrics Meeting that a recent Internal Audit Report did not meet required timelines and related communications had not been initiated. Identified that QA Specialists in some areas did not have SOP QAC-001 as part of their assigned training and were not up to date with the latest version of that SOP.

Printed by: Gretchen Dixon on 24-Jun-2019 16:57:57 © SOLABS 2019- Page 1 of 3

Using the Audit Trail

Users with the **SOLABS System Administrator** role assignment, will also see the **Audit Trail** option on the right-hand **Related Information** menu.

Related Information
Audit Trail
Summary Report

There you will find all the details for every step of the Deviation 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 > DEV-000012 > Audit Trail	
Process Name: DEV-000012	
Action Details: Process Completed Process Task Name: N/A Date: 10-Oct-2018 14:19:03 Role: FCT_Manager QA Compliance Username (Full Name): mturner (Marilyn Turner) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: Final QA Assessment Date: 10-Oct-2018 14:19:03 Role: FCT_Manager QA Compliance Username (Full Name): mturner (Marilyn Turner) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: Investigation Execution Date: 10-Oct-2018 13:57:38 Role: FCT_Auditor - QA Compliance Username (Full Name): dbarnes (Donald Barnes) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: QA Assessment Date: 10-Oct-2018 13:49:10 Role: FCT_Manager QA Compliance Username (Full Name): mturner (Marilyn Turner) Reason for Change: N/A	Print
Action Details: Dependent Process Started Process Task Name: N/A Date: 10-Oct-2018 13:45:57 Role: N/A Username (Full Name): gdixson (Gretchen Dixon) Reason for Change: N/A	Print
Action Details: Task Performed Process Task Name: Initiation and Immediate Action(s) Date: 10-Oct-2018 13:45:56 Role: FCT_QMS System Administrator Username (Full Name): gdixson (Gretchen Dixon) Reason for Change: N/A	Print
Action Details: Process Started Process Task Name: N/A Date: 01-Oct-2018 12:20:52 Role: N/A Username (Full Name): gdixson (Gretchen Dixon) Reason for Change: N/A	Print
Expand all Print all View 1	

Deviation Process Notifications

The Notifications available with the Off-the-Shelf Deviation Process APP P0054 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 Notifications are associated with the off-the-shelf Deviation Process P0054 APP.

When Step 1 is confirmed with a value of Does this deviation impact distributed Product? = yes, the following notification is sent:

To: All users in the role of PR_DEV_QA_Approver

Subject: Deviation DEV-XXXXXX is potentially impacting distributed product

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field Title]

Description: [Step 1 field Description of Deviation]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field Date Deviation Occurred]

Where DEV-XXXXXX is a hyperlink to the process

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type = Unplanned**.

When Step 1 is confirmed, the following notification is sent:

To: Department Head of user who confirmed Step 1

Subject: Deviation DEV-XXXXXX has been initiated

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field Title]

Description: [Step 1 field Description of Deviation]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field Date Deviation Occurred]

Initiator: [User who confirmed Step 1]

Where DEV-XXXXXX is a hyperlink to the process

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type = Unplanned**.

When Step 2 is confirmed with **Decision** = *Approve – continue deviation process* or *Approve – close deviation process*, the following notification is sent:

To: Users selected in Step 2 Committee Notification

Subject: Deviation DEV-XXXXXX has been opened

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field **Title**]

Description: [Step 1 field **Description of Deviation**]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field **Date Deviation Occurred**]

Where DEV-XXXXXX is a hyperlink to the process

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type** = *Unplanned*.

When Step 6 is confirmed with **Decision** = *Approve* and **Deviation Classification** ≠ *Critical* or *Critical Incident*, the following notification is sent:

To: Users selected in Step 2 Committee Notification

Subject: Deviation DEV-XXXXXX has been dispositioned

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field **Title**]

Description: [Step 1 field **Description of Deviation**]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field **Date Deviation Occurred**]

Where DEV-XXXXXX is a hyperlink to the process

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type** = *Unplanned*.

When Step 7 is confirmed with **Decision** = *Approve*, the following notification is sent:

To: Users selected in Step 2 Committee Notification

Subject: Deviation DEV-XXXXXX has been dispositioned

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field **Title**]

Description: [Step 1 field **Description of Deviation**]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field **Date Deviation Occurred**]

Where DEV-XXXXXX is a hyperlink to the process

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type** = *Unplanned*.

When all Secondary Tasks of type TASK have a status of Completed, the following notification is sent:

To: Users identified as **Lead Investigator**

Subject: All TASK Secondary Task are completed for Deviation DEV-XXXXXX

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field Title]

Description: [Step 1 field Description of Deviation]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field Date Deviation Occurred]

Where DEV-XXXXXX is a hyperlink to the process

Must be reevaluated every time Secondary Task of type = TASK change status.

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type** = *Unplanned*.

When all Secondary Tasks of type Pre-Disposition have a status of Completed, the following notification is sent:

To: Users identified as **Assigned QA Approver**

Subject: All Pre-Disposition Secondary Task are completed for Deviation DEV-XXXXXX

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field Title]

Description: [Step 1 field Description of Deviation]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field Date Deviation Occurred]

Where DEV-XXXXXX is a hyperlink to the process

Must be reevaluated every time Secondary Task of type = Pre-Disposition change status.

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type** = *Unplanned*.

When all Secondary Tasks of type Post-Disposition have a status of Completed, the following notification is sent:

To: Users identified as **Assigned Head of Quality**

Subject: All Post-Disposition Secondary Task are completed for Deviation DEV-XXXXXX

Body:

DEV-XXXXXX

Deviation Title: [Step 1 field Title]

Description: [Step 1 field Description of Deviation]

Initiation Date: [date the process was initiated format yyyy-mm-dd]

Date Deviation Occurred: [Step 1 field Date Deviation Occurred]

Where DEV-XXXXXX is a hyperlink to the process

Must be reevaluated every time Secondary Task of type = Post-Disposition change status.

The label and value **Date Deviation Occurred** is displayed only if **Deviation Type** = *Unplanned*.

Additional Notification Available on Request – Option 2

There is one additional Notification available as “Option 2” per the PUFDS. It can be enabled upon request.

When Secondary Task Due Date < Today, the following notification is sent:

To: Secondary Task Assignee and Secondary Task Assignee’s Department Head

Subject: The Secondary Task [Secondary Task Name] is overdue.

Body:

The Secondary Task [Secondary Task Name] associated with process DEV-XXXXXX is overdue.

Where DEV-XXXXXX is a hyperlink to the process

Where [Secondary Task Name] is a hyperlink to the Secondary Task view page (in the body only).