

# SOLABS QM10: Pharmaceutical Product Complaint Process P0056 User Guide

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## Introduction

This document provides instructions on the use of the **SOLABS QM10 Pharmaceutical Product Complaint (PPC) Process APP P0056** – 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.

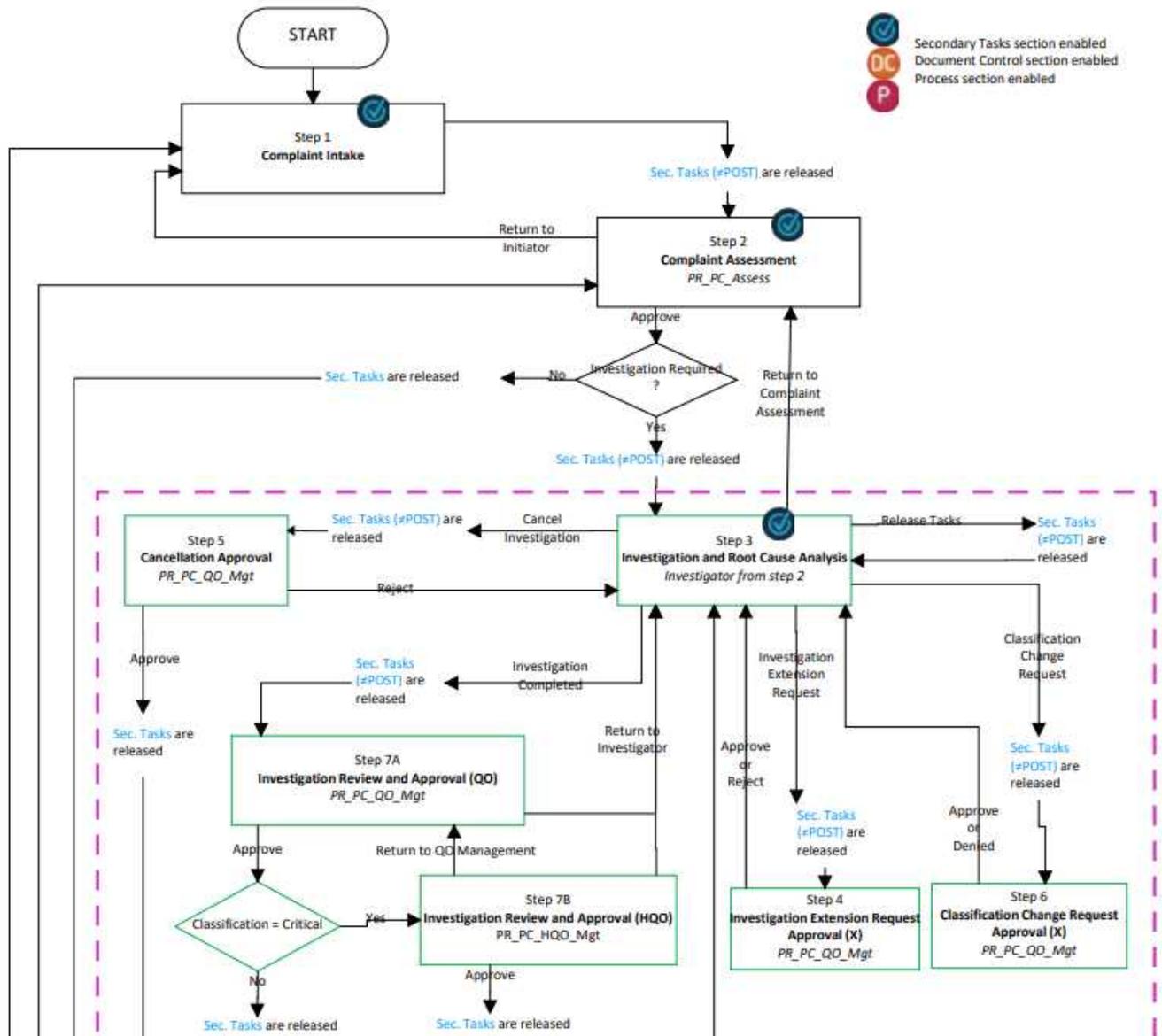
Refer to the following documents available in the SOLABS Knowledge Base for general information, navigation and functionality common to any **SOLABS QM Process APP** in the **SOLABS QM10 PROCESS Section**.

- **SOLABS QM10: Introduction to PROCESS Section**
- **SOLABS QM10: Notifications Guide**

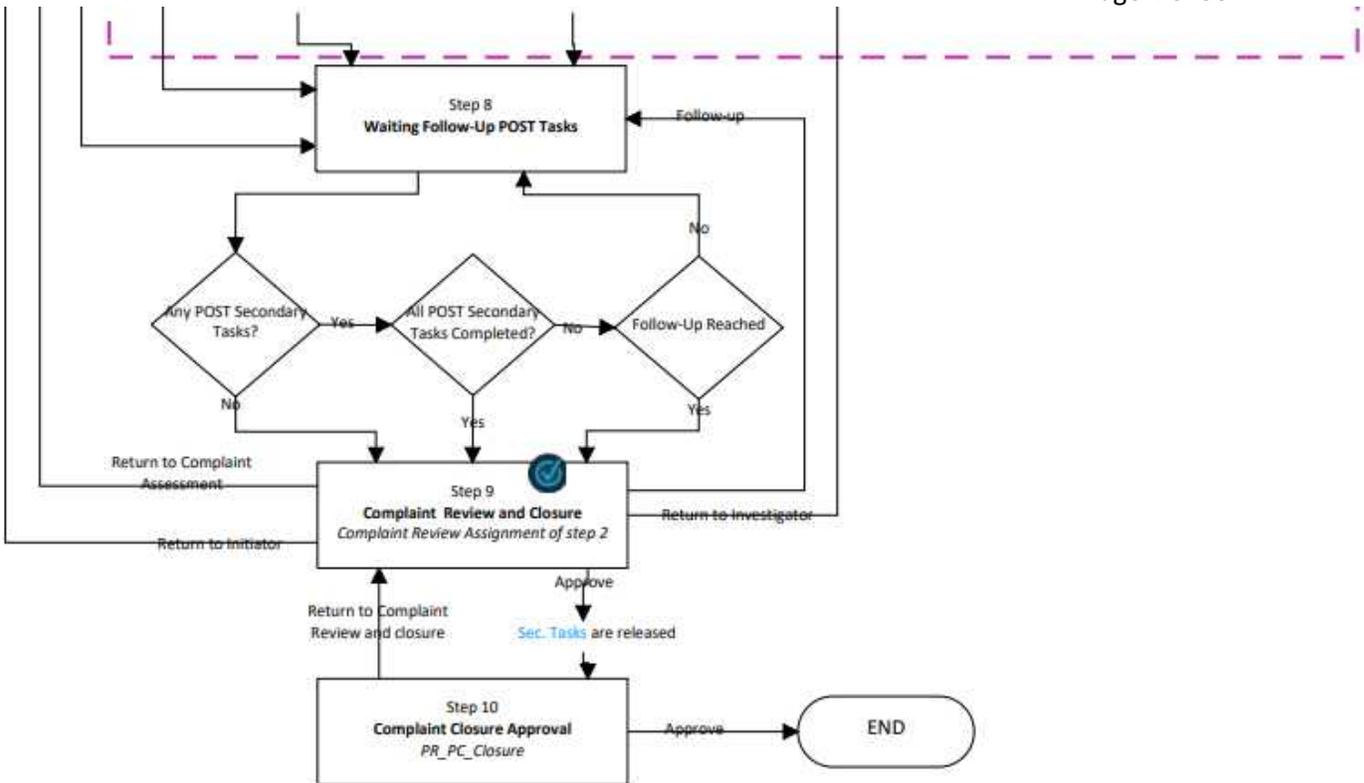
Different steps in a process are assigned to different roles and/or users in the system. You take action on the step assigned to you. For example, you may be assigned an **Investigation Review and Approval** step in a **PPC** process. A manager can monitor the status of process tasks assigned to their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

## Pharmaceutical Product Complaint (PPC) Process Flowcharts

The **PPC Process Flowcharts** displayed in this section are for informational purposes only – to show that it is a multi-step process with related decision paths and multiple options. This User Guide is organized into sections for each step in the PPC Process. **The flowchart section for each of those steps will be displayed in larger, more readable format within those sections.**



Continued on next page...



There are some **Options** that will be available with this Process APP in a future release. Some of these options result in changes to the process flow represented in the above Flow Chart. See Page 48 for additional detail on these future options.

## Pharmaceutical Product Complaint (PPC) Process – Process Roles

Decisions made by those involved in the process act to progress the workflow to the next Step or return it to a prior Step. The following **PPC Process Roles** are associated with the **Pharmaceutical Product Complaint Process P0056** and must be assigned to the Users in **SOLABS QM10** who will make the related decisions.

When SOLABS QM10 Users are assigned a Process Role, their names are then available on drop-down lists to be selected for their assigned steps in the process. The process will automatically notify them to Act On that Step. They will see the step in the Process Section of their SOLABS QM10 HOME Page and will also receive an email Notification. Contact your SOLABS System Administrator if any of these PPC Process Roles need to be assigned to additional Users.

### **PR\_PPC\_Assess:**

This Process Role must be assigned to those Users who will need to Act on the following Step:

- Step 2: Complaint Assessment

*If there are no users assigned that process role, Step 2 will go to all users with the SOLABS Document Administrator role. If there are no users with that role, it will go to all users with the SOLABS System Administrator role.*

### **PR\_PPC\_Inv:**

This Process Role must be assigned to those Users who will need to Act on the following Step:

- Step 3: Investigation and Root Cause Analysis

### **PR\_PPC\_QO\_Management:**

This Process Role must be assigned to those Users who will need to Act on the following Steps:

- Step 4: Investigation Extension Request Approval
- Step 5: Cancellation Approval
- Step 6: Classification Change Request Approval
- Step 7A: Investigation Review and Approval (QO)

*If there are no users in the role of PR\_PPC\_QO\_Management the process will go to all users with the SOLABS Document Administrator role. If there are no users with that role, it will go to all users with the SOLABS System Administrator role.*

### **PR\_PPC\_HQO\_Management:**

This Process Role must be assigned to those Users who will need to Act on the following Steps:

- Step 7B: Investigation Review and Approval (HQO)

*If there are no users in the role of PR\_PPC\_HQO\_Management the process will go to all users with the SOLABS Document Administrator role. If there are no users with that role, it will go to all users with the SOLABS System Administrator role.*

### **PR\_PPC\_Review:**

This Process Role must be assigned to those Users who will need to Act on the following Step:

- Step 9: Complaint Review and Closure

### **PR\_PPC\_Closure:**

This Process Role must be assigned to those Users who will need to Act on the following Step:

- Step 10: Complaint Closure Approval

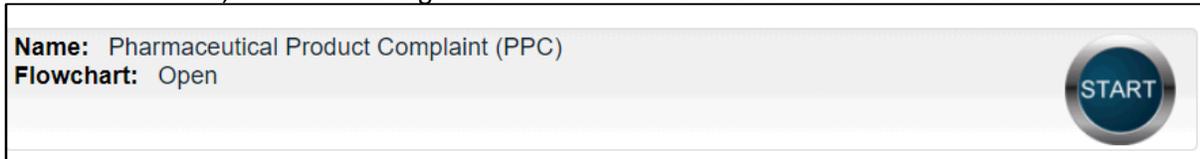
*If there are no users in the role of PR\_PPC\_Closure the process will go to all users with the SOLABS Document Administrator role. If there are no users with that role, it will go to all users with the SOLABS System Administrator role.*

## Starting the Pharmaceutical Product Complaint (PPC) Process

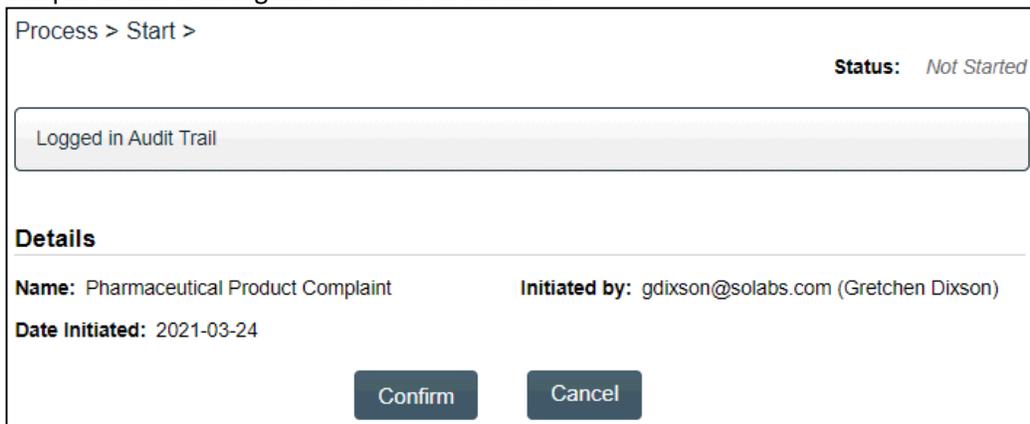
From the PROCESS Section in SOLABS QM10, choose Start Process from the Quick Access Process Menu.



At the next screen, locate the listing for the PPC 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 PPC Process.



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



## Step 1: Complaint Intake

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

The fields on the **Process Task Form** include editable text fields, text areas, single-item selection fields or multi-item selection fields. Those with an asterisk (\*) are mandatory.

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

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

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

**Secondary Tasks** can be initiated at Step 1 and are released to assignees upon submission of Step 1, unless they are POST tasks. Related Processes and Document Control Processes cannot be initiated at this step so the related options are grayed out.

At the very bottom of the screen there is a **Save Draft** option if you cannot complete all the required fields at one time or when you need to use the right-hand menus to **Link Documents** or to **Link Processes**.



Process > Pharmaceutical Product Complaint > Complaint Intake > Act on

Status: In Process

**Process Details**

Unique ID: PPC-000008 Flowchart: Open

Current Process Tasks: Complaint Intake

**Process Values**

**Process Tasks**

Name: Complaint Intake Expand all Print all

**Process Task Form - Complaint Intake**

Complaint Reference Number:  
PPC-000008

\* Contact Type:  
-----

\* Date of Complaint:  
----- Clear

\* Complaint Reporter:  
-----

\* Complaint Description:  
[Quick Text]

\* Reported Adverse Event for Pharmacovigilance:  
-----

External Case ID:  
-----

\* Product Type:  
-----

**Process Actions**

- View
- Modify Values
- Reassign Tasks
- Cancel
- Get Link
- Email Link
- Move Out of Waiting

**Act on**

- Complaint Intake

**Related Items**

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

**Related Information**

- Audit Trail
- Summary Report

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

\* Product Name:  
-----

Start typing for items to be displayed in the list.

\* Strength:  
-----

\* Product Description:  
-----

\* Lot Number:  
-----

Serial Number:  
-----

\* Manufacturer-Vendor:  
-----

Additional Product Information:  
[Quick Text]

\* Expiration Date:  
----- Clear

Unknown

\* Complaint Category:  
-----

\* Preexisting Related Complaints?:  
-----

\* Refund Requested?:  
-----

\* Acknowledgement Letter Required?:  
-----

\* Classification:  
-----

Comments:  
[Quick Text]

**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 PPC 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 of the fields in the **Process Task Form** at PPC

#### Process Step 1.

The **Complaint Reference Number** field will be automatically populated with the assigned Unique ID.

The **Contact Type** field is a mandatory single-item selection list of values from a configurable Custom List.

**Name:** SOL047\_Contact\_Type\_List

The **Date of Complaint** is mandatory date field that can be populated with today's date or with previous dates, using the calendar.

**Complaint Reporter** is a mandatory single-item selection field that is not customizable and includes a list of 3 set values. Each choice will bring up a set of **Contact Group** fields to enter the reporter information.

The **Contact Group** fields can be populated manually, or you can **Search By** Last Name or Phone Number for previous values that are stored in an EDI Table (EDI list Contact) after entry.

**Last Name**  
**Phone Number**

Clear values brought in by **Search**, with the **Clear** option.

The following **Contact Group** fields are Single-item selection fields populated by values from configurable Custom Lists:

Title: **Name:** SOL181\_Title\_List

Suffix: **Name:** SOL180\_Suffix\_List

State: **Name:** SOL171\_State\_List

Country: **Name:** SOL050\_Country\_List

If **Complaint Reporter = Patient**, a Yes/No option for **Pharmacy Information Required?** is displayed. A choice of “Yes” brings up another set of **Contact Group** fields for entry of that information. Similarly, if **Complaint Reporter = Pharmacy**, a Yes/No option for **Patient Information Required?** is displayed. A choice of “Yes” brings up another set of **Contact Group** fields for entry of that information.

\* Patient Information Required?:

Yes

No

\* Pharmacy Information Required?:

Yes

No

\* Complaint Description:

Complaint Description 1

Complaint Description 2

Complaint Description 3

[Quick Text]

\* Reported Adverse Event for Pharmacovigilance:

-----

External Case ID:

**Complaint Description** is a mandatory Text Area field allowing for up to 8000 characters. It can also be populated by **Quick Text**. Quick Text is an editable **Custom List** of values.

**Name:** SOL201\_Complaint\_Description\_QuickText\_List

**Reported Adverse Event for Pharmacovigilance** is a mandatory single-item selection field that is not customizable and allows for a selection of either **Yes** or **No**. If **Yes** is selected, the **External Case ID** field will become mandatory. This is a Text Field allowing for up to 1024 characters.

\* Product Type:

-----

Commercial  
Clinical

**Product Type** is a mandatory single-item selection field that is not customizable and includes a list of 2 set values.

- If **Product Type = Clinical**, the following fields are displayed:

Study Number:

Site Number:

Subject Number:

\* Device Caused/Contributed to AE:

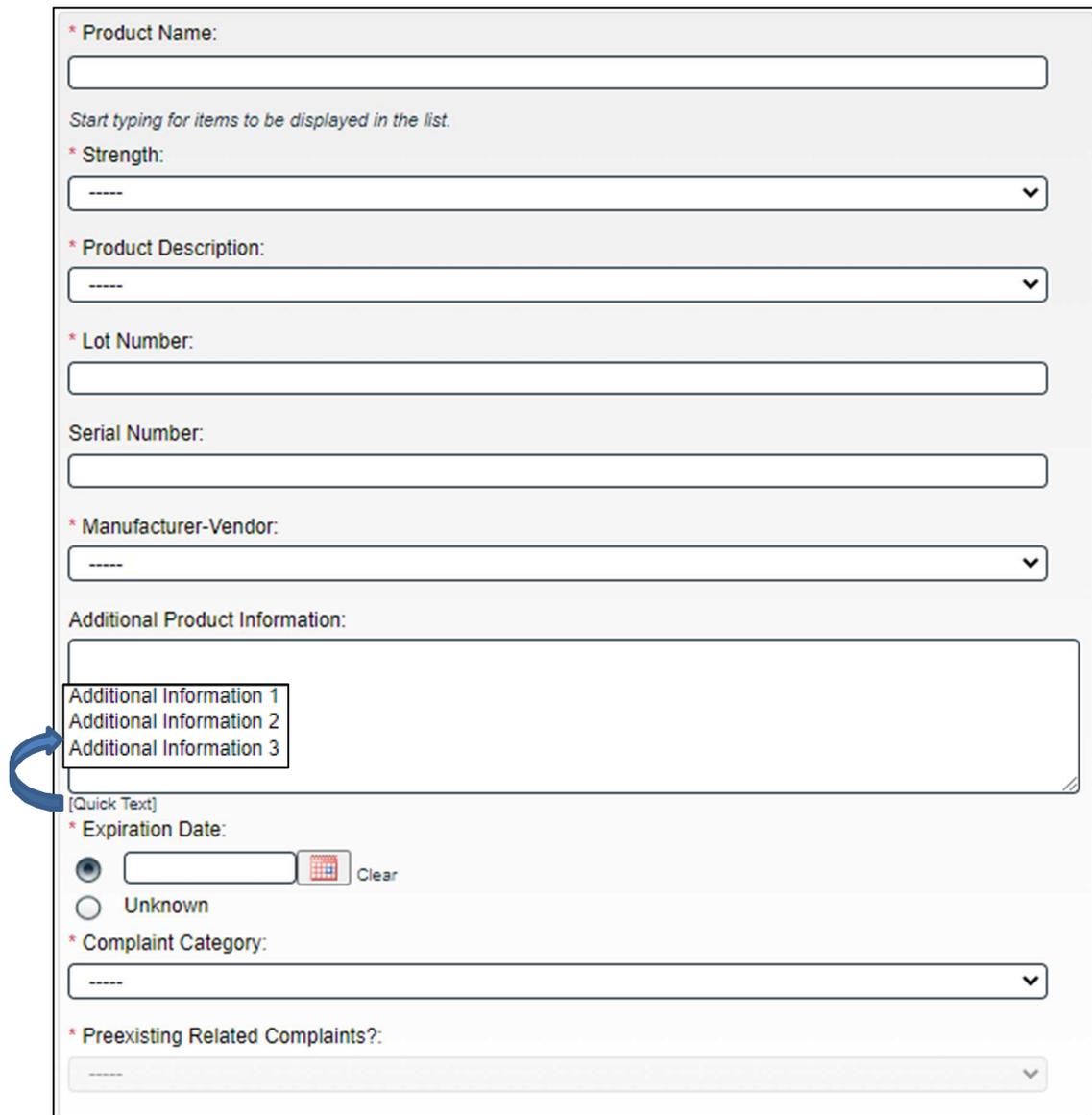
-----

**Study Number**, **Site Number** and **Site Number** are all optional Text Fields allowing entry of up to 1024 characters each. **Device Caused/Contributed to AE** is a mandatory single-item selection field that is not customizable and allows for a selection of either **Yes**, **No** or **N/A**.

- For either **Product Type**, a set of **Product Group** fields are displayed in order to enter the product information.

The **Product Name**, **Strength**, **Product Description**, **Manufacturer-Vendor** and **Complaint Category** are all mandatory single-item selection fields with values from an EDI Table **EDI list Product** that you provide to SOLABS so that they can create dependencies on the values for these fields. Once the **Product Name** is entered, the values displayed in the **Strength**, **Product Description**, **Manufacturer-Vendor** and **Complaint Category** lists will be only the ones that apply to that particular product.

Reference Knowledge Base article titled **Client Procedure for Updating EDI Tables** for more information on EDI Tables.



\* Product Name:

*Start typing for items to be displayed in the list.*

\* Strength:

\* Product Description:

\* Lot Number:

Serial Number:

\* Manufacturer-Vendor:

Additional Product Information:

Additional Information 1

Additional Information 2

Additional Information 3

[Quick Text]

\* Expiration Date:



Unknown

\* Complaint Category:

\* Preexisting Related Complaints?:

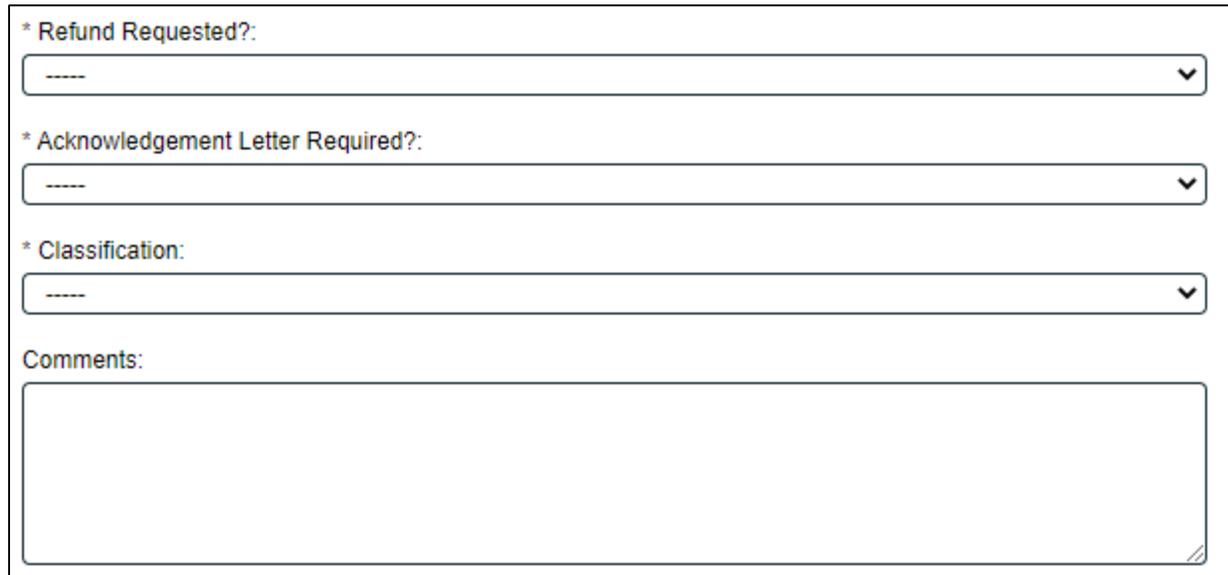
**Lot Number** and **Serial Number** are text fields allowing for entry of up to 1024 characters. The **Lot Number** field is mandatory.

**Additional Product Information** is an optional text area field allowing for entry of up to 8000 characters and/or the use of **Quick Text**. Quick Text is an editable **Custom List** of values.

**Name:** SOL203\_Additional\_Product\_Information\_QuickText\_List

**Expiration Date** is a mandatory radio button allowing for either entry of a date or selection of **Unknown**.

The **Preexisting Related Complaints?** field is not editable at Step 1. It is editable at Step 3, where it is a mandatory single-item **Yes** or **No** selection that is not customizable. When **Yes** is selected a mandatory **Complaint History** text area field will be displayed, allowing entry of up to 8000 characters.



The screenshot shows a form with the following elements:

- A dropdown menu labeled "\* Refund Requested?:" with a downward arrow on the right.
- A dropdown menu labeled "\* Acknowledgement Letter Required?:" with a downward arrow on the right.
- A dropdown menu labeled "\* Classification:" with a downward arrow on the right.
- A text area labeled "Comments:" with a small diagonal icon in the bottom right corner.

**Refund Requested?** is a mandatory single-item selection field that is not customizable and that allows for selection of either **Yes** or **No**.

**Acknowledgement Letter Required?** is a mandatory single-item selection field that is not customizable and that allows for selection of either **Yes** or **No**.

**Classification** is a mandatory single-item selection field that is not customizable and that allows for selections of **Critical, Major, Moderate, Minor, TBD** and **N/A**. Your internal SOPs should define when each of these are to be used. Whenever the process may be sent back to Step 1, this field will be populated with the latest confirmed value and is modifiable.

**Comments** is an optional text field allowing for entry of up to 8000 characters.

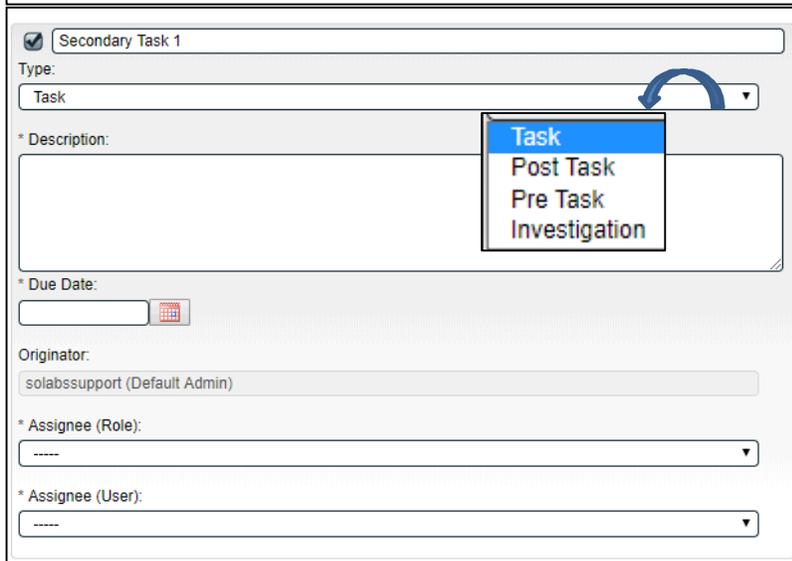
## Creating Secondary Tasks

The initiator of the Pharmaceutical Product Complaint (PPC) Process can create **Secondary Tasks** that will be associated with the PPC. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the PPC. All but Post tasks will be released to assignees upon submission/confirmation of Step 1.

The **Secondary Task** section is underneath the Process Task Form, but still on the Complaint Intake > Act on screen. A **+ADD** button is available to create as many Secondary Tasks as needed.



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



Replace the text “Secondary Task 1” with an appropriate **Title** for the task.

The task **Type** can then be chosen from a drop-down list of four types.

The **Description** and **Due Date** fields are mandatory for each Secondary Task. Choose due dates appropriate to ensure tasks are completed in a time frame that supports on time closure of the Pharmaceutical Product Complaint process.

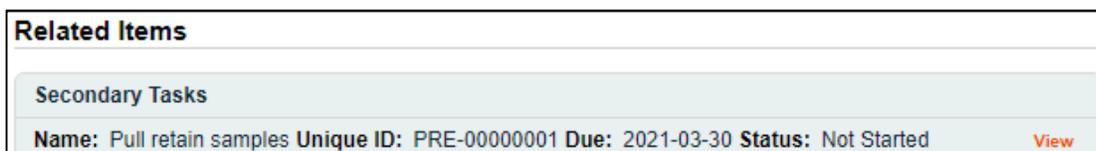
The **Originator** field will default to the User initiating the PPC Process and completing Step 1.

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 closure of the process.

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.

Use the **+ADD** button to create additional Secondary Tasks as needed.

When Step 1 is submitted and confirmed, the Assignees will receive email Notifications and see the View/Act On options for their assigned Secondary Tasks on their SOLABS QM10 HOME Page. The **Secondary Tasks**, and the status, are listed under **Related Items** at the bottom of the screen at any Process Step.

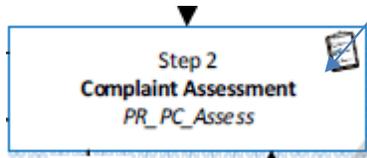


As mentioned previously, Related Processes and related Document Control Processes cannot be initiated at Step 1 so those sections are grayed out.

### Submit and Confirm

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

The Process Flowchart will highlight the next step of the process. Step 2 will be assigned to users with the Process Role **PR\_PPC\_Assess**. They will receive an email Notification.



Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)
<b>Day(s) opened:</b> 5	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/1)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b> Complaint Assessment	<b>Currently with</b> gdixson@solabs.com (Gretchen Dixson); mc[...]

Flowchart: [Open](#)

---

**Process Values**

Process Tasks	
<b>Name:</b> Complaint Intake	<b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment	

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

---

**Related Items**

Secondary Tasks			
<b>Name:</b> Pull retain samples	<b>Unique ID:</b> PRE-00000001	<b>Due:</b> 2021-03-30	<b>Status:</b> Not Started <a href="#">View</a>

[Expand all](#)

## Step 2: Complaint Assessment

At this step in the PPC Process, users with the role **PR\_PPC\_Assess** will receive an email Notification and will see the **Complaint Assessment** task listed in the Process section of the SOLABS QM10 HOME Page.

Home > Views

---

**PROCESSES**

Received this week / last week	
<b>Unique ID:</b> PPC-000008	<b>Date Initiated:</b> 2021-03-24 <b>Status:</b> In Process <a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Complaint Assessment	

### Viewing the Complaint Assessment Task

When the user with the role **PR\_PPC\_Assess** clicks on the **View** option to the right of the Process Task, they will get the same screen shown above.

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

In this example, clicking on View for a Secondary Task listed in PPC-000008 brings up the **Task Details** screen for that assigned Task.

PPC-000008 is listed as a **Related Item** for that Task. To get back to PPC-000008, the Reviewer can click on the **View** option.

Task > View

---

**Task Details**

Name: Pull retain samples

Type: Pre Task Unique ID: PRE-00000001

Description: Pull retain samples for ProductName1 Lot 007.

Reference Date: 2021-03-26 UTC-04:00

Location: Root\PPC-000008 Process Task Group\Complaint Intake Task Group

Estimated Start Day Offset: 0 Estimated End Day Offset: 3

Estimated Start Date: 2021-03-26 UTC-04:00 Estimated End Date: 2021-03-30 UTC-04:00

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

Status: Not Started

Comments:

---

**Task Ownership**

Originator: gdixson@solabs.com (Gretchen Dixson)

Assignee (Role): any

Assignee (User): solabs\_test\_user\_1 (Solabs User1)

---

**Related Items**

**Main Related Process**

Unique ID: PPC-000008 Date Initiated: 2021-03-24 Status: In Process [View](#)

Current Process Task: Complaint Assessment

## Acting on the Complaint Assessment Task

When the user with the PR\_PPC\_Assess role clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Complaint Assessment** task. As described above, the **Expand all** option under the Process Values table can be used to review all information entered at Step 1.

The **Process Task Form** for Step 2 includes fields to enter information related to the complaint assessment. Fields with an asterisk (\*) are mandatory. Some fields will be pre-populated with information from Step 1 but are editable.

The right-hand **Related Items** menus can be used to **Link Documents** or **Link Processes**. 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.

Process > Pharmaceutical Product Complaint > Complaint Assessment > Act on

Status: In Process Process Actions

---

**Process Details**

Unique ID: PPC-000008

Current Process Tasks: Comp

---

**Process Values**

Process Tasks	
Name: Complaint Intake	Last Confirmation Date: 2021-03-26 12:35:24
Name: Complaint Assessment	
Expand all Print all	

---

**Process Task Form - Complaint Assessment**

\* Sample Available?:

\* Type of Product:

\* Follow-up Letter Needed?:

**Each of the fields in the Process Task Form will be displayed more clearly and described in detail later in this section.**

Move Out of mailing

---

**Act on**

Complaint Assessment

---

**Related Items**

Link Documents

Link Processes

Modify Description

Remove Links

---

**Related Information**

Audit Trail

Summary Report

Initiation of more Secondary Tasks, is allowed at Step 2.

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**.



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

\* Complaint Review Assignment:  
-----

\* Product Name:  
PN1.77174

Start typing for items to be displayed

\* Strength:  
Sth 1.77174

\* Product Description:  
Desc 1.77174

\* Lot Number:  
007

Serial Number:  
1234

\* Manufacturer-Vendor:  
ManuName 1.77174

Additional Product Information:  
Additional Information 1

[Quick Text]

\* Expiration Date:  
 2024-03-20    
 Unknown

\* Complaint Category:  
PrimCat 2679.25

\* Preexisting Related Complaints?:  
-----

\* Investigation Required?:  
-----

\* Classification:  
Major

\* Complaint Assessment Decision:  
 Approve  
 Return to initiator for modification with comments

Complaint Assessment Comments:

**Each of the fields in the Process Task Form will be displayed more clearly and described in detail later in this section.**

**Process Task Form - Complaint Assessment**

\* Sample Available?:  
-----

**Sample Available?** is a single-item selection field that is not customizable and allows values of **Yes** or **No**. If **Yes** is selected, two additional mandatory fields are displayed: **Sample Arrived?** and **Quantity**.

\* Sample Arrived?:  
-----

\* Quantity:

- **Sample Arrived?** is a single-item selection field that is not customizable and allows values of **Yes** or **No**.
  - If **Yes** is selected, a mandatory **Sample Received Date** field is displayed.
  - If **No** is selected, a POST Secondary Task is automatically generated for **Follow-up for Sample Arrival** that is editable for details and can be assigned with a due date to any user.
- **Quantity** is a mandatory text field allowing for up to 1024 characters.

\* Sample Received Date:

Clear

**Follow-Up for Sample Arrival**  
 Type:  

Post Task

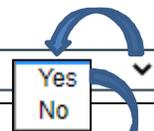
\* Type of Product:

The **Type of Product** field is a mandatory single-item selection list of values from a configurable Custom List.

**Name:** SOL137\_Product\_Type\_List

\* Follow-up Letter Needed?:

**Follow-up Letter Needed??** is a single-item selection field that is not customizable and allows values of **Yes** or **No**. If **Yes** is selected, a POST Secondary Task is automatically generated for **Follow-up letter to** that is editable for details and can be assigned with a due date to any user.



**Follow-Up letter to**  
 Type:  

Post Task

\* Complaint Review Assignment:

The **Complaint Review Assignment** field is a mandatory single-item selection list of users who have the process role assignment of **PR\_PPC\_Review**.

The set of **Product Group** fields is displayed at Step 2. The following 9 fields are pre-populated with the information entered at Step 1 but can be edited. See Page 10 for a description of these fields.

- |                              |                              |   |
|------------------------------|------------------------------|---|
| • <b>Product Name</b>        | • <b>Lot Number</b>          | • <b>Additional Product Information</b> |
| • <b>Strength</b>            | • <b>Serial Number</b>       | • <b>Expiration Date</b>                |
| • <b>Product Description</b> | • <b>Manufacturer-Vendor</b> | • <b>Complaint Category</b>             |

\* Investigation Required?:

**Investigation Required?** is a single-item selection field that is not customizable with values of **Yes** or **No**.

- If **No** is selected, a mandatory text area field is displayed for **Rationale**. It allows entry of up to 8000 characters. Also, if No is selected the Sample Available? field is no longer mandatory (see Page 15).
- If **Yes** is selected, a mandatory single-item selection field for **Lead Investigator** is displayed. It is a list of users who have the process role assignment of **PR\_PPC\_Inv**.

\* Lead Investigator:

\* Rationale:

\* Classification:

The **Classification** field (see Page 11) field will be pre-populated with the value selected at Step 1 or the last Confirmed Step (if the process is sent back) but is editable.

**NOTE:** If the **Investigation Required?** field = **Yes** but the **Classification** field is set to either TBD or N/A, Step 2 will not be able to be submitted. The Submit button will be grayed out and the following message will be displayed in red underneath the **Classification** field. **“The Classification level must be selected before proceeding with the investigation. Values TBD and N/A are not accepted.”**

If one or more Secondary Tasks of Task Type = PRE do not have a status of either Completed or Cancelled, the following warning will appear above the Complaint Assessment Decision section. This is for informational purposes.

Secondary Task(s) of type PRE are not completed.

The **Complaint Assessment Decision** section for Step 2 includes two choices:

\* Complaint Assessment Decision:

Approve

Return to initiator for modification with comments

Complaint Assessment Comments:

- **Approve** – if this choice is selected, the **Complaint Assessment Comments** field is not mandatory. Depending on the selections for other fields, certain conditions will apply.
- **Return to initiator for modification with comments** – if this choice is selected, the **Complaint Assessment Comments** field will be mandatory and the PPC Process will move back to Step 1.

If **Approve** is selected for **Complaint Assessment Decision** and the selection for **Lead investigator** and **Complaint Review Assignment** is the same, the following error message is displayed in red and the process is not submitted when the Submit button is clicked. **“Please have different users selected as Lead Investigator and Complaint Review Assignment.”**

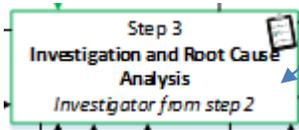
If **Approve** is selected for **Complaint Assessment Decision** and **Investigation Required?** = **Yes**, all Secondary Tasks except for Task Type = POST will be released to the assignees and the PPC process moves to **Step 3, Investigation and Root Cause Analysis** on confirmation.

If **Approve** is selected for **Complaint Assessment Decision** and **Investigation Required?** = **No**, all Secondary Tasks will be released to the assignees and the PPC process moves to **Step 8, Waiting Follow-Up POST Tasks** on confirmation.

## Submit and Confirm

When all information has been entered into the **Process Task Form**, any **Linked Documents** or **Linked Processes** have been added and any **Secondary Tasks** have been created, click **Submit** and then **Confirm** to progress the PPC process to **Step 3 – Investigation and Root Cause Analysis** or to **Step 8 – Waiting Follow-up POST Tasks** (see Page 36).

The Process Flowchart will highlight the next step of the process. Step 3 will be assigned to the chosen Lead Investigator. They will receive an email Notification.



Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)
<b>Day(s) opened:</b> 6	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)

**Current Process Tasks** Currently with

Investigation and Root Cause Analysis	gdixson@solabs.com (Gretchen Dixson)
---------------------------------------	--------------------------------------

Flowchart: [Open](#)

---

**Process Values**

Process Tasks
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis

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

---

**Related Items**

Secondary Tasks
<b>Name:</b> Pull retain samples <b>Unique ID:</b> PRE-00000001 <b>Due:</b> 2021-03-30 <b>Status:</b> Not Started <a href="#">View</a>
<b>Name:</b> Follow-Up for Sample[...] <b>Unique ID:</b> POST-00000002 <b>Due:</b> 2021-04-09 <b>Status:</b> Pending <a href="#">View</a>

[Expand all](#)

## Step 3: Investigation and Root Cause Analysis

At this step in the PPC Process, the **Lead Investigator** chosen at Step 2 will receive an email Notification and will see the **Investigation and Root Cause Analysis** task listed in the Process section of the SOLABS QM10 HOME Page.

PROCESSES
Received this week / last week
<b>Unique ID:</b> PPC-000008 <b>Date Initiated:</b> 2021-03-24 <b>Status:</b> In Process <span style="float: right;"><a href="#">View</a>   <a href="#">Act on</a></span>
<b>Current Process Task:</b> Investigation and Root Cause Analysis

## Viewing the Investigation and Root Cause Analysis Task

If the Lead Investigator clicks on the **View** option to the right of the Process Task, they will get the same screen shown above.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps. They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

## Acting on the Investigation and Root Cause Analysis 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 and Root Cause Analysis** task.

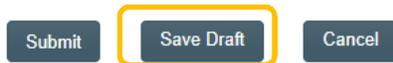
As described above, the **Lead Investigator** can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

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

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

Initiation of Secondary Tasks is allowed at Step 3. Any initiated will all have Task Type = Investigation, but Task Type can be edited. Initiation of Related Processes or of a Document Control Process are not allowed at Step 3 so those sections are grayed out.

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**.



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

**Process Values**

Process Tasks	
Name: Complaint Intake	Last Confirmation Date: 2023-03-03 15:54:22
Name: Complaint Assessment	Last Confirmation Date: 2023-03-03 15:58:18
Name: Investigation and Root Cause Analysis	
Expand all Print all	

**Process Task Form - Investigation and Root Cause Analysis**

Investigation Start Date: 2023-03-03

Investigation Due Date: 2023-04-02

\* Investigation Details:

[Quick Text]

\* Product Name:

Start typing for items to be displayed in the list.

\* Strength:

\* Product Description:

\* Lot Number:

Serial Number:

\* Manufacturer-Vendor:

Additional Product Information:

[Quick Text]

\* Expiration Date:  2024-03-20    Unknown

\* Complaint Category:

\* Preexisting Related Complaints?:

\* Identify Probable Root Cause(s):

\* Root Cause Categories:

Man Expand  
 Material

\* Investigation and Root Cause Analysis Decision:

Release tasks

Investigation completed

Investigation extension request

Classification change request

Return to complaint assessment with comments

Cancel investigation

Comments:

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

### Process Task Form - Investigation and Root Cause Analysis

Investigation Start Date:  
 2021-03-30 

Investigation Due Date:  
 2021-05-14 

\* Investigation Details:

Investigation Details 1  
 Investigation Details 2  
 Investigation Details 3

[Quick Text]

The **Investigation Start Date** field defaults to the date on which Step 3 is initiated for the first time and is not editable.

The **Investigation Due Date** field is set based on the following rules and is not editable:

Classification and Corresponding Delay	Is it the first time Investigation Due Date is calculated?	Sample Received Date has a date	Investigation Due Date value
Critical: Delay = 21 days	No	Yes	$\max(\text{actual Investigation Due Date}; \text{Sample Received Date} + 21 \text{ days})$
		No	$\max(\text{actual Investigation Due Date}; \text{Investigation Start Date} + 21 \text{ days})$
	Yes	Yes	<u>Sample Received Date</u> + 21 days
		No	<u>Investigation Start Date</u> + 21 days
Major: Delay = 30 days	No	Yes	$\max(\text{actual Investigation Due Date}; \text{Sample Received Date} + 30 \text{ days})$
		No	$\max(\text{actual Investigation Due Date}; \text{Investigation Start Date} + 30 \text{ days})$
	Yes	Yes	<u>Sample Received Date</u> + 30 days
		No	<u>Investigation Start Date</u> + 30 days
Moderate: Delay = 30 days	No	Yes	$\max(\text{actual Investigation Due Date}; \text{Sample Received Date} + 30 \text{ days})$
		No	$\max(\text{actual Investigation Due Date}; \text{Investigation Start Date} + 30 \text{ days})$
	Yes	Yes	<u>Sample Received Date</u> + 30 days
		No	<u>Investigation Start Date</u> + 30 days
Minor: Delay = 45 days	No	Yes	$\max(\text{actual Investigation Due Date}; \text{Sample Received Date} + 45 \text{ days})$
		No	$\max(\text{actual Investigation Due Date}; \text{Investigation Start Date} + 45 \text{ days})$
	Yes	Yes	<u>Sample Received Date</u> + 45 days
		No	<u>Investigation Start Date</u> + 45 days

**Investigation Details** is a text area allowing for entry of up to 8000 characters and that can also be populated by Quick Text – a configurable Custom List of values. **Name:** SOL200\_Investigation\_Details\_QuickText\_List

The set of **Product Group** fields is displayed again at Step 3. The following 9 fields are pre-populated with the information entered at Step 1 but can be edited. See Page 10 for a description of these fields.

- **Product Name**                      • **Lot Number**                                      • **Additional Product Information**
- **Strength**                              • **Serial Number**                                      • **Expiration Date**
- **Product Description**              • **Manufacturer-Vendor**                              • **Complaint Category**

\* Preexisting Related Complaints?:

-----

Yes  
No

▼

\* Complaint History:

The **Preexisting Related Complaints?** field, which was part of the **Product Group** in Steps 1 and 2 but was grayed out, is now a mandatory single-item selection field with options of **Yes** or **No** selection that is not customizable.

When Yes is selected, a mandatory text area for Complaint History is displayed, allowing for entry of up to 8000 characters.

\* Identify Probable Root Cause(s):

**Identify Probable Root Cause(s)** is a mandatory text area allowing for entry of up to 8000 characters.

\* Root Cause Categories:

- Man
- Material
- Method
- Machine
- Environment

**Root Cause Categories** is a multiple-item Selection field with set choices of **Man, Material, Method, Machine** or **Environment**. For each category selected, another single-item Selection field will be displayed for a more detailed Root Cause. The values for those fields are configurable from shared Custom Lists maintained by the System Administrator.

\* Man Category:

-----
▼

**Name:** SOL095\_Man\_Category\_List

\* Material Category:

-----
▼

**Name:** SOL099\_Material\_Category\_List

\* Method Category:

-----
▼

**Name:** SOL102\_Method\_Category\_List

\* Machine Category:

-----
▼

**Name:** SOL094\_Machine\_Category\_List

\* Environment Category:

-----
▼

**Name:** SOL066\_Environment\_Category\_List

**Secondary Tasks** initiated at Step 3 will default to a Task Type of **Investigation**. If one or more Secondary Tasks of Task Type = Investigation are not at a status of *Completed* or *Cancelled*, the **Investigation completed** option will be grayed out in the **Investigation and Root Cause Analysis Decision** section.

The **Investigation and Root Cause Analysis Decision** section includes 6 choices and an 8000 character text area for **Comments**. Confirmation of any choices will release all Secondary Tasks except Task Type = POST to the assignees.

- For decisions of **Release tasks** or **Investigation completed**, the **Comments** field is not mandatory.
  - The **Release tasks** decision will keep the PPC process at **Step 3, Investigation and Root Cause Analysis** upon confirmation.
  - The **Investigation completed** decision will move the PPC process to **Step 7A, Investigation Review and Approval (QO)** upon confirmation.
- For a decision of **Investigation extension request** a mandatory **Proposed Extension Date** field is displayed. Confirmation of this decision will move the PPC process to **Step 4, Investigation Extension Request Approval** upon confirmation.

**\* Investigation and Root Cause Analysis Decision:**

Release tasks

Investigation completed

Investigation extension request

Classification change request

Return to complaint assessment with comments

Cancel investigation

Comments:

**\* Proposed Extension Date:**

- For a decision of **Classification change request** two additional fields are displayed – a single-item selection for **Proposed Classification Change** and an uneditable field for Classification Change New Due Date Estimated. The date in that field is calculated based on the rules on Page 20. Confirmation of this decision will move the PPC process to **Step 6, Classification Change Request Approval**.

**\* Proposed Classification Change:**

Minor
▼

**Classification Change New Due Date Estimated:**

2021-05-14

- Confirmation of a decision of **Return to complaint assessment with comments** will move the PPC process back to **Step 2, Complaint Assessment**.
- Confirmation of a decision of **Cancel investigation** will move the PPC process to **Step 5, Cancellation Approval**.

### Submit and Confirm

When all information has been entered into the **Process Task Form**, any **Linked Documents** or **Linked Processes** have been added and any **Secondary Tasks** have been created, click **Submit** and then **Confirm** to progress the PPC process as described above. The Process Flowchart will highlight the next step of the process and the

Process View page will identify the current step and assignees. Assignees will receive an email Notification for their assigned process step. Use the Table of Contents to see information on the various process steps.

## Step 4: Investigation Extension Request Approval

At this step in the PPC Process, users with the process role assignment PR\_PPC\_QO\_Management will receive an email Notification and will see the **Investigation Extension Request Approval** task listed in the Process section of the SOLABS QM10 HOME Page. The number in parenthesis after task name indicates the number of times an Investigation Extension has been requested. In this example, it is the first time.

PROCESSES	
Received this week / last week	
<b>Unique ID:</b> PPC-000008 <b>Date Initiated:</b> 2021-03-24 <b>Status:</b> In Process <b>Current Process Task:</b> Investigation Extension Request Approval (1)	<a href="#">View</a>   <a href="#">Act on</a>

### Viewing the Investigation Extension Request Approval Task

If the assigned user clicks on the **View** option to the right of the Process Task, they will get the following screen.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps.

They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

Process > Pharmaceutical Product Complaint > View **Status:** In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)
<b>Day(s) opened:</b> 7	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b>	<b>Currently with</b>
Investigation Extension Request Approval (1)	gdixson@solabs.com (Gretchen Dixson); mc[...]

**Flowchart:** [Open](#)

---

**Process Values**

Process Tasks	
<b>Name:</b> Complaint Intake	<b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment	<b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis	<b>Last Confirmation Date:</b> 2021-03-31 14:21:17
<b>Name:</b> Investigation Extension Request Approval (1)	

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

---

**Related Items**

Secondary Tasks	
<b>Name:</b> Pull retain samples	<b>Unique ID:</b> PRE-00000001 <b>Due:</b> 2021-03-30 <b>Status:</b> Not Started <span style="float: right;"><a href="#">View</a></span>
<b>Name:</b> Follow-Up for Sample[...]	<b>Unique ID:</b> POST-00000002 <b>Due:</b> 2021-04-09 <b>Status:</b> Pending <span style="float: right;"><a href="#">View</a></span>

## Acting on the Investigation Extension Request Approval Task

When the assignee 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 Extension Request Approval** task.

As described above, the assignee can use the **Expand all** option under the Process Values table to see all information entered in prior steps. The right-hand **Related Items** menu allows the assignee to **Link Documents** or **Link Processes**, if applicable.

Initiation of Secondary Tasks, Related Processes or a Document Control Process are not allowed at Step 4 so those sections are grayed out.

Process > Pharmaceutical Product Complaint > Investigation Extension Request Approval (1) > Act on

**Status:** In Process

### Process Details

**Unique ID:** PPC-000008      **Flowchart:** Open

**Current Process Tasks:** Investigation Extension Request Approval (1)

**Process Actions**

- View
- Modify Values
- Reassign Tasks
- Cancel
- Get Link
- Email Link
- Move Out of Waiting

### Process Values

Process Tasks
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis <b>Last Confirmation Date:</b> 2021-03-31 14:21:17
<b>Name:</b> Investigation Extension Request Approval (1)

Expand all   Print all

### Process Task Form - Investigation Extension Request Approval (1)

\* Investigation Extension Request Approval Decision:

Approve  
 Denied

The Investigation Due Date is to be updated to the following date:

2021-06-30

Comments:

**Act on**

Investigation Extension Requestes[...]

---

**Related Items**

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

---

**Related Information**

- Audit Trail
- Summary Report

The **Investigation Extension Request Approval Decision** defaults to **Approve** and displays the requested date in a noneditable date field. There is also a statement in a yellow box indicating the request for an updated date.

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**.



**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 option click the **Act on** option from the Process section of your HOME Page, or search for the PPC Process and then use the right-hand Act on Menu to open the Process Task Form fields.

If the **Investigation Extension Request Approval Decision** is changed to **Denied**, the 8000-character text area field for **Comments** becomes a mandatory field.

\* Investigation Extension Request Approval Decision:

Approve

Denied

\* Comments:

A decision of **Approve** moves the PPC process back to **Step 3, Investigation and Root Cause Analysis** and the **Investigation Due Date** will have been changed to the new date.

A decision of **Denied** will also move the PPC process back to **Step 3, Investigation and Root Cause Analysis** but the **Investigation Due Date** will not have been changed. The Lead Investigator will have the opportunity to review and respond to the **Comments**.

- At that point the Lead Investigator will again have the option to request a new Due Date. That request will go back to Step 4 with (2) after the task name.

### Submit and Confirm

When all information has been entered into the **Process Task Form** and any **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to move the PPC process back to **Step 3, Investigation and Root Cause Analysis**. Refer back to Page 19.

### Step 5: Cancellation Approval

At this step in the PPC Process, users with the process role assignment PR\_PPC\_QO\_Management will receive an email Notification and will see the **Cancellation Approval** task listed in the Process section of the SOLABS QM10 HOME Page.

PROCESSES	
Received this week / last week	
Unique ID: PPC-000008 Date Initiated: 2021-03-24 Status: In Process Current Process Task: Cancellation Approval	View   Act on

## Viewing the Cancellation Approval Task

If the assigned user clicks on the **View** option to the right of the Process Task, they will get the following screen.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps.

They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixon)
<b>Day(s) opened:</b> 7	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b> Cancellation Approval	<b>Currently with</b> gdixson@solabs.com (Gretchen Dixon); mc[...]
<b>Flowchart:</b> Open	

---

**Process Values**

Process Tasks	
<b>Name:</b> Complaint Intake	<b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment	<b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis	<b>Last Confirmation Date:</b> 2021-03-31 15:26:56
<b>Name:</b> Investigation Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval	

Expand all Print all

---

**Related Items**

Secondary Tasks			
<b>Name:</b> Pull retain samples	<b>Unique ID:</b> PRE-00000001	<b>Due:</b> 2021-03-30	<b>Status:</b> Not Started <span style="float: right;">View</span>
<b>Name:</b> Follow-Up for Sample[...]	<b>Unique ID:</b> POST-00000002	<b>Due:</b> 2021-04-09	<b>Status:</b> Pending <span style="float: right;">View</span>

## Acting on the Cancellation Approval Task

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

As described above, the assignee can use the **Expand all** option under the Process Values table to see all information entered in prior steps. The right-hand **Related Items** menu allows the assignee to **Link Documents** or **Link Processes**, if applicable.

Initiation of Secondary Tasks, Related Processes or a Document Control Process are not allowed at Step 5 so those sections are grayed out.

Process > Pharmaceutical Product Complaint > Cancellation Approval > Act on

**Status:** In Process

### Process Details

Unique ID: PPC-000008 Flowchart: [Open](#)

Current Process Tasks: Cancellation Approval

### Process Values

Process Tasks
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis <b>Last Confirmation Date:</b> 2021-03-31 15:26:56
<b>Name:</b> Investigation Extension Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval

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

#### Process Actions

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

#### Act on

- [Cancellation Approval](#)

#### Related Items

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

#### Related Information

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

### Process Task Form - Cancellation Approval

\* Cancellation Approval:

Approve

Reject

Comments:

The **Cancellation Approval** decision defaults to **Approve** with an 8000-character text area for **Comments** that is not mandatory.

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

If the **Cancellation Approval Decision** is changed to **Reject**, the 8000-character text area field for **Comments** becomes a mandatory field.

\* Cancellation Approval:

Approve

Reject

\* Comments:

A decision of **Approve** moves the PPC process back to **Step 8, Waiting Follow-up POST Tasks**. All Secondary Tasks are released to their assignees upon confirmation of that decision.

A decision of **Reject** will move the PPC process back to **Step 3, Investigation and Root Cause Analysis** and results in the **Comments** field becoming mandatory. The Lead Investigator will have the opportunity to review and respond to the **Comments**.

### Submit and Confirm

When all information has been entered into the **Process Task Form** and any **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to move the PPC as described above. Refer to the Table of Contents for this document for information on the specific steps.

## Step 6: Classification Change Request Approval

At this step in the PPC Process, users with the process role assignment PR\_PPC\_QO\_Management will receive an email Notification and will see the **Classification Change Request Approval** task listed in the Process section of the SOLABS QM10 HOME Page. The number in parenthesis after task name indicates the number of times a Classification Change has been requested. In this example, it is the first time.

PROCESSES	
Received this week / last week	
<b>Unique ID:</b> PPC-000008 <b>Date Initiated:</b> 2021-03-24 <b>Status:</b> In Process <b>Current Process Task:</b> Classification Change Request Approval (1)	<a href="#">View</a>   <a href="#">Act on</a>

## Viewing the Classification Change Request Approval Task

If the assigned user clicks on the **View** option to the right of the Process Task, they will get the following screen.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps.

They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)
<b>Day(s) opened:</b> 7	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b> Classification Change Request Approval (1)	<b>Currently with</b> gdixson@solabs.com (Gretchen Dixson); mc[...]

**Flowchart:** [Open](#)

---

**Process Values**

Process Tasks	
<b>Name:</b> Complaint Intake	<b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment	<b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis	<b>Last Confirmation Date:</b> 2021-03-31 17:01:46
<b>Name:</b> Investigation Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval	<b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1)	

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

---

**Related Items**

Secondary Tasks			
<b>Name:</b> Pull retain samples	<b>Unique ID:</b> PRE-00000001	<b>Due:</b> 2021-03-30	<b>Status:</b> Not Started <span style="float: right;"><a href="#">View</a></span>
<b>Name:</b> Follow-Up for Sample[...]	<b>Unique ID:</b> POST-00000002	<b>Due:</b> 2021-04-09	<b>Status:</b> Pending <span style="float: right;"><a href="#">View</a></span>

## Acting on the Classification Change Request Approval Task

When the assignee clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Classification Change Request Approval** task.

As described above, the assignee can use the **Expand all** option under the Process Values table to see all information entered in prior steps. The right-hand **Related Items** menu allows the assignee to **Link Documents** or **Link Processes**, if applicable.

Initiation of Secondary Tasks, Related Processes or a Document Control Process are not allowed at Step 6 so those sections are grayed out.

Process > Pharmaceutical Product Complaint > Classification Change Request Approval (1) > Act on

**Status:** In Process

**Process Actions**

- View
- Modify Values
- Reassign Tasks
- Cancel
- Get Link
- Email Link
- Move Out of Waiting

---

**Process Details**

Unique ID: PPC-000008 Flowchart: [Open](#)

Current Process Tasks: Classification Change Request Approval (1)

---

**Process Values**

Process Tasks
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis <b>Last Confirmation Date:</b> 2021-03-31 17:01:46
<b>Name:</b> Investigation Extension Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval <b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1)

Expand all Print all

---

**Process Task Form - Classification Change Request Approval (1)**

Classification Change:

The Investigation Due Date is to be updated to the following date, due to the classification change:

\* Classification Change Request Approval Decision:

Approve

Denied

Comments:

**Act on**

[Classification Change Request \[...\]](#)

---

**Related Items**

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

---

**Related Information**

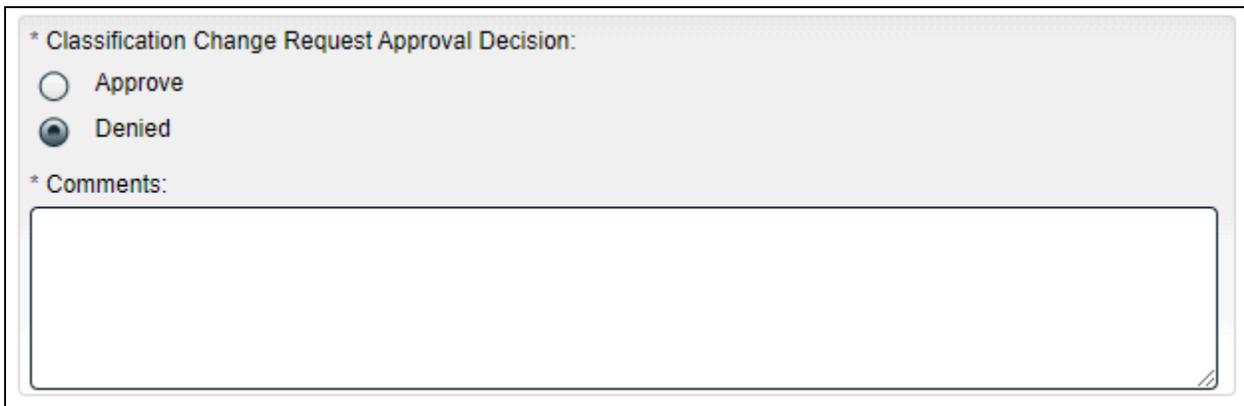
- [Audit Trail](#)
- [Summary Report](#)

The **Classification Change Request Approval Decision** defaults to **Approve** and displays the proposed **Classification Change** and the revised **Investigation Due Date** associated with the requested classification (refer to Table on Page 20), both in noneditable fields. There is also a statement in a yellow box indicating that the **Investigation Due Date** is to be updated due to the classification change. An 8000-character text area is available for **Comments**.

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**.

**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 option click the **Act on** option from the Process section of your HOME Page, or search for the PPC Process and then use the right-hand Act on Menu to open the Process Task Form fields.

If the **Classification Change Request Approval Decision** is changed to **Denied**, the 8000-character text area field for **Comments** becomes a mandatory field.



\* Classification Change Request Approval Decision:

Approve

Denied

\* Comments:

A decision of **Approve** moves the PPC process back to **Step 3, Investigation and Root Cause Analysis** where the **Classification** and the **Investigation Due Date** will have been changed to reflect the new information.

A decision of **Denied** will also move the PPC process back to **Step 3, Investigation and Root Cause Analysis** but the **Classification** and the **Investigation Due Date** will not have been changed. The Lead Investigator will have the opportunity to review and respond to the **Comments**.

- At that point the Lead Investigator will again have the option to request a new Classification. That request will go back to Step 6 with (2) after the task name.

## Submit and Confirm

When all information has been entered into the **Process Task Form** and any **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to move the PPC process back to **Step 3, Investigation and Root Cause Analysis**. Refer back to Page 19.

## Step 7A: Investigation Review and Approval (QO)

Step 7A can be reached only when the **Investigation and Root Cause Analysis Decision** at **Step 3, Investigation and Root Cause Analysis** is **Investigation completed**.

At this step in the PPC Process, users with the process role assignment PR\_PPC\_QO\_Management will receive an email Notification and will see the **Investigation Review and Approval (QO)** task listed in the Process section of the SOLABS QM10 HOME Page.

PROCESSES	
Received this week / last week	
Unique ID: PPC-000008 Date Initiated: 2021-03-24 Status: In Process Current Process Task: Investigation Review and Approval (QO)	<a href="#">View</a>   <a href="#">Act on</a>

## Viewing the Investigation Review and Approval Task

If the assigned user clicks on the **View** option to the right of the Process Task, they will get the following screen.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps.

Depending on how many times the PPC process may have gone to Steps 4, 5 or 6 for Extension Requests, Classification Change Requests or Cancellation Requests, there could be many steps in the Process Values table by this point.

They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixon)
<b>Day(s) opened:</b> 8	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b>	<b>Currently with</b>
Investigation Review and Approval (QO)	gdixson@solabs.com (Gretchen Dixon); mc[...]

**Flowchart:** [Open](#)

---

**Process Values**

Process Tasks	
<b>Name:</b> Complaint Intake	<b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment	<b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis	<b>Last Confirmation Date:</b> 2021-04-01 10:04:04
<b>Name:</b> Investigation Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval	<b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 17:17:54
<b>Name:</b> Investigation Review and Approval (QO)	

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

---

**Related Items**

Secondary Tasks			
<b>Name:</b> Pull retain samples	<b>Unique ID:</b> PRE-00000001	<b>Due:</b> 2021-03-30	<b>Status:</b> Not Started <a href="#">View</a>
<b>Name:</b> Follow-Up for Sample[...]	<b>Unique ID:</b> POST-00000002	<b>Due:</b> 2021-04-09	<b>Status:</b> Pending <a href="#">View</a>

## Acting on the Investigation Review and Approval (QO) Task

When the assignee 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 Review and Approval (QO)** task. As described above, the assignee can use the **Expand all** option under the Process Values table to see all information entered in prior steps. The right-hand **Related Items** menu allows the assignee to **Link Documents** or **Link Processes**, if applicable.

Initiation of Secondary Tasks, Related Processes or a Document Control Process are not allowed at Step 7A so those sections are grayed out.

Process > Pharmaceutical Product Complaint > Investigation Review and Approval (QO) > Act on

**Status:** In Process

**Process Actions**

View

Modify Values

Reassign Tasks

Cancel

Get Link

Email Link

Move Out of Waiting

---

**Process Details**

Unique ID: PPC-000008 Flowchart: [Open](#)

Current Process Tasks: Investigation Review and Approval (QO)

---

**Process Values**

Process Tasks
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis <b>Last Confirmation Date:</b> 2021-04-01 10:04:04
<b>Name:</b> Investigation Extension Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval <b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 17:17:54
<b>Name:</b> Investigation Review and Approval (QO)

Expand all Print all

**Act on**

Investigation Review and Appro[...]

**Related Items**

Link Documents

Link Processes

Modify Description

Remove Links

---

**Process Task Form - Investigation Review and Approval (QO)**

\* QO Decision:

Approve

Return to investigator

Comments:

**Related Information**

Audit Trail

Summary Report

The **QO Decision** section includes two options. It defaults to **Approve**, with an 8000-character text area for **Comments**, that is not mandatory.

- An **Approve** decision for complaint **Classification = Critical** will move the PPC process to **Step 7B, Investigation Review and Approval (HQO)** upon confirmation.
- An **Approve** decision for complaint **Classification ≠ Critical** will move the PPC process to **Step 8, Waiting Follow-up POST Tasks** upon confirmation. All Secondary Tasks will be released to the assignees and each Secondary Task with **Task Type = POST** will have its **Due Date** set to 10 days after confirmation of Step 7A.
- A **Return to investigator** decision will require mandatory **Comments** and move the PPC process back to **Step 3, Investigation and Root Cause Analysis** upon confirmation.

\* QO Decision:

Approve

Return to investigator

\* Comments:

## Submit and Confirm

When all information has been entered into the **Process Task Form** and any **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to move the PPC process as described above. Refer to Page 19 for information on Step 3 and see below for information on Steps 7B and 8.

## Step 7B: Investigation Review and Approval (HQO)

Step 7B is applicable only when a complaint of **Classification = Critical** is approved at Step 7A.

At this step in the PPC Process, users with the process role assignment PR\_PPC\_HQO\_Management will receive an email Notification and will see the **Investigation Review and Approval (HQO)** task listed in the Process section of the SOLABS QM10 HOME Page.

PROCESSES	
Received this week / last week	
<b>Unique ID:</b> PPC-000008 <b>Date Initiated:</b> 2021-03-24 <b>Status:</b> In Process <b>Current Process Task:</b> Investigation Review and Approval (HQO)	<a href="#">View</a>   <a href="#">Act on</a>
Expand all <b>1</b>	

## Viewing the Investigation Review and Approval (HQO) Task

If the assigned user clicks on the **View** option to the right of the Process Task, they will get the following screen.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps.

They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details, Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

Process > Pharmaceutical Product Complaint > View		Status: In Process
<b>Process Details</b>		
<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54	
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixon)	
<b>Day(s) opened:</b> 8	<b>Date Closed :</b> <empty>	
<b>Secondary Tasks Completion (%):</b> 50 (1/2)	<b>Dependent Processes Completion (%) :</b> 0 (0/0)	
<b>Current Process Tasks</b> Investigation Review and Approval (HQO)	<b>Currently with</b> gdixson@solabs.com (Gretchen Dixon); mc[...]	
<b>Flowchart:</b> Open		
<b>Process Values</b>		
<b>Process Tasks</b>		
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24		
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06		
<b>Name:</b> Investigation and Root Cause Analysis <b>Last Confirmation Date:</b> 2021-04-01 12:02:34		
<b>Name:</b> Investigation Extension Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 15:20:08		
<b>Name:</b> Cancellation Approval <b>Last Confirmation Date:</b> 2021-03-31 16:57:37		
<b>Name:</b> Classification Change Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 17:17:54		
<b>Name:</b> Investigation Review and Approval (QO) <b>Last Confirmation Date:</b> 2021-04-01 12:05:27		
<b>Name:</b> Classification Change Request Approval (2) <b>Last Confirmation Date:</b> 2021-04-01 12:01:48		
<b>Name:</b> Investigation Review and Approval (HQO)		
Expand all Print all		
<b>Related Items</b>		
<b>Secondary Tasks</b>		
<b>Name:</b> Pull retain samples <b>Unique ID:</b> PRE-00000001 <b>Due:</b> 2021-03-30 <b>Status:</b> Completed <a href="#">View</a>		
<b>Name:</b> Follow-Up for Sample[...] <b>Unique ID:</b> POST-00000002 <b>Due:</b> 2021-04-09 <b>Status:</b> Pending <a href="#">View</a>		
Expand all		

## Acting on the Investigation Review and Approval (HQO) Task

When the assignee 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 Review and Approval (HQO)** task. As described above, the assignee can use the **Expand all** option under the Process Values table to see all information entered in prior steps. The right-hand **Related Items** menu allows the assignee to **Link Documents** or **Link Processes**, if applicable.

Initiation of Secondary Tasks, Related Processes or a Document Control Process are not allowed at Step 7B so those sections are grayed out.

Process > Pharmaceutical Product Complaint > Investigation Review and Approval (HQO) > Act on

**Status:** In Process

### Process Details

Unique ID: PPC-000008 Flowchart: [Open](#)

**Current Process Tasks:** Investigation Review and Approval (HQO)

#### Process Actions

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

### Process Values

Process Tasks
<b>Name:</b> Complaint Intake <b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment <b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis <b>Last Confirmation Date:</b> 2021-04-01 12:02:34
<b>Name:</b> Investigation Extension Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval <b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1) <b>Last Confirmation Date:</b> 2021-03-31 17:17:54
<b>Name:</b> Investigation Review and Approval (QO) <b>Last Confirmation Date:</b> 2021-04-01 12:05:27
<b>Name:</b> Classification Change Request Approval (2) <b>Last Confirmation Date:</b> 2021-04-01 12:01:48
<b>Name:</b> Investigation Review and Approval (HQO)

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

### Act on

- [Investigation Review and Appro\[...\]](#)

### Related Items

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

### Related Information

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

### Process Task Form - Investigation Review and Approval (HQO)

\* HQO Decision:

Approve

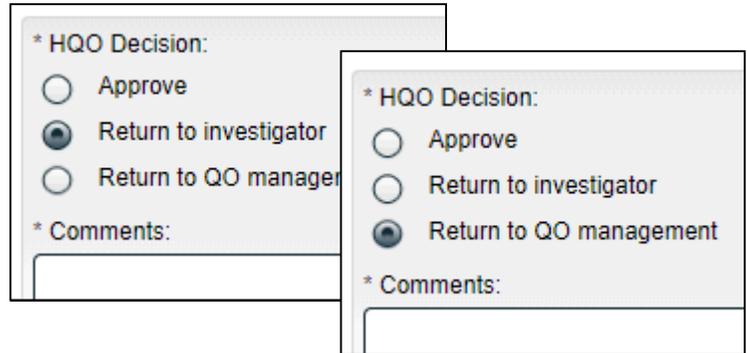
Return to investigator

Return to QO management

Comments:

The **HQO Decision** section includes three options. It defaults to **Approve**, with an 8000-character text area for **Comments**, that is not mandatory.

- An **Approve** decision will move the PPC process to **Step 8, Waiting Follow-up POST Tasks** upon confirmation. All Secondary Tasks will be released to the assignees and each Secondary Task with **Task Type = POST** will have its **Due Date** set to 3 days after confirmation of Step 7B.
- A **Return to investigator** decision will require mandatory **Comments** and move the PPC process back to **Step 3, Investigation and Root Cause Analysis** upon confirmation.
- A **Return to QO management** decision will require mandatory **Comments** and move the PPC process back to **Step 7A, Investigation Review and Approval (QO)**.



### Submit and Confirm

When all information has been entered into the **Process Task Form** and any **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to move the PPC process as described above.

### Step 8: Waiting Follow-up POST Tasks

Step 8 is a Waiting Phase for any Secondary Tasks that have not been completed or cancelled. As mentioned in Steps 7A and 7B, due dates for POST Task Types will have been set at either 10 days after confirmation of Step 7A or 3 days after confirmation of Step 7B.

**NOTE:** If there are no POST Tasks the PPC Process will have skipped Step 8 and will have progressed to **Step 9, Complaint Review and Closure**.

Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

Name: Pharmaceutical Product Complaint	Date Initiated: 2021-03-24 14:42:54
Unique ID: PPC-000008	Initiated by: gdixson@solabs.com (Gretchen Dixson)
Day(s) opened: 8	Date Closed : <empty>
Secondary Tasks Completion (%): 50 (1/2)	Dependent Processes Completion (%) : 0 (0/0)
Current Process Tasks Waiting Follow-Up POST Tasks	Currently with N/A

If all POST Tasks are at a status of either Completed or Cancelled the PPC Process will move to **Step 9, Complaint Review and Closure**.

Under certain other situations, the PPC process will also move from Step 8 to **Step 9, Complaint Review and Closure**:

- The PPC Process at this point is not back at Step 8 from Step 9 and the complaint Classification ≠ Critical and the current date is now 9 days past the date Step 8 was initiated
- The PPC Process at this point is not back at Step 8 from Step 9 and the complaint Classification = Critical and the current date is now 2 days past the date Step 8 was initiated

All Secondary Tasks are listed in the **Related Items** section where their status is visible when viewing the PPC Process View screen. Clicking on the listing for Secondary Tasks not at a status of Completed, will provide detail on who it is assigned to, in order to allow follow-up with the assignee as necessary.

**Related Items**

---

**Secondary Tasks**

Name: Pull retain samples Unique ID: PRE-00000001 Due: 2021-03-30 Status: Completed View

Name: Follow-Up for Sample[...] Unique ID: POST-00000002 Due: 2021-04-04 Status: Not Started View

**Secondary Tasks**

Name: Pull retain samples Unique ID: PRE-00000001 Due: 2021-03-30 Status: Completed View

Name: Follow-Up for Sample[...] Unique ID: POST-00000002 Due: 2021-04-04 Status: Not Started View

**Main Related Process:** PPC-000008 [Preview](#) [View](#)

**Name:** Follow-Up for Sample Arrival

**Description:** Send sample to lab when received.

**Originator:** gdixson@solabs.com (Gretchen Dixson)

**Assignee (Role):** any

**Assignee (User):** solabs\_test\_user\_1 (Solabs User1)

**Comments:**

**Start Date:** N/A

**End Date:** N/A

**Completed by:** N/A

**External Document(s):** <empty>

## Step 9: Complaint Review and Closure

When this step in the PPC Process is reached, the user selected at Step 2 for **Complaint Review Assignment** will receive an email Notification and will see the **Complaint Review and Closure** task listed in the Process section of the SOLABS QM10 HOME Page.

**PROCESSES**

---

Received this week / last week

Unique ID: PPC-000008 Date Initiated: 2021-03-24 Status: In Process View | Act on

Current Process Task: Complaint Review and Closure

## Viewing the Complaint Review and Closure Task

If the assigned user clicks on the **View** option to the right of the Process Task, they will get the following screen.

From there, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to see more detail on the information entered at prior steps.

They can also click on the **View** option to the right of any individual **Related Items** to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

Creation of additional Secondary Tasks is allowed at Step 9.

Initiation of Related Processes or a Document Control Process is not allowed at Step 9 so those sections are grayed out.

Process > Pharmaceutical Product Complaint > View Status: In Process

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)
<b>Day(s) opened:</b> 8	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 100 (2/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b> Complaint Review and Closure	<b>Currently with</b> solabs_test_user_9 (Solabs User9)

**Flowchart:** Open

---

**Process Values**

Process Tasks	
<b>Name:</b> Complaint Intake	<b>Last Confirmation Date:</b> 2021-03-26 12:35:24
<b>Name:</b> Complaint Assessment	<b>Last Confirmation Date:</b> 2021-03-30 14:33:06
<b>Name:</b> Investigation and Root Cause Analysis	<b>Last Confirmation Date:</b> 2021-04-01 12:02:34
<b>Name:</b> Investigation Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval	<b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 17:17:54
<b>Name:</b> Investigation Review and Approval (QO)	<b>Last Confirmation Date:</b> 2021-04-01 12:05:27
<b>Name:</b> Classification Change Request Approval (2)	<b>Last Confirmation Date:</b> 2021-04-01 12:01:48
<b>Name:</b> Investigation Review and Approval (HQO)	<b>Last Confirmation Date:</b> 2021-04-01 12:23:19
<b>Name:</b> Complaint Review and Closure	

Expand all Print all

---

**Related Items**

Secondary Tasks	
<b>Name:</b> Pull retain samples	<b>Unique ID:</b> PRE-00000001 <b>Due:</b> 2021-03-30 <b>Status:</b> Completed <span style="float: right; color: red;">View</span>
<b>Name:</b> Follow-Up for Sample[...]	<b>Unique ID:</b> POST-00000002 <b>Due:</b> 2021-04-04 <b>Status:</b> Completed <span style="float: right; color: red;">View</span>

Expand all

## Acting on the Complaint Review and Closure Task

When the assignee clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Complaint Review and Closure** task. As described above, the assignee can use the **Expand all** option under the Process Values table to see all information entered in prior steps. The right-hand **Related Items** menu options are available to allow the assignee to **Link Documents** or **Link Processes**, if applicable.

**Process Task Form - Complaint Review and Closure**

Follow-Up Date:

Clear

\* Sample Received?:

\* Complaint Review Decision:

- Approve
- Return to initiator for modification with comments
- Return to complaint assessment with comments
- Return to investigator with comments
- Follow-up needed

Comments:

**Secondary Tasks**

- Pull retain samples  
Due Date: 2021-03-30 Type: Pre Task  
Originator: gdixson@solabs.com (Gretchen Dixon)

Modify Remove

- Follow-Up for Sample Arrival  
Due Date: 2021-04-04 Type: Post Task  
Originator: gdixson@solabs.com (Gretchen Dixon)

Modify Remove

**+ADD**

The fields displayed on this page, and the options enabled in the **Complaint Review Decision** section will vary based on selections made at this step and at some previous steps.

The **Follow-Up Date** field is mandatory only if the **Complaint Review Decision** is chosen as **Follow-up needed**. It will not allow entry of dates in the past.

The 8000-character text area for **Comments** is mandatory for all **Complaint Review Decision** selections except for **Approve**.

The mandatory **Sample Received?** field is displayed only if at **Step 2 Sample Available? = Yes** and **Sample Arrived? = No**. It is a single-item selection field with values of **Yes** or **No**. If **Yes** is selected, the **Complaint Review Decision** will default to **Return to complaint assessment with comments**. Other decisions are still available.

If the entry at **Step 2** for **Investigation Required? = No**, the **Complaint Review Decision** of **Return to investigator with comments** is disabled and grayed out.

If there are any Secondary Tasks of Task Type = POST that are not at a status of either Completed or Cancelled, the following warning message is displayed in orange: “Secondary Tasks of type POST are not completed.”

If there are any Secondary Tasks of Task Type = POST that are not at a status of either Completed or Cancelled, the **Complaint Review Decision** of **Approve** will be disabled and grayed out.

If there are any Secondary Tasks of Task Type = POST that are not at a status of either Completed or Cancelled and **Sample Received? ≠ Yes**, the **Complaint Review Decision** will default to **Follow-up needed**.

The confirmed selection for **Complaint Review Decision** will move the PPC Process as follows:

- **Approve** moves the PPC process to **Step 10, Complaint Closure Approval**
- **Return to initiator for modification with comments** moves the PPC process to **Step 1, Complaint Intake**
- **Return to complaint assessment with comments** moves the PPC process to **Step 2, Complaint Assessment**
- **Return to investigator with comments** moves the PPC process to **Step 3, Investigation and Root Cause Analysis**
- **Follow-up needed** moves the PPC process to **Step 8, Waiting Follow-Up POST Tasks**

## Submit and Confirm

When all information has been entered into the **Process Task Form** and any **Linked Documents** or **Linked Processes** have been added, click **Submit** and then **Confirm** to move the PPC process as described above.

## Step 10: Complaint Closure Approval

When this step in the PPC Process is reached, all users with the process role **PR\_PPC\_Closure** will receive an email Notification and will see the **Complaint Review and Closure** task listed in the Process section of the SOLABS QM10 HOME Page.

PROCESSES	
Received this week / last week	
Unique ID: PPC-000008 Date Initiated: 2021-03-24 Status: In Process Current Process Task: Complaint Closure Approval	<a href="#">View</a>   <a href="#">Act on</a>

## Viewing the Complaint Closure Approval Task

This is the last step in the Pharmaceutical Product Complaint (PPC) Process. If the assigned user clicks on the **View** option to the right of the Process Task, they will get the same right-hand menu options as described in other steps. Secondary Tasks, Related Processes and a Document Control Process cannot be initiated at this step so those sections are grayed out.

## Acting on the Complaint Closure Approval Task

**Process Task Form - Complaint Closure Approval**

---

\* Complaint Closure Approval Decision:

Approve

Return to complaint review and closure

Comments:

The **Complaint Closure Approval Decision** section includes two options. It defaults to **Approve**, with an 8000-character text area for **Comments**, that is not mandatory.

A decision of **Approve** will close the PPC process upon confirmation, putting the status to **Completed**.

If at least one Secondary Task is not at a status of Completed or Cancelled, the **Approve** option is disabled and the following message is displayed in red below the Decision field: “**Process cannot be closed. Some Secondary Tasks are pending.**”

A decision of **Return to complaint review and closure** will result in the **Comments** field becoming mandatory, and will move the PPC process back to **Step 9, Complaint Review and Closure** upon confirmation.

Process > Pharmaceutical Product Complaint > View

**Status:** Completed

---

**Process Details**

<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)
<b>Day(s) opened:</b> 8	<b>Date Closed :</b> 2021-04-01 15:39:17
<b>Secondary Tasks Completion (%):</b> 100 (2/2)	<b>Dependent Processes Completion (%):</b> 0 (0/0)
<b>Current Process Tasks</b> N/A	<b>Currently with</b> N/A

## Viewing Details for a Completed Pharmaceutical Product Complaint (PPC) Process

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

Process Details		Status: Completed
<b>Name:</b> Pharmaceutical Product Complaint	<b>Date Initiated:</b> 2021-03-24 14:42:54	
<b>Unique ID:</b> PPC-000008	<b>Initiated by:</b> gdixson@solabs.com (Gretchen Dixson)	
<b>Day(s) opened:</b> 8	<b>Date Closed :</b> 2021-04-01 15:39:17	
<b>Secondary Tasks Completion (%)</b> : 100 (2/2)	<b>Dependent Processes Completion (%)</b> : 0 (0/0)	
<b>Current Process Tasks</b> N/A	<b>Currently with</b> N/A	
<b>Flowchart:</b> Open		

<b>Name:</b> Classification Change Request Approval (2)	<b>Last Confirmation Date:</b> 2021-04-01 12:01:48
<b>Classification:</b> Critical	
<b>Classification Change New Due Date Estimated:</b> 2021-05-14	
<b>Classification Change Request Approval Decision:</b> Approve	
<b>Comments:</b> N/A	
<b>Sign-off by:</b> gdixson@solabs.com (Gretchen Dixson)	

<b>Name:</b> Investigation Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 15:20:08
<b>Name:</b> Cancellation Approval	<b>Last Confirmation Date:</b> 2021-03-31 16:57:37
<b>Name:</b> Classification Change Request Approval (1)	<b>Last Confirmation Date:</b> 2021-03-31 17:17:54
<b>Name:</b> Investigation Review and Approval (QO)	<b>Last Confirmation Date:</b> 2021-04-01 12:05:27
<b>Name:</b> Classification Change Request Approval (2)	<b>Last Confirmation Date:</b> 2021-04-01 12:01:48
<b>Name:</b> Investigation Review and Approval (HQO)	<b>Last Confirmation Date:</b> 2021-04-01 12:23:19
<b>Name:</b> Complaint Review and Closure	<b>Last Confirmation Date:</b> 2021-04-01 15:21:52
<b>Name:</b> Complaint Closure Approval	<b>Last Confirmation Date:</b> 2021-04-01 15:39:17

Expand all Print all

## Using the Related Items Table

Information on any **Secondary Tasks** 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: Pull retain samples	Unique ID: PRE-00000001 Due: 2021-03-30 Status: Completed <span style="float: right; border: 1px solid orange; border-radius: 50%; padding: 2px;">View</span>
Name: Follow up	Completed <span style="float: right; border: 1px solid orange; border-radius: 50%; padding: 2px;">View</span>
<a href="#">Expand all</a>	

**Task Details**

Name: Pull retain samples  
 Type: Pre Task Unique ID: PRE-00000001  
 Description: Pull retain samples for ProductName1 Lot 007.  
 Reference Date: 2021-03-26 UTC-04:00  
 Location: RootPPC-000008 Process Task Group\Complaint Intake Task Group  
 Estimated Start Day Offset: 0 Estimated End Day Offset: 3  
 Estimated Start Date: 2021-03-26 UTC-04:00 Estimated End Date: 2021-03-30 UTC-04:00  
 Start Date: 2021-04-01 UTC-04:00 End Date: 2021-04-01 UTC-04:00  
 Status: Completed  
 Comments:

**Task Ownership**

Originator: gdixson@solabs.com (Gretchen Dixson)  
 Assignee (Role): any  
 Assignee (User): solabs\_test\_user\_1 (Solabs User1)

**Related Items**

Main Related Process
Unique ID: PPC-000008 Date Initiated: 2021-03-24 Status: Completed
Current Process Task: N/A <span style="float: right; border: 1px solid orange; border-radius: 50%; padding: 2px;">View</span>

## Creating a Summary Report

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

**Related Information**

Audit Trail

Summary Report

**Process Details**

Name: Pharmaceutical Product Complaint Date Initiated: 2021-03-24 14:42:54  
 Unique ID: PPC-000008 Initiated by: gdixson@solabs.com  
 Day(s) opened: 0 Date Closed: 2021-04-01 15:39:17  
 Secondary Tasks Completion (%): 100 (2/2) Dependent Processes Completed: 0  
 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)

Generate Report
Cancel

Status: Completed

SOLABS  
777, rue de la Commune Ouest  
Suite 330  
Montreal, Quebec  
H3C 1Y1, Canada  
514.287.1368 ext. 219  
www.solabs.com

**PPC-000008**

Name: Pharmaceutical Product Complaint Date Initiated: 2021-03-24 14:42:54  
 Unique ID: PPC-000008 Initiated by: gdixson@solabs.com (Gretchen Dixson)  
 Days opened: 8 Date Closed: 2021-04-01 15:39:17  
 Secondary Tasks Completion (%): 100 (2/2) Dependent Processes Completion (%): 0 (0/0)  
 Current Process Tasks: N/A Currently with: N/A

**Process Values**

Name: Complaint Intake Last Confirmation Date: 2021-03-26 12:35:24

Contact Type: ContactType1  
 Date of Complaint: 2021-03-26  
 Complaint Reporter: Patient  
 Title: Ms.  
 Occupation: Occupation1  
 First Name: Mary  
 Last Name: Clark  
 Suffix: I  
 Business Name: ABCD  
 Address #1: 12 ABCD Street  
 Address #2: N/A  
 City: Anytown  
 State: AR  
 Postal Code: XXXXX  
 Country: USA  
 Phone Number: xxx-xxx-xxxx  
 Email Address: mc123@aol.com  
 Pharmacy Information Required?: No  
 Complaint Description: Complaint Description 1  
 Reported Adverse Event for Pharmacovigilance: No  
 External Case ID: N/A  
 Product Type: Clinical  
 Study Number: 1234  
 Site Number: 1234  
 Subject Number: 1234  
 Device Caused/Contributed to AE: No  
 Product Name: ProductName1  
 Strength: P1\_Strength1  
 Product Description: P1\_Description1

Printed by: Gretchen Dixson on: 2021-04-01 15:56:19 / © SOLABS 2019+ Page 1 of 5

March 2023



## 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.

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

**Related Information**

- Audit Trail
- Summary Report

Process > PPC-000008 > Audit Trail

Process Name: PPC-000008	
<b>Action Details: Process Completed</b> Process Task Name: N/A Date: 2021-04-01 15:39:17 Role: FCT_P0056 Admin Username (Full Name): Automatic by System Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Complaint Closure Approval Date: 2021-04-01 15:39:17 Role: FCT_P0056 Admin Username (Full Name): solabs_test_user_9 (Solabs User9) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Complaint Review and Closure Date: 2021-04-01 15:21:52 Role: FCT_P0056 Admin Username (Full Name): solabs_test_user_9 (Solabs User9) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Investigation Review and Approval (HQO) Date: 2021-04-01 12:23:19 Role: FCT_P0056 Admin Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Investigation Review and Approval (QO) Date: 2021-04-01 12:05:27 Role: FCT_P0056 Admin Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Investigation and Root Cause Analysis Date: 2021-04-01 12:02:34 Role: FCT_P0056 Admin Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Classification Change Request Approval (2) Date: 2021-04-01 12:01:48 Role: FCT_P0056 Admin Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Complaint Assessment Date: 2021-03-30 14:33:06 Role: FCT_P0056 Admin Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Complaint Intake Date: 2021-03-26 12:35:24 Role: FCT_P0056 Admin Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Process Started</b> Process Task Name: N/A Date: 2021-03-24 14:42:54 Role: N/A Username (Full Name): gdixson@solabs.com (Gretchen Dixson) Reason for Change: N/A	<a href="#">Print</a>

Expand all Print all View 1

## Pharmaceutical Product Complaint (PPC) Process Notifications

As mentioned throughout this document, Users will see process tasks listed on their SOLABS QM10 HOME Page and can View or Act on them from there. They will also receive Email Notifications, that include a link to SOLABS QM10.

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**.

Some additional Custom Notifications are available with Pharmaceutical Product Complaint (PPC) Process P0056.

### Custom Notifications

<p>When Step 2 is confirmed with <b>Classification</b> = <i>Critical</i>, the following notification is sent:</p> <p><b>Subject:</b> For Your Information: The following Pharmaceutical Product Complaint <i>[PPC-XXXXXX]</i> has been evaluated as a Critical Complaint.</p> <p><b>To:</b> All users in role <i>PR_PPC_QO_Management</i> and <i>PR_PPC_HQO_Management</i>.</p> <p><b>Body:</b> Please note that a Critical Complaint has been created as <i>[PPC-XXXXXX]</i>.</p> <p><i>[PPC-XXXXXX]</i><sup>1</sup>  <b>Description:</b> <i>[Complaint Description]</i></p> <hr/> <p><b>Where</b>  <i>[PPC-XXXXXX]</i> = Step 1 field <b>Complaint Reference Number</b>  <sup>1</sup>: Is an hyperlink  <i>[Complaint Description]</i> = Step 1 <b>Complaint Description</b></p>
--

<p>When today = Investigation Due Date – 3days, and Step 3 is not completed (submitted with <b>Investigation and Root Cause Analysis Decision</b> = <i>Investigation Completed</i>) the notification is sent:</p> <p><b>Subject:</b> For Your Information: Investigation and Root Cause Analysis related to <i>[PPC-XXXXXX]</i> is due in 3 days.</p> <p><b>To:</b> User assigned specifically assigned to step 3 and their manager.</p> <p><b>Body:</b> Please note that the Investigation and Root Cause Analysis related to <i>[PPC-XXXXXX]</i> is due in 3 days.  <i>[PPC-XXXXXX]</i><sup>1</sup>  <b>Description:</b> <i>[Complaint Description]</i>  <b>Investigation Due Date:</b> <i>[Investigation Due Date]</i></p> <hr/> <p><b>Where</b>  <i>[PPC-XXXXXX]</i> = Step 1 field <b>Complaint Reference Number</b>  <sup>1</sup>: Is an hyperlink  <i>[Complaint Description]</i> = Step 1 <b>Complaint Description</b>  <i>[Investigation Due Date]</i> = step 3 field <b>Investigation Due Date</b></p>
--

When today = Investigation Due Date – 1days, and Step 3 is not completed (submitted with **Investigation and Root Cause Analysis Decision = Investigation Completed**) the notification is sent:

**Subject:** For Your Information: Investigation and Root Cause Analysis related to [PPC-XXXXXX] is due in 1 days.

**To:** User assigned specifically assigned to step 3 and their manager.

**Body:** Please note that the Investigation and Root Cause Analysis related to [PPC-XXXXXX] is due in 1 days.  
[PPC-XXXXXX]<sup>1</sup>

**Description:** [Complaint Description]

**Investigation Due Date:** [Investigation Due Date]

**Where**

[PPC-XXXXXX] = Step 1 field **Complaint Reference Number**

<sup>1</sup>: Is an hyperlink

[Complaint Description] = Step 1 **Complaint Description**

[Investigation Due Date] = step 3 field **Investigation Due Date**

When today = Investigation Due Date + 1days, and Step 3 is not completed (submitted with **Investigation and Root Cause Analysis Decision = Investigation Completed**) the notification is sent:

**Subject:** For Your Information: Investigation and Root Cause Analysis related to [PPC-XXXXXX] is 1 day overdue.

**To:** User assigned specifically assigned to step 3 and their manager.

**Body:** Please note that the Investigation and Root Cause Analysis related to [PPC-XXXXXX] is 1 day overdue.  
[PPC-XXXXXX]<sup>1</sup>

**Description:** [Complaint Description]

**Investigation Due Date:** [Investigation Due Date]

**Where**

[PPC-XXXXXX] = Step 1 field **Complaint Reference Number**

<sup>1</sup>: Is an hyperlink

[Complaint Description] = Step 1 **Complaint Description**

[Investigation Due Date] = step 3 field **Investigation Due Date**

When today = Investigation Due Date + 7days, and Step 3 is not completed (submitted with **Investigation and Root Cause Analysis Decision = Investigation Completed**) the notification is sent:

**Subject:** For Your Information: Investigation and Root Cause Analysis related to [PPC-XXXXXX] is 7 day overdue.

**To:** User assigned specifically assigned to step 3 and their manager.

**Body:** Please note that the Investigation and Root Cause Analysis related to [PPC-XXXXXX] is 7 day overdue.  
[PPC-XXXXXX]<sup>1</sup>

**Description:** [Complaint Description]

**Investigation Due Date:** [Investigation Due Date]

**Where**

[PPC-XXXXXX] = Step 1 field **Complaint Reference Number**

<sup>1</sup>: Is an hyperlink

[Complaint Description] = Step 1 **Complaint Description**

[Investigation Due Date] = step 3 field **Investigation Due Date**

When subsequent Investigation Extension are requested after the second one (i.e. Investigation Extension Request Approval\_QO (X), where X>2), the following notification is sent:

**Subject:** For Your Information: Recurrent Investigation Extension Requests for Process [PPC-XXXXXX].

**To:** All users in role PR\_PC\_HQO\_Management.

**Body:** Please note that the Investigation Due Date of [PPC-XXXXXX] has been requested to be change more than [X] times.

[PPC-XXXXXX]<sup>1</sup>

**Description:** [Complaint Description]

**Investigation Due Date:** [Investigation Due Date]

**Investigation Due Date Extension Requested:** [Proposed Investigation Due Date]

**Where**

[PPC-XXXXXX] = Step 1 Complaint Reference Number

<sup>1</sup>: Is an hyperlink

[X] = number of times a new instance of step 4 have been initiated.

[Complaint Description] = Step 1 field Complaint Description

[Investigation Due Date] = step 3 field Investigation Due Date

[Proposed Investigation Due Date] = step 3 field Proposed Extension Date

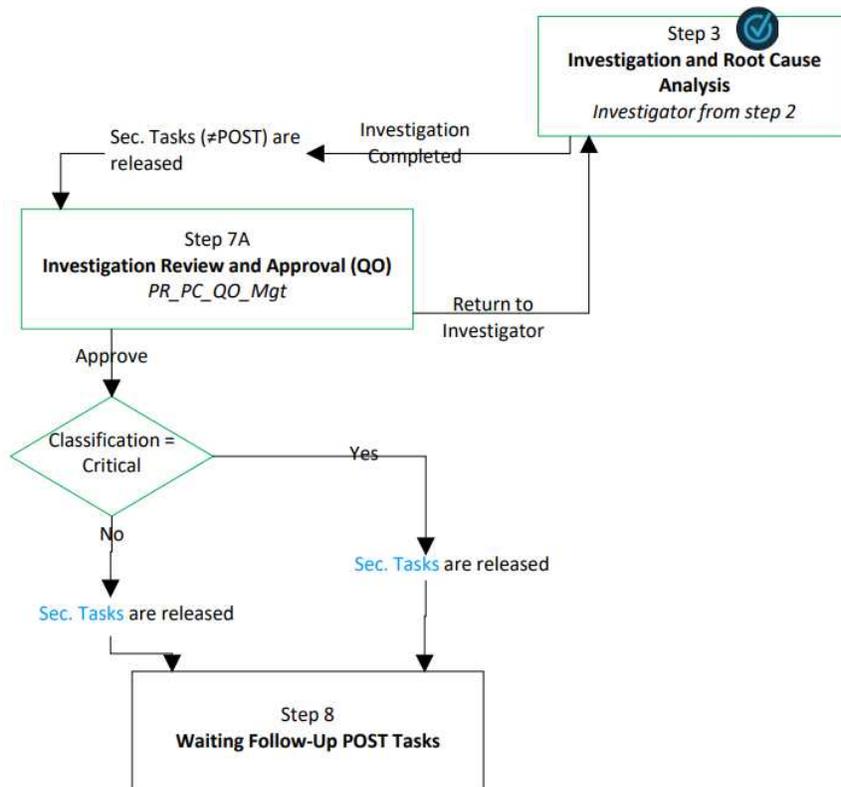
## Available Options for Pharmaceutical Product Complaint (PPC) Process

**NOTE:** The options described in this section are planned for a future release of this Process APP.

**Option 1A:** Option to change some of the field labels on the Process Task Forms

**Option 2:** This option modifies the flow of the process to by-pass the second investigation approval (Step 7B). If the **QO Decision** = *Approve* and the Step 2 field **Classification** = *Critical*, all Secondary Tasks are made available to their assignees on confirmation. Each Secondary Task with a Task Type of POST will have the Due Date set to {Date of Step 7B confirmation} + 3 days.

### Representation of Option 2



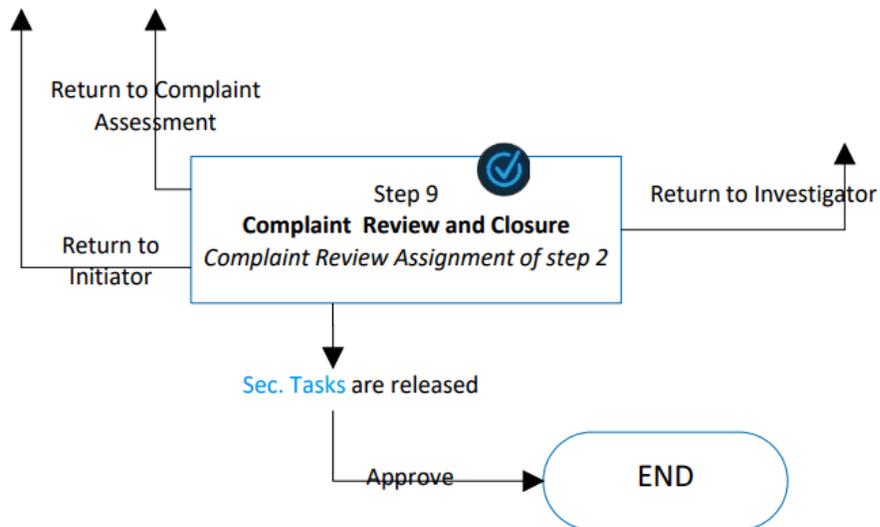
**Option 3:** This option limits the number of investigation extensions that are allowed. If 2 or more Investigation Extensions have been approved (via Step 4), the option *Investigation Extension* is grayed out and disabled in the **Investigation and Root Cause Analysis Decision** at Step 3.

**Option 4:** This option automatically creates a Secondary Task for Refund. If *Yes* is selected for **Refund Requested?** At Step 1, the following Secondary Task is automatically generated:

**Name:** *Issue Refund Request*  
**Task Type:** PRE  
**Description:** *Refund Request*  
**Due Date:** *[leave empty]*  
**User Role:** *[leave empty]*  
**User Name:** *[leave empty]*

**Option 5:** This option modified the flow of the process to by-pass Step 10, allowing the process to close after Step 9. A **Complaint Review Decision** of *Approve* at Step 9 closes the process on confirmation. If at least one Secondary Task is not *Completed* or *Cancelled*, the decision option *Approve* is disabled and the following message is displayed in red below the Decision field: "Process cannot be closed. Some Secondary Tasks are pending."

### Representation of Option 5



**Option 6:** This option modifies the flow of the process to add an Adverse Drug Reaction investigation, Step 3A. At Step 2, if **Investigation Required?** = *Yes*, then a mandatory Yes/No field **ADR Investigation Required?** is displayed. If **ADR Investigation Required?** = *Yes*, then the field **ADR Investigator** is displayed.

If *Approve* is selected for **Complaint Assessment Decision** at Step 2 and the selection for **ADR Investigator** and **Complaint Review Assignment** is the same, the following error message is displayed in red below the decision and the process is not submitted when the Submit button is clicked: "Please have different users selected as **ADR Investigator** and **Complaint Review Assignment**."

If *Approve* is selected for **Complaint Assessment Decision** at Step 2, **Investigation Required?** = *Yes* and **ADR Investigation Required?** = *Yes*, the process moves to Step 3 and 3A on confirmation.

At Step 3, if **ADR Investigation Required?** = *Yes* and Step 3A is not completed, the decision option of *Investigation Completed* is disabled and grayed out.

If implementing this option, Step 3A is called **ADR Investigation** and is assigned to the user selected in Step 2 as **ADR Investigator**. This step includes a mandatory 8000-character Text Area called **ADR Investigation Details** that can be populated with Quick Text. Secondary Tasks can be added at this step but Related Processes and Document Control Processes cannot. Secondary Tasks initiated at Step 3A

have a Task Type that defaults to *ADR Investigation*. If one or more of these tasks does not have the status of *Completed* or *Cancelled*, the decision *ADR Investigation Completed* is disabled and grayed out.

If the **ADR Investigation Decision** is set to *Release Tasks* or to *ADR Investigation Completed* the **Comments** field is not mandatory.

If the **ADR Investigation Decision** = *Release Tasks*, the process moves back to Step 3A on confirmation.

If the **ADR Investigation Decision** = *ADR Investigation Completed* or *Cancel ADR Investigation*, the process continues to other steps on confirmation. All Secondary Tasks, except Task Type = POST are made available to their assignees on confirmation of Step 3A.

Representation of Option 6

