

# SOLABS QM10: Laboratory Investigation Request Process P0055 User Guide

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## Introduction

This document provides instructions on the use of the **SOLABS QM10 Laboratory Investigation Request (LIR) Process APP P0055** – 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**
- **SOLABS QM10 PROCESS Section: Parent/Child Process Relationships**

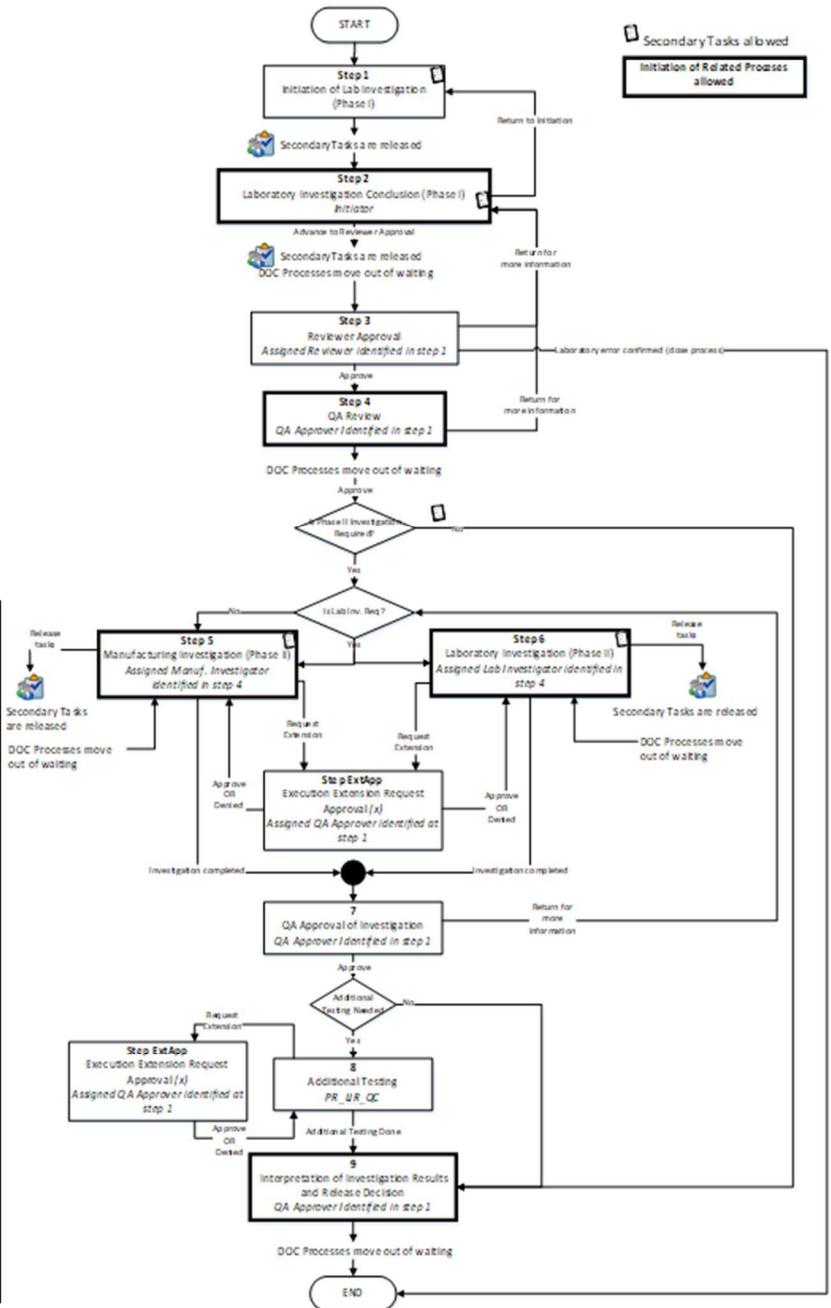
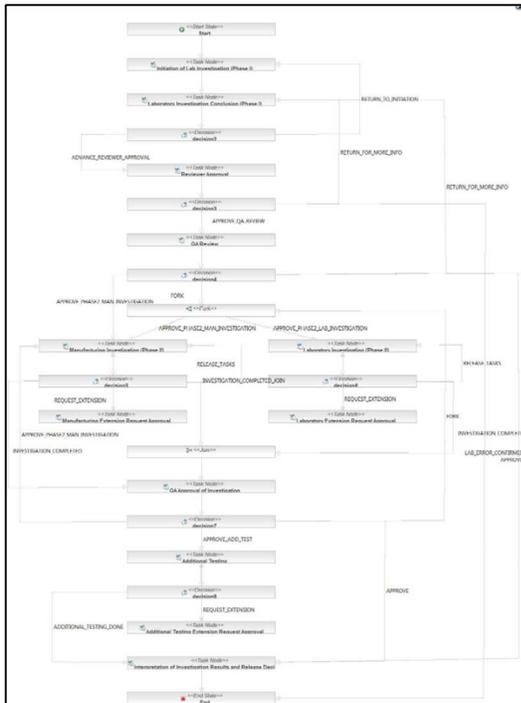
Different steps in a process are assigned to different roles and/or users in the system. You take action on the step assigned to you. For example, you may be assigned a **QA Approval of Investigation** step in a **LIR** process. A manager can monitor the status of process tasks assigned to their employees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

## Laboratory Investigation Request (LIR) Process Flowcharts

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

The flowchart shown at the right is available as part of the Process User Functional Design Specification (UFDS) document that is provided with the Process App.

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



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

## Laboratory Investigation Request (LIR) 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 **LIR Process Roles** are associated with the **Laboratory Investigation Process P0055** and must be assigned to the Users in **SOLABS QM 0** 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 LIR Process Roles need to be assigned to additional Users.

### **PR\_LIR\_Laboratory\_Investigator:**

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

- Step 6: Laboratory Investigation (Phase II)

### **PR\_LIR\_Manufacturing\_Investigator:**

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

- Step 5: Manufacturing Investigation (Phase II)

### **PR\_LIR\_QA\_Approver:**

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

- Step 4: QA Review
- Step 7: QA Approval of Investigation
- Extension Request Approvals
- Step 9: Interpretation of Investigation Results and Release Decision

### **PR\_LIR\_QC:**

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

- Step 8: Additional Testing

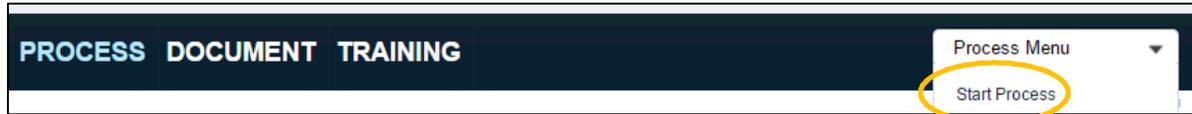
### **PR\_LIR\_QA\_Reviewer:**

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

- Step 3: Reviewer Approval

## Starting the Laboratory Investigation Request (LIR) Process

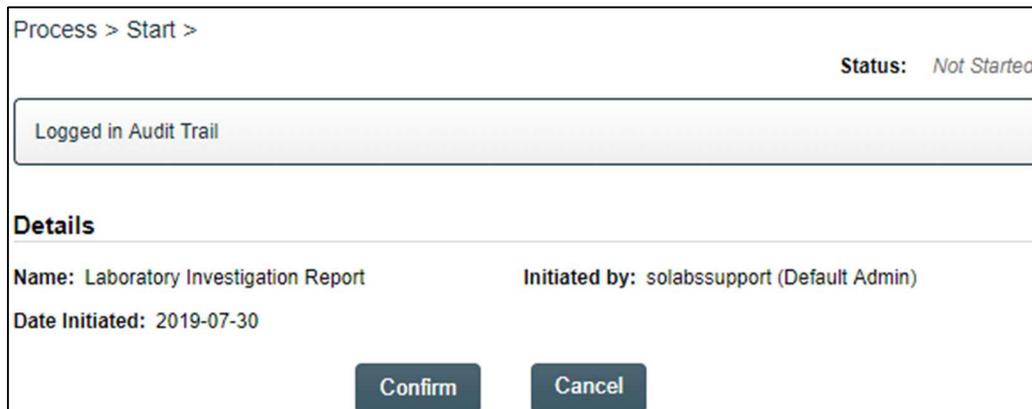
From the PROCESS Section in SOLABS QM10, choose Start Process from the Quick Access Process Menu.



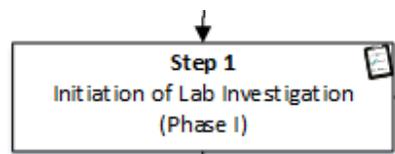
At the next screen, locate the listing for the LIR Process and click the blue START button.



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 LIR Process.



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



## Step 1: Initiation of Lab Investigation (Phase I)

At Step 1 the user initiating the LIR 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. Related Processes and Document Control Processes cannot be initiated at this step, so the related options are grayed out.

At the 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**.

Submit **Save Draft** Cancel

Process > Laboratory Investigation Report > **Initiation of Lab Investigation (Phase I)** > Act on

Status: In Process

---

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: Initiation of Lab Investigation (Phase I)

---

**Process Values**

Process Tasks

**Name:** Initiation of Lab Investigation (Phase I) Expand all Print all

---

**Process Task Form - Initiation of Lab Investigation (Phase I)**

Unique ID: LIR-000003

\* Title:

\* Testing Type:

\* Lot Number(s):

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

\* Product/Material:

\* Part #:

\* Stage:

\* Material Type:

\* Strength/Dose:

\* Packaging Configuration:

\* Description:

\* Date Result Obtained:

\* Testing Site:

\* Manufacturing Site:  Expand

Site 1

Site 2

Comments:

\* Assigned Reviewer:

\* Assigned QA Approver:

**Process Actions**

View

Modify Values

Reassign Tasks

Cancel

Get Link

Email Link

Move Out of Waiting

**Act on**

Initiation of Lab Investigation[...]

**Related Items**

Link Documents

Link Processes

Modify Description

Remove Links

**Related Information**

Audit Trail

Summary Report

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

### Completing the Process Task Form:

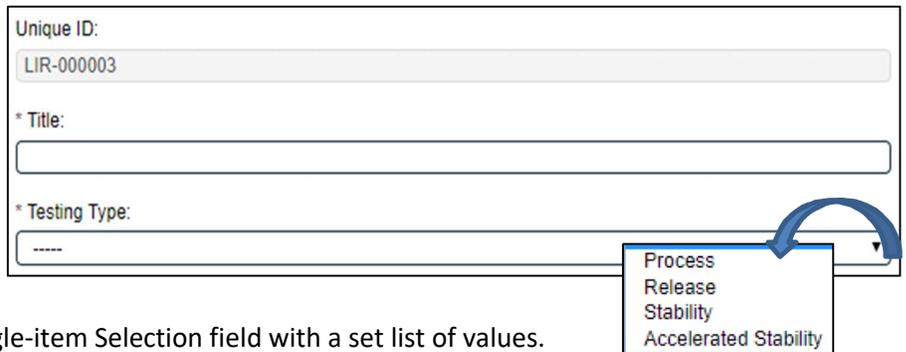
This sub-section covers the information required for each of the fields in the **Process Task Form at LIR**

#### Process Step 1.

The **Unique ID** field will be automatically populated with the next available LIR number.

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

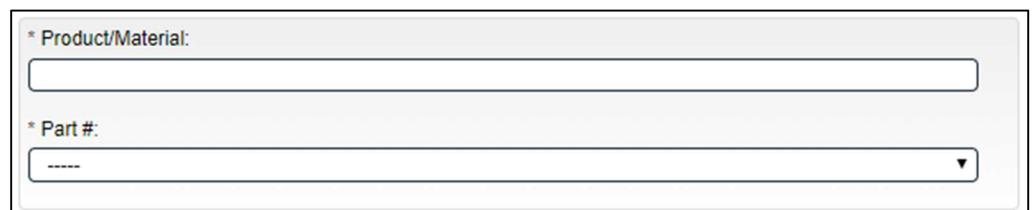
The **Testing Type** is mandatory Single-item Selection field with a set list of values.



**Lot Number(s)** is a mandatory text area field allowing for up to 8000 characters.



**Product/Material** is a mandatory Autocomplete, Delimited Values field based on the productname column of the client-specific EDI List **EDI\_Product**.

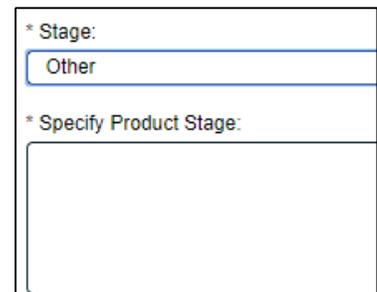


**Part #** is a mandatory, customizable Single-item Selection field based on the codeNumber column of the client-specific EDI List **EDI\_Product**.

**Stage** is a mandatory Single-item Selection field. The values are configurable using a shared Custom List called **SOL169\_Stage\_List**. There is also a value for **Other**.



**Name:** SOL169\_Stage\_List **Status:** Active  
**Values :** Stage 1 ; Stage 2 ; Stage 3



When **Other** is selected, a mandatory field called **Specify Product Stage** is displayed, allowing for entry of up to 8000 characters.

**Material Type** is a mandatory configurable Single-item Selection field based on the materialType column of the client-specific EDI List **PR\_EDM\_Material**.

\* Material Type: [-----] ▼

\* Strength/Dose: [-----] ▼

\* Packaging Configuration: [-----] ▼

**Material Type** is grouped with mandatory Single-item Selection fields for **Strength/Dose** and **Packaging Configuration**. Both fields are configurable based on the strengthDose column of the client specific EDI list **PR\_EDM\_Material** and the packagingConfiguration column of the client specific EDI list **PR\_EDM\_Material**.

**Description** is a mandatory text area field allowing for up to 8000 characters.

\* Description:

\* Date Result Obtained:

Clear

August 2019 ▼

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	8	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

**Date Result Obtained** is a mandatory date field that can be populated from a calendar. It does not allow input of future dates.

**Testing Site** is a mandatory Single-item Selection field. The values are configurable using a shared Custom List called **SOL\_161\_Site\_List**.

\* Testing Site: [-----] ▼

**Manufacturing Site** is a mandatory Multiple-item Selection field with values also configurable using the shared Custom List called **SOL\_161\_Site\_List**.

**Name:** SOL161\_Site\_List **Status:** Active  
**Values :** Site 1 ; Site 2 ; Site 3

\* Manufacturing Site:

Site 1

Site 2

Expand

**Comments** is an optional text area field allowing up to 8000 characters.

Comments:

\* Assigned Reviewer:

\* Assigned QA Approver:

The **Assigned Reviewer** and **Assigned QA Approver** fields are both mandatory.

- **Assigned Reviewer** is a Single-item Selection field that includes the list of SOLABS QM10 Users are assigned the Process Role **PR\_LIR\_QA\_Reviewer**.
- **Assigned QA Approver** is a Single-item Selection field that includes the list of SOLABS QM10 Users are assigned the Process Role **PR\_LIR\_QA\_Approver**.

### Creating Secondary Tasks

The initiator of the Laboratory Investigation Request (LIR) Process can create **Secondary Tasks** that will be associated with the LIR. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the LIR and 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 Initiation of Lab Investigation (Phase I) screen. A **+ADD** button is available to create as many Secondary Tasks as needed.

**Secondary Tasks**

Secondary Task 1

Remove

+ADD

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

Secondary Task 1

Type: Task

Task

Manufacturing Investigation

Laboratory Investigation

\* Description:

\* Due Date:

Originator:

solabssupport (Default Admin)

\* Assignee (Role):

\* Assignee (User):

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 three 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 Laboratory Investigation process.

The **Originator** field will default to the User initiating the LIR 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.

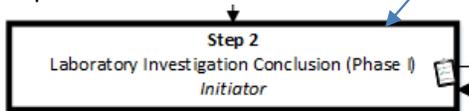
TASKS	
Due this week / last week	
Name: Review Data from all[...] ID: Task-00000001 (LIR-000003) Due: 2019-08-09 Status: Not Started	<a href="#">View</a>   <a href="#">Act on</a>

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 LIR process to **Step 2 – Laboratory Investigation Conclusion (Phase I)**.

The Process Flowchart will highlight the next step of the process. Step 2 will be assigned to the same person who initiated Step 1. They will receive a new email Notification so that activities for **Laboratory Investigation Conclusion (Phase I)** are captured as a separate step.



Status: In Process

---

**Process Details**

Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
Day(s) opened: 7	Date Closed: <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

**Current Process Tasks**  
 Laboratory Investigation Conclusion (Phase I) Currently with solabssupport (Default Admin)

Flowchart: [Open](#)

---

**Process Values**

Process Tasks	
Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	
<a href="#">Expand all</a> <a href="#">Print all</a>	

---

**Related Items**

Secondary Tasks	
Name: Review Data from all[...] Unique ID: Task-00000001 Due: 2019-08-09 Status: Not Started	<a href="#">View</a>
<a href="#">Expand all</a>	

Default Admin

Home > Views

---

**PROCESSES**

Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process	<a href="#">View</a>   <a href="#">Act on</a>
Current Process Task: Laboratory Investigation Conclusion (Phase I)	

## Step 2: Laboratory Investigation Conclusion (Phase I)

### Viewing the Laboratory Investigation Conclusion (Phase I) Task

If the initiator 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, which 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 LIR 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 LIR-000003 brings up the Task Details screen for that assigned Task.

LIR-000003 is listed as a **Related Item** for that Task. To get back to LIR-000003, the Reviewer can click on the **View** option.

Task > View	
<b>Task Details</b>	
Name: Review Data from all previous Stability pulls	
Type: Task	Unique ID: Task-00000001
Description: Review Data from all previous Stability pulls	
Reference Date:	
Location: Root\LIR-000003 Process Task Group\Initiation of Lab Investigation (Phase I) Task Group	
Estimated Start Day Offset: N/A	Estimated End Day Offset: N/A
Estimated Start Date: N/A	Estimated End Date: 2019-08-09
Start Date: N/A	End Date: N/A
Status: Not Started	
Comments:	
<b>Task Ownership</b>	
Originator: solabssupport (Default Admin)	
Assignee (Role): any	
Assignee (User): qc (q c)	
<b>Related Items</b>	
<b>Main Related Process</b>	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process	
Current Process Task: Laboratory Investigation Conclusion (Phase I) <span style="float: right;"><a href="#">View</a></span>	

### Acting on the Laboratory Investigation Conclusion (Phase I) Task

When the **Initiator** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the **Act on** screen for their **Laboratory Investigation Conclusion (Phase I)** 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 laboratory investigation. Fields with an asterisk (\*) are mandatory. More information on the use of these fields is provided starting below.

The right-hand **Related Items** menus can be used 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 more Secondary Tasks, Related Processes or a Document Control Process are all 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 LIR Process and then use the right-hand Act on Menu to open the Process Task Form fields.

The mandatory **Laboratory Investigation Conclusion** field allows up to 8000 characters to describe the investigation conducted.

**Was Lab Error Determined?** is a Radio Button allowing for a selection of **Yes** or **No**, that defaults to **Yes**. If No is selected, the following mandatory field is displayed and allows for up to 8000 characters.

When **Was Lab Error Determined?** is selected as **Yes**, a group of fields are displayed to enter the related information.

\* Description of Error:

\* Identify Laboratory Probable Root Cause(s):

\* Laboratory Root Cause Categories:

Man
  Material
  Method
  Machine
  Environment
 Collapse

**Description of Error** and **Identify Laboratory Probable Root Cause(s)** are mandatory text area fields allowing for up to 8000 characters.

**Laboratory 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.

<p>* Laboratory Man Category:</p> <div style="border: 1px solid black; padding: 2px;">-----</div>	<p><b>Name:</b> SOL095_Man_Category_List <b>Status:</b> Active</p> <p><b>Values :</b> Man 1 ; Man 2 ; Man 3</p>
<p>* Laboratory Material Category:</p> <div style="border: 1px solid black; padding: 2px;">-----</div>	<p><b>Name:</b> SOL099_Material_Category_List <b>Status:</b> Active</p> <p><b>Values :</b> Material 1 ; Material 2 ; Material 3</p>
<p>* Laboratory Method Category:</p> <div style="border: 1px solid black; padding: 2px;">-----</div>	<p><b>Name:</b> SOL102_Method_Category_List <b>Status:</b> Active</p> <p><b>Values :</b> Method 1 ; Method 2 ; Method 3</p>
<p>* Laboratory Machine Category:</p> <div style="border: 1px solid black; padding: 2px;">-----</div>	<p><b>Name:</b> SOL094_Machine_Category_List <b>Status:</b> Active</p> <p><b>Values :</b> Machine 1 ; Machine 2 ; Machine 3</p>
<p>* Laboratory Environment Category:</p> <div style="border: 1px solid black; padding: 2px;">-----</div>	<p><b>Name:</b> SOL066_Environment_Category_List <b>Status:</b> Active</p> <p><b>Values :</b> Environment 1 ; Environment 2 ; Environment 3</p>

Use the **+ADD** button if more **Secondary Tasks** are required at Step 2. See Page 9-10 for using this section.

**Secondary Tasks**

Review Data from all previous Stability pulls  
 Due Date: 2019-08-09 Type: Task  
 Originator: solabssupport (Default Admin)

Modify Remove

**+ADD**

**Related Processes** and **Document Control Processes** can also be initiated at Step 2.

## Initiating a Related Process

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

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

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

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

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

Whether linking an existing process or initiating a new one, the **Related Processes** will be listed in the **Related Items** section, along with any **Secondary Tasks** and **Related Documents**, when LIR **Step 2** is Submitted and Confirmed.

Related Items	
<b>Secondary Tasks</b>	
<b>Name:</b> Review Data from all[...]	<b>Unique ID:</b> Task-00000001 <b>Due:</b> 2019-08-09 <b>Status:</b> Not Started <a href="#">View</a>
<a href="#">Expand all</a>	
<b>Related Processes</b>	
<b>Unique ID:</b> CAPA-000001 <b>Date Initiated:</b> 2019-08-07 <b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Initiation and CAPA Definition	

## Initiating a Document Control Process

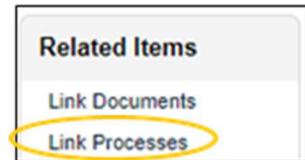
To initiate a new **SOLABS QM10 Document Control Process** to manage any document updates required for this Laboratory Investigation, select **Yes**. One or more documents can be included in a Document Control Process.

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



When the **Process Relation** is selected as **Dependent Process**, the process from which it was initiated is considered the **Parent Process**.

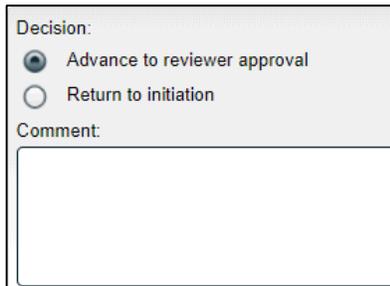
If a Document Control Process was already initiated, separately from this LIR, it can be linked as a Related Item using the right-hand menu option under **Related Items**. In this case, leave the above setting at the default of **No**.



When the **Yes** option is selected, Step 1 of the Document Control Process will be launched immediately upon submission of Step 2 – Laboratory Investigation Conclusion (Phase I), so that the person initiating the LIR can also concurrently initiate the Document Control Process. The LIR Process will be considered the **Parent Process**.

Whether linking an existing Doc Control Process or initiating a new one, it will be listed in the **Related Items** section when LIR Step 2 is Submitted and Confirmed.

Related Items			
<b>Secondary Tasks</b>			
<b>Name:</b> Review Data from all[...]	<b>Unique ID:</b> Task-00000001	<b>Due:</b> 2019-08-09	<b>Status:</b> Not Started <a href="#">View</a>
<a href="#">Expand all</a>			
<b>Related Processes</b>			
<b>Unique ID:</b> CAPA-000001	<b>Date Initiated:</b> 2019-08-07	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Initiation and CAPA Definition			
<b>Unique ID:</b> DOC-000001	<b>Date Initiated:</b> 2019-08-07	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Change Request for Creation, Review or Withdrawal of Document			



The Decision section for Step 2 includes two choices:

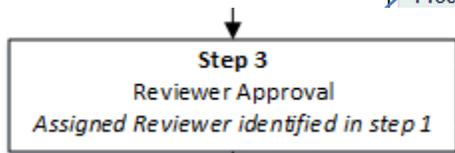
- **Advance to reviewer approval** will progress the LIR Process to **Step 3 – Reviewer Approval**. A **Comment** field is available for optional comments.
- **Return to initiation** will send the LIR Process back to **Step 1 – Initiation of Lab Investigation (Phase I)**. The **Comment** field is then mandatory.

## 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 new **Secondary Tasks**, **Related Processes** or **Document Control Processes** have been initiated, click **Submit** and then **Confirm** to progress the LIR process to **Step 3 – Reviewer Approval**.

The **Process Details** will list the **Current Process Task** and who it is **Currently with** (the Assigned Reviewer selected at Step 1).

The **Process Flowchart** will highlight the next step of the process.



Status: In Process

---

**Process Details**

<b>Name:</b> Laboratory Investigation Report	<b>Date Initiated:</b> 2019-07-30 12:05:14
<b>Unique ID:</b> LIR-000003	<b>Initiated by:</b> solabssupport (Default Admin)
<b>Day(s) opened:</b> 8	<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>	<b>Currently with</b>
Reviewer Approval	reviewer (reviewer)

Flowchart: [Open](#)

---

**Process Values**

Process Tasks

: Initiation of Lab Investigation (Phase I)	<b>Last Confirmation Date:</b> 2019-08-06 13:54:30
: Laboratory Investigation Conclusion (Phase I)	<b>Last Confirmation Date:</b> 2019-08-07 14:54:22
: Reviewer Approval	

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

---

**Related Items**

**Secondary Tasks**

<b>Name:</b> Review Data from all[...]	<b>Unique ID:</b> Task-00000001	<b>Due:</b> 2019-08-09	<b>Status:</b> Not Started	<a href="#">View</a>
--	---------------------------------	------------------------	----------------------------	----------------------

[Expand all](#)

**Related Processes**

<b>Unique ID:</b> CAPA-000001	<b>Date Initiated:</b> 2019-08-07	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Initiation and CAPA Definition			
<b>Unique ID:</b> DOC-000001	<b>Date Initiated:</b> 2019-08-07	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Change Request for Creation, Review or Withdrawal of Document			

[Expand all](#)

### Step 3: Reviewer Approval

At this step in the LIR Process, the **Assigned Reviewer** chosen at Step 1 will receive an email Notification and will see their **Reviewer Approval** task listed in the Process section of their SOLABS QM10 HOME Page.

Home > Views

---

**PROCESSES**

Received this week / last week

<b>Unique ID:</b> LIR-000003	<b>Date Initiated:</b> 2019-07-30	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Reviewer Approval			

## Viewing the Reviewer Approval Task

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

From the View screen, 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** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

## Acting on the Reviewer Approval Task

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

As described above, the **Assigned Reviewer** 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.

Process: Laboratory Investigation Report > Reviewer Approval > Act on

Status: In Process

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: Reviewer Approval

**Process Values**

**Process Tasks**

Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval	

Expand all Print all

**Process Task Form - Reviewer Approval**

Decision:

Approve - Proceed to QA review

Laboratory error confirmed (close process)

Return for more information

Does this potentially impact distributed product?:

Yes

No

Comment:

**Process Actions**

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

**Act on**

- Reviewer Approval

**Related Items**

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

**Related Information**

- Summary Report

Initiation of Secondary Tasks, Related Processes or 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 LIR Process and then use the right-hand Act on Menu to open the Process Task Form fields.

Decision:

Approve - Proceed to QA review

Laboratory error confirmed (close process)

Return for more information

Does this potentially impact distributed product?:

Yes

No

Comment:

The **Decision** section at LIR Step 3 allows three choices:

The default is **Approve – Proceed to QA review** and will bring up additional fields to enter information about possible impacted product and a related **Comment**.

Submission and confirmation of this decision moves the LIR Process to **Step 4 – QA Review**.

A decision of **Laboratory error confirmed (close process)** at Step 3 will close the Laboratory Investigation Request process. The **Comment** field is mandatory with this decision.

A decision of **Return for more information** at Step 3 will send the LIR Process back to Step 2. The **Comment** field is mandatory with this decision so that the initiator can then provide the requested information.

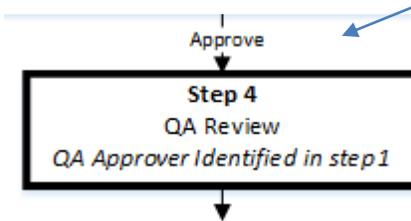
## Submit and Confirm

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**.

If the **Decision** was **Approve – Proceed to QA review**, the LIR process will move to **Step 4 – QA Review**.

The **Process Details** will list the **Current Process Task** and who it is **Currently with** (the Assigned QA Approver selected at Step 1).

The Process Flowchart will highlight the next step of the process.



**Process Details**

Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
Day(s) opened: 9	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
<b>Current Process Tasks</b>	<b>Currently with</b>
QA Review	qa (q a)

Flowchart: Open

**Process Values**

Process Tasks	
Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review	

Expand all Print all

**Related Items**

Secondary Tasks	
Name: Review Data from all[...]	Unique ID: Task-00000001 Due: 2019-08-09 Status: Not Started <a href="#">View</a>

Expand all

Related Processes	
Unique ID: CAPA-000001 Date Initiated: 2019-08-07 Status: In Process	<a href="#">View</a>
Current Process Task: Initiation and CAPA Definition	
Unique ID: DOC-000001 Date Initiated: 2019-08-07 Status: In Process	<a href="#">View</a>
Current Process Task: Change Request for Creation, Review or Withdrawal of Document	

## Step 4: QA Review

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

Home > Views	
<b>PROCESSES</b>	
Received this week / last week	
Unique ID: LIR-000003	Date Initiated: 2019-07-30 Status: In Process <a href="#">View</a>   <a href="#">Act on</a>
Current Process Task: QA Review	

### Viewing the QA Review Task

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

From the View screen, 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** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details, Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

### Acting on the QA Review Task

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

As described above, the **Assigned QA Approver** 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 QA Approver** 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.

New Secondary Tasks are not allowed at Step 4 but new Related Processes or a Document Control Process can be initiated.

The **Save Draft** option is 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**.

Process > Laboratory Investigation Report > QA Review > Act on

Status: In Process

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: QA Review

**Process Values**

Process Tasks

Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review	

Expand all Print all

**Process Task Form - QA Review**

\* Event Type: -----

Is this a Recurring Event?:

Yes

No

\* Event #:

Event Description:

+ADD

Is Phase II Investigation Required?

Yes

No

\* Assigned Manufacturing Investigator:

-----

Is Laboratory Investigation Required?:

Yes

No

\* Assigned Laboratory Investigator:

-----

\* Investigation Due Date:

2019-09-04

Decision:

Approve

Return for more information

Comment:

-----

**Process Actions**

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

**Act on**

- QA Review

**Related Items**

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

**Related Information**

- Summary Report

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

**Event Type** is a mandatory Single-item Selection field with three choices: OOS, OOT or OOE.

**Is this a Recurring Event?** is a **Yes** or **No** radio button that defaults to **Yes**. The selection of **Yes** brings up a group of additional fields to provide information on the previous events. A **+ADD** button is available to add another group of fields if there were multiple previous events.

**Event#** is a mandatory, autocomplete, field that will bring up LIR processes that are present in the system with a status  $\neq$  *Cancelled*. Starting to type the LIR number or title will bring up a list of LIR Processes matching that criterion. Click on one to select it.

**Event Description** is an optional Text Area field, allowing entry of up to 8000 characters.

**Is Phase II Investigation Required?** is a **Yes** or **No** radio button that defaults to **Yes**.

The selection of **Yes** brings up a Single-item Selection field to choose the **Assigned Manufacturing Investigator**. The values include all active users who are assigned the Process Role **PR\_LIR\_Manufacturing\_Investigator**. It also brings up the field **Is Laborator Investigation Required?**

**Is Laboratory Investigation Required?** is a **Yes** or **No** radio button that defaults to **Yes**.

The selection of **Yes** brings up a Single-item Selection field to choose the **Assigned Laboratory Investigator**. The values include all active users who are assigned the Process Role **PR\_LIR\_Laboratory\_Investigator**.

**Investigation Due Date** is a mandatory date field that is auto-populated with a date 30 days from the **Date Result Obtained** that was entered at Step 1. If the default date is changed (past dates are not allowed), a mandatory text field is displayed for entry of the **Reason for Date Change**.

Decision:

Approve

Return for more information

Comment:

There are two choices for a Decision at Step 4.

- A choice of **Approve** will progress the LIR Process to **Step 5 – Manufacturing Investigation (Phase II)** and possibly **Step 6 – Laboratory Investigation (Phase II)**, depending on the choices made at this step.
- A choice of **Return for more information** will send the LIR Process back to Step 2. The **Comment** field is mandatory for that choice.

<p>If <b>Yes</b> was selected at Step 4 for <b>Is Phase II Investigation Required</b>, the LIR Process moves to <b>Step 5 – Manufacturing Investigation (Phase II)</b> and is assigned to the <b>Assigned Manufacturing Investigator</b>.</p>	<p>If <b>Yes</b> was selected at Step 4 for <b>Is Laboratory Investigation Required</b>, the LIR Process also moves to <b>Step 6 – Manufacturing Investigation (Phase II)</b> and is assigned to the <b>Assigned Laboratory Investigator</b>.</p>
---	---

The **Process Details** will list the **Current Process Tasks** and who they are **Currently with** (the Assigned Manufacturing Investigator and/or the Assigned Laboratory Investigator selected at Step 4).

The **Process Flowchart** will highlight the next step(s) of the process.

**Process Details**

Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
Day(s) opened: 10	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)

Current Process Tasks	Currently with
Laboratory Investigation (Phase II)	erika (Erika)
Manufacturing Investigation (Phase II)	diane (Diane)

Flowchart: [Open](#)

**Process Values**

Process Tasks
Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review Last Confirmation Date: 2019-08-09 14:27:29
Name: Laboratory Investigation (Phase II)
Name: Manufacturing Investigation (Phase II)

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

---

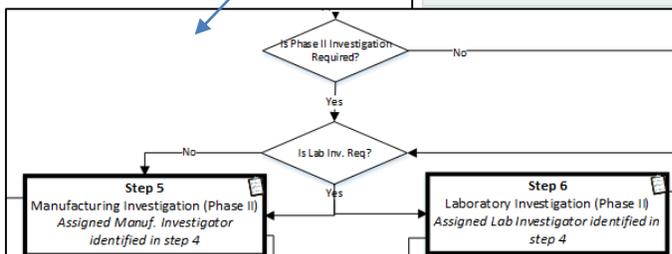
Unique ID: Task-00000001	Due: 2019-08-09
Status: Not Started <a href="#">View</a>	

[Expand all](#)

**Related Processes**

Unique ID: LIR-000001	Date Initiated: 2019-07-15
Status: In Process <a href="#">View</a>	
Current Process Task: Laboratory Investigation Conclusion (Phase I)	
Unique ID: CAPA-000001	Date Initiated: 2019-08-07
Status: In Process <a href="#">View</a>	
Current Process Task: Initiation and CAPA Definition	
Unique ID: DOC-000001	Date Initiated: 2019-08-07
Status: In Process <a href="#">View</a>	
Current Process Task: Change Request for Creation, Review or Withdrawal of Document	

[Expand all](#)



## Step 5: Manufacturing Investigation (Phase II)

At this step in the LIR Process, the **Assigned Manufacturing Investigator** chosen at Step 4 will receive an email Notification and will see their **Manufacturing Investigation (Phase II)** task listed in the Process section of their SOLABS QM10 HOME Page.

Home > Views	
<b>PROCESSES</b>	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process	View   Act on
Current Process Task: Manufacturing Investigation (Phase II)	

### Viewing the Manufacturing Investigation (Phase II) Task

If the **Assigned Manufacturing Investigator** clicks on the **View** option to the right of the Process Task, they will get the same screen shown on page 21 above.

As with other steps, from the View screen, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to review detail from prior steps. They can also click on the **View** option to the right of any individual **Related Items** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details, Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

### Acting on the Manufacturing Investigation (Phase II) Task

When the **Assigned Manufacturing 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 **Manufacturing Investigation (Phase II)** task. As described above, the **Assigned Manufacturing Investigator** can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

The **Process Task Form** includes the fields necessary to enter the details regarding the manufacturing investigation. These are described in more detail on the next page.

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

Process > Laboratory Investigation Report > Manufacturing Investigation (Phase II) > Act on Status: In Process

<b>Process Details</b>	<b>Process Actions</b>									
Unique ID: LIR-000003 <span style="float: right;">Flowchart: Open</span>	View									
Current Process Tasks: Laboratory Investigation (Phase II); Manufacturing Investigation (Phase II)	Get Link									
	Email Link									
	Move Out of Waiting									
<b>Process Values</b>	<b>Act on</b>									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><th colspan="2">Process Tasks</th></tr> <tr><td>Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30</td></tr> <tr><td>Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22</td></tr> <tr><td>Name: Reviewer Approval Last Confirmation Date: 2019-08-08 17:03:14</td></tr> <tr><td>Name: QA Review Last Confirmation Date: 2019-08-09 14:27:29</td></tr> <tr><td>Name: Laboratory Investigation (Phase II)</td></tr> <tr><td>Name: Manufacturing Investigation (Phase II)</td></tr> <tr><td style="text-align: right;">Expand all Print all</td></tr> </table>	Process Tasks		Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22	Name: Reviewer Approval Last Confirmation Date: 2019-08-08 17:03:14	Name: QA Review Last Confirmation Date: 2019-08-09 14:27:29	Name: Laboratory Investigation (Phase II)	Name: Manufacturing Investigation (Phase II)	Expand all Print all	Manufacturing Investigation (P[...])
Process Tasks										
Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30										
Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22										
Name: Reviewer Approval Last Confirmation Date: 2019-08-08 17:03:14										
Name: QA Review Last Confirmation Date: 2019-08-09 14:27:29										
Name: Laboratory Investigation (Phase II)										
Name: Manufacturing Investigation (Phase II)										
Expand all Print all										
	<b>Related Items</b>									
	Link Documents									
	Link Processes									
	Modify Description									
	Remove Links									
	<b>Related Information</b>									
	Summary Report									

**Process Task Form - Manufacturing Investigation (Phase II)**

\* Manufacturing Investigation Plan:

\* Was Root Cause or Probable Root Cause:

\* Conclusion:

Decision:

Release tasks

Request extension

Investigation completed

Each of the fields in the Process Task Form is displayed more clearly and described on the next page.

November 2021

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.

New **Secondary Tasks, Related Processes** and a **Document Control Process** can be initiated at Step 5. Secondary Tasks initiated at Step 5 default to a Task **Type of Manufacturing Investigation** and are released to assignees upon submission and confirmation of Step 5.

As with previous steps, 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 LIR Process and then use the right-hand Act on Menu to open the Process Task Form fields.

\* Manufacturing Investigation Plan:

The mandatory **Manufacturing Investigation Plan** field is a text area that allows up to 8000 characters to enter information about the investigation plan.

\* Was Root Cause or Probable Root Cause of OOS/OOT/OOE Identified?:

-----

**Was Root Cause or Probable Root Cause of OOS/OOT/OOE Identified?** is a Single-item Selection field with choices of **Yes** or **No**.

\* Manufacturing Cause Description:

\* Manufacturing Cause Categories:

Man  
 Material  
 Method  
 Machine  
 Environment

Select all Deselect all

If **Yes** is selected, additional mandatory fields are displayed for **Manufacturing Cause Description** (text area for up to 8000 characters) and **Manufacturing Cause Categories** (Multi-item Selection field). 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 (refer to Page 13).

\* Conclusion:

A mandatory **Conclusion** field (text area allowing up to 8000 characters) is available when the Assigned Manufacturing Investigator is ready.

Decision:

Release tasks

Request extension

Investigation completed

The **Decision** at Step 5 allows three choices:

- A decision of **Release tasks** will release new Secondary Tasks to the assignees. Those new tasks will be **Task Type = Manufacturing Investigation**. The LIR Process will then stay at Step 5 upon confirmation.

- A decision of **Investigation completed** moves the Process to **Step 7 – QA Approval of Investigation** as soon as Step 6 (if required) is completed with a Decision of Investigation Completed. See Page 28.
- A decision of **Request extension** will bring up additional fields to enter **Proposed Extension Date** and **Reason for the Extension Request**.

\* Proposed Extension Date:

Clear

\* Reason for the Extension Request:

**Proposed Extension Date** is mandatory and cannot be set before the **Investigation Due Date** entered at Step 4.

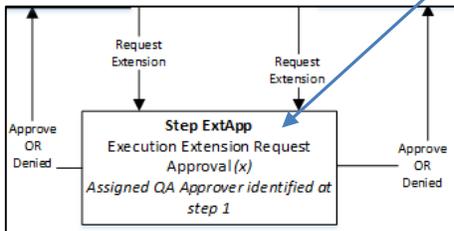
**Reason for the Extension Request** is a mandatory text area allowing for up to 8000 characters.

This decision will move the LIR Process to **Step ExtApp5 – Manufacturing Extension Request Approval** upon confirmation.

The **Process Details** will list the **Current Process Tasks** and who they are **Currently with**. The number in parenthesis after the **Manufacturing Extension Request Approval** task indicates the number of extensions requested (in this case the first one). This step is assigned to the **Assigned QA Approver** entered at Step 1.

Process Details	
Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
Day(s) opened: 14	Date Closed : <empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
<b>Current Process Tasks</b>	<b>Currently with</b>
Laboratory Investigation (Phase II)	erika (Erika)
Manufacturing Extension Request Approval (1)	qa (q a)
Flowchart: Open	
Process Values	
Process Tasks	
Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review	Last Confirmation Date: 2019-08-09 14:27:29
Name: Laboratory Investigation (Phase II)	
Name: Manufacturing Investigation (Phase II)	Last Confirmation Date: 2019-08-13 09:51:10
Name: Manufacturing Extension Request Approval (1)	
Expand all   Print all	

The **Process Flowchart** will highlight the next step of the process. Since this is the same step used if an extension is required at other process steps, the flowchart is labeled as simply **Step ExtApp -Execution Extension Request Approval**.



## Step ExtApp 5: Manufacturing Extension Request Approval (x)

At this step in the LIR Process, the Assigned **QA Approver** chosen at Step 1 will receive an email Notification and will see their **Manufacturing Extension Request Approval (x)** task listed in the Process section of their SOLABS QM10 HOME Page. The number in parenthesis will indicate the number of extensions requested so far for this Step 5.

Home > Views

**PROCESSES**

Received this week / last week

Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process View | Act on

Current Process Task: Manufacturing Extension Request Approval (1)

## Viewing the Manufacturing Extension Request Approval Task

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

From the View screen, 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** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

## Acting on the Manufacturing Extension Request Approval Task

When the Assigned QA Approver clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Manufacturing Extension Request Approval** task. As described above, the Assigned QA Approver can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

No Secondary Tasks, Related Processes or Document Control Process can be initiated at this step.

The **QA Extension Request Approval Decision** allows three choices.

- A decision of **Approve** will display the requested extended due date in **The Investigation Due Date is to be updated to the following date:** field. **Comments** are optional.
- A decision of **Return for more information** will result in the **Comments** field being mandatory.
- A decision of **Denied** will also result in the **Comments** field being mandatory.

All decisions will move the LIR Process back to **Step 5 – Manufacturing Investigation (Phase II)** upon confirmation so that the Assigned Investigator can continue to complete their investigation against the new due date.

Refer to Page 22 for **Step 5 – Manufacturing Investigation (Phase II)**.

Process > Laboratory Investigation Report > Manufacturing Extension Request Approval (1) > Act on

Status: In Process

**Process Actions**

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

**Act on**

- Manufacturing Extension Request Approval (1)

**Related Items**

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

**Related Information**

- Summary Report

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: Laboratory Investigation (Phase II); Manufacturing Extension Request Approval (1)

**Process Values**

Process Tasks
Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review Last Confirmation Date: 2019-08-09 14:27:29
Name: Laboratory Investigation (Phase II)
Name: Manufacturing Investigation (Phase II) Last Confirmation Date: 2019-08-13 09:51:10
Name: Manufacturing Extension Request Approval (1)

Expand all Print all

**Process Task Form - Manufacturing Extension Request Approval (1)**

QA Extension Request Approval Decision:

Approve

Return for more information

Denied

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

2019-10-09

Comments:

## Step 6: Laboratory Investigation (Phase II)

At this step in the LIR Process, the **Assigned Laboratory Investigator** chosen at Step 4 will receive an email Notification and will see their **Laboratory Investigation (Phase II)** task listed in the Process section of their SOLABS QM10 HOME Page.

Home > Views	
<b>PROCESSES</b>	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process	<a href="#">View</a>   <a href="#">Act on</a>
Current Process Task: Laboratory Investigation (Phase II)	

### Viewing the Laboratory Investigation (Phase II) Task

If the **Assigned Laboratory Investigator** clicks on the **View** option to the right of the Process Task, they will get the same screen shown on page 21 above.

As with other steps, from the View screen, they can use the **Expand all** options under the **Process Values** table and the **Related Items** table to review detail from prior steps. They can also click on the **View** option to the right of any individual **Related Items** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details, Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

### Acting on the Laboratory Investigation (Phase II) Task

When the **Assigned Laboratory 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 **Laboratory Investigation (Phase II)** task. As described above, the **Assigned Laboratory Investigator** can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

The **Process Task Form** includes the fields necessary to enter the details regarding the laboratory investigation. These are described in more detail on the next page.

The right-hand **Related Items** menu allows the **Assigned Laboratory Investigator** 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.

Process > Laboratory Investigation Report > **Laboratory Investigation (Phase II) > Act on** Status: In Process

<b>Process Details</b>		<b>Process Actions</b> <a href="#">View</a> <a href="#">Get Link</a> <a href="#">Email Link</a> <a href="#">Move Out of Waiting</a>																
Unique ID: LIR-000003 <span style="float: right;">Flowchart: Open</span>																		
Current Process Tasks: Laboratory Investigation (Phase II); Manufacturing Investigation (Phase II)																		
<b>Process Values</b>		<b>Act on</b> <a href="#">Laboratory Investigation (Phase II)</a>																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Process Tasks</th> </tr> </thead> <tbody> <tr> <td>Name: Initiation of Lab Investigation (Phase I)</td> <td>Last Confirmation Date: 2019-08-06 13:54:30</td> </tr> <tr> <td>Name: Laboratory Investigation Conclusion (Phase I)</td> <td>Last Confirmation Date: 2019-08-07 14:54:22</td> </tr> <tr> <td>Name: Reviewer Approval</td> <td>Last Confirmation Date: 2019-08-08 17:03:14</td> </tr> <tr> <td>Name: QA Review</td> <td>Last Confirmation Date: 2019-08-09 14:27:29</td> </tr> <tr> <td colspan="2">Name: Laboratory Investigation (Phase II)</td> </tr> <tr> <td colspan="2">Name: Manufacturing Investigation (Phase II)</td> </tr> <tr> <td>Name: Manufacturing Extension Request Approval (1)</td> <td>Last Confirmation Date: 2019-08-13 11:07:35</td> </tr> </tbody> </table> <div style="text-align: right;"> <a href="#">Expand all</a> <a href="#">Print all</a> </div>		Process Tasks		Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30	Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22	Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14	Name: QA Review	Last Confirmation Date: 2019-08-09 14:27:29	Name: Laboratory Investigation (Phase II)		Name: Manufacturing Investigation (Phase II)		Name: Manufacturing Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:07:35	<b>Related Items</b> <a href="#">Link Documents</a> <a href="#">Link Processes</a> <a href="#">Modify Description</a> <a href="#">Remove Links</a>
Process Tasks																		
Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30																	
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22																	
Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14																	
Name: QA Review	Last Confirmation Date: 2019-08-09 14:27:29																	
Name: Laboratory Investigation (Phase II)																		
Name: Manufacturing Investigation (Phase II)																		
Name: Manufacturing Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:07:35																	
<b>Process Task Form - Laboratory Investigation (Phase II)</b>		<b>Related Information</b> <a href="#">Summary Report</a>																
<p>* Laboratory Investigation Plan:</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>* Was Root Cause or Probable Root Cause:</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div> <p>* Conclusion:</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>Decision:</p> <p> <input checked="" type="radio"/> Release tasks  <input type="radio"/> Request extension  <input type="radio"/> Investigation completed         </p>																		

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

New **Secondary Tasks**, **Related Processes** and a **Document Control Process** can be initiated at Step 6. Secondary Tasks initiated at Step 6 default to a Task **Type** of **Laboratory Investigation** and are released to assignees upon submission and confirmation of Step 6.

As with previous steps, 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 LIR Process and then use the right-hand Act on Menu to open the Process Task Form fields.

The mandatory **Laboratory Investigation Plan** field is a text area that allows up to 8000 characters to enter information about the investigation plan.

\* Laboratory Investigation Plan:

**Was Root Cause or Probable Root Cause of OOS/OOT/OOE Identified?** is a Single-item Selection field with choices of **Yes** or **No**.

\* Was Root Cause or Probable Root Cause of OOS/OOT/OOE Identified?:

-----

If **Yes** is selected, additional mandatory fields are displayed for **Laboratory Cause Description** (text area for up to 8000 characters) and **Laboratory Cause Categories** (Multi-item Selection field with 5 set choices).

\* Laboratory Cause Description:

\* Laboratory Cause Categories:

Man  
 Material  
 Method  
 Machine  
 Environment

Collapse

Select all
Deselect all

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 (refer to Page 13).

\* Conclusion:

A mandatory **Conclusion** field (text area allowing up to 8000 characters) is available when the Assigned Laboratory Investigator is ready.

Decision:

- Release tasks
- Request extension
- Investigation completed

\* Proposed Extension Date:

Clear

\* Reason for the Extension Request:

The **Decision** at Step 6 allows three choices:

- A decision of **Release tasks** will release new Secondary Tasks to the assignees. These tasks will be **Task Type = Laboratory Investigation**. The LIR Process will then stay at Step 6 upon confirmation.
- A decision of **Request extension** will bring up additional fields to enter **Proposed Extension Date** and **Reason for the Extension Request**. **Proposed Extension Date** is mandatory and cannot be set before the **Investigation Due Date** entered at Step 4.

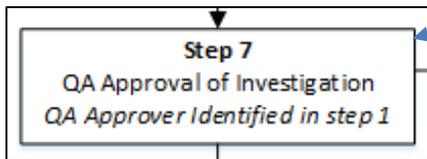
**Reason for the Extension Request** is a mandatory text area allowing for up to 8000 characters.

This decision will move the LIR Process to **Step ExtApp6 – Laboratory Extension Request Approval** upon confirmation.

- A decision of **Investigation completed** moves the Process to **Step 7 – QA Approval of Investigation** as soon as Step 5 (if required) is completed with a Decision of Investigation Completed.

The **Process Details** will list the **Current Process Task** and who it is **Currently with**. This step is assigned to the **Assigned QA Approver** entered at Step 1.

The **Process Flowchart** will highlight the next step of the process.



**Process Details**

<b>Name:</b> Laboratory Investigation Report	<b>Date Initiated:</b> 2019-07-30 12:05:14
<b>Unique ID:</b> LIR-000003	<b>Initiated by:</b> solabssupport (Default Admin)
<b>Day(s) opened:</b> 14	<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>	<b>Currently with</b>
QA Approval of Investigation	qa (q a)

**Flowchart:** Open

**Process Values**

Process Tasks	
<b>Name:</b> Initiation of Lab Investigation (Phase I)	<b>Last Confirmation Date:</b> 2019-08-06 13:54:30
<b>Name:</b> Laboratory Investigation Conclusion (Phase I)	<b>Last Confirmation Date:</b> 2019-08-07 14:54:22
<b>Name:</b> Reviewer Approval	<b>Last Confirmation Date:</b> 2019-08-08 17:03:14
<b>Name:</b> QA Review	<b>Last Confirmation Date:</b> 2019-08-09 14:27:29
<b>Name:</b> Laboratory Investigation (Phase II)	<b>Last Confirmation Date:</b> 2019-08-13 11:46:49
<b>Name:</b> Manufacturing Investigation (Phase II)	<b>Last Confirmation Date:</b> 2019-08-13 11:52:28
<b>Name:</b> Manufacturing Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2019-08-13 11:07:35
<b>Name:</b> Laboratory Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2019-08-13 11:45:54
<b>Name:</b> QA Approval of Investigation	

Expand all Print all

## Step ExtApp 6: Laboratory Extension Request Approval (x)

At this step in the LIR Process, the Assigned **QA Approver** chosen at Step 1 will receive an email Notification and will see their **Laboratory Extension Request Approval (x)** task listed in the Process section of their SOLABS QM10 HOME Page. The number in parenthesis will indicate the number of extensions requested so far for Step 6. Although the Step Name is different, the options, fields and decisions for this step are exactly the same as for **Step ExtApp 5: Manufacturing Extension Request Approval (x)**. Refer to Page 24-25.

All decisions will move the LIR Process back to **Step 6 – Laboratory Investigation (Phase II)** upon confirmation so that the Assigned Investigator can continue to complete their investigation against the new due date. Refer to Page 26 for **Step 6 – Laboratory Investigation (Phase II)**.

## Step 7: QA Approval of Investigation

At this step in the LIR Process, the **Assigned QA Approver** chosen at Step 1 will receive an email Notification and will see the **QA Approval of Investigation** task listed in the Process section of their SOLABS QM10 HOME Page.

Home > Views	
<b>PROCESSES</b>	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process	<a href="#">View</a>   <a href="#">Act on</a>
Current Process Task: QA Approval of Investigation	

## Viewing the QA Approval of Investigation Task

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

From the View screen, 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** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

## Acting on the QA Approval of Investigation Task

When the **Assigned QA Approver** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **QA Approval of Investigation** task. As described above, the **Assigned QA Approver** can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

The **Process Task Form** includes the fields necessary to enter the details regarding the potential impact on batches and whether any additional testing may be needed. These are described in more detail on the next page.

The right-hand **Related Items** menu allows the **Assigned Laboratory Investigator** 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.

As with previous steps, 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**.



Process > Laboratory Investigation Report > QA Approval of Investigation > Act on

Status: In Process

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: QA Approval of Investigation

**Process Values**

Process Tasks	
Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review	Last Confirmation Date: 2019-08-09 14:27:29
Name: Laboratory Investigation (Phase II)	Last Confirmation Date: 2019-08-13 11:46:40
Name: Manufacturing Investigation (Phase II)	Last Confirmation Date: 2019-08-13 11:52:28
Name: Manufacturing Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:07:35
Name: Laboratory Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:45:54
Name: QA Approval of Investigation	

Expand all Print all

**Process Task Form - QA Approval of Investigation**

Are other batches potentially impacted?:

Yes

No

\* List Batches Impacted:

Additional Lab Testing Needed?:

Yes

No

\* Lab Testing Comment:

Decision:

Approve

Return for more information

Comment:

**Process Actions**

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

**Act on**

- QA Approval of Investigation

**Related Items**

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

**Related Information**

- Summary Report

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

No Secondary Tasks, Related Processes or Document Control Process can be initiated at Step 7.

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

Are other batches potentially impacted?:

Yes → \* List Batches Impacted:

No

**Are other batches potentially impacted?** is a **Yes** or **No** radio button selection, that defaults to **Yes**. When **Yes** is selected, a mandatory text area field (up to 8000 characters) is displayed for **List Batches Impacted**.

Additional Lab Testing Needed?:

Yes → \* Lab Testing Comment:

No

**Additional Lab Testing Needed?** is a **Yes** or **No** radio button selection, that defaults to **Yes**. When **Yes** is selected, a mandatory text area field (up to 8000 characters) is displayed for **Lab Testing Comment**. If **No** is selected, a mandatory text area field (up to 8000 characters) is displayed for **Rationale for No Additional Lab Testing**.

Additional Lab Testing Needed?:

Yes

No → \* Rationale for No Additional Lab Testing:

Decision:

Approve

Return for more information

Comment:

The **Decision** at Step 7 allows for two options:

- For a decision of **Approve**, the **Comment** field is optional. Confirmation of this decision will move the LIR Process forward as follows:
  - If **Additional Lab Testing Needed = Yes**, the LIR Process will progress to **Step 8 – Additional Testing**.
  - If **Additional Lab Testing Needed = No**, the LIR Process will progress to **Step 9 – Interpretation of Investigation Results and Release Decision**. (See Page 35)
- For a decision of **Return for more information**, the Comment field will become mandatory. Confirmation of this decision will move the LIR Process backward as follows:
  - At Step 4, if **Is Phase II Investigation Required? = Yes** and **Is Phase II Laboratory Investigation Required? = Yes**, then the LIR Process will move back to **Step 5 – Manufacturing Investigation (Phase II)** and **Step 6 – Laboratory Investigation (Phase II)** upon confirmation of Step 7. (See Pages 22 and 26)
  - At Step 4, if **Is Phase II Investigation Required? = Yes** and **Is Phase II Laboratory Investigation Required? = No**, then the LIR Process will move back to **Step 5 – Manufacturing Investigation (Phase II)** upon confirmation of Step 7. (See Page 22)

## Step 8: Additional Testing

The **Process Details** will list the **Current Process Task** and who it is **Currently with**. This step is assigned to anyone with the Process Role assignment PR\_LIR\_QC.

The **Process Flowchart** will highlight the next step of the process.

**Process Details**

<b>Name:</b> Laboratory Investigation Report	<b>Date Initiated:</b> 2019-07-30 12:05:14
<b>Unique ID:</b> LIR-000003	<b>Initiated by:</b> solabssupport (Default Admin)
<b>Day(s) opened:</b> 15	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/1)	<b>Dependent Processes Completion (%):</b> 0 (0/0)

**Current Process Tasks**      **Currently with**  
 Additional Testing      kathy (kathy); qc (q c); so (so)

**Flowchart:** Open

**Process Values**

Process Tasks	Last Confirmation Date
<b>Name:</b> Initiation of Lab In	
<b>Name:</b> Laboratory Invest	
<b>Name:</b> Reviewer Approv	
<b>Name:</b> QA Review Las	
<b>Name:</b> Laboratory Invest	
<b>Name:</b> Manufacturing Investigation (Phase II)	<b>Last Confirmation Date:</b> 2019-08-13 11:52:28
<b>Name:</b> Manufacturing Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2019-08-13 11:07:35
<b>Name:</b> Laboratory Extension Request Approval (1)	<b>Last Confirmation Date:</b> 2019-08-13 11:45:54
<b>Name:</b> QA Approval of Investigation	<b>Last Confirmation Date:</b> 2019-08-14 12:23:00
<b>Name:</b> Additional Testing	

Expand all   Print all

Note that an **Extension Request** is allowed at Step 8. If needed, it would be **Step ExtApp 8** and would follow the same process as Extensions requested at Steps 5 and 6. See Page 24-25 for **Extension Request Approval** options, fields and decisions.

At this step in the LIR Process, all users with the PR\_LIR\_QC Role assignment will receive an email Notification and will see the **Additional Testing** task listed in the Process section of their SOLABS QM10 HOME Page.

[Home](#) > [Views](#)

**PROCESSES**

Received this week / last week

<b>Unique ID:</b> LIR-000003	<b>Date Initiated:</b> 2019-07-30	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Additional Testing			

## Viewing the Additional Testing Task

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

From the View screen, 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** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

## Acting on the Additional Testing Task

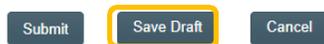
When the **QC User** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Additional Testing** task. As described above, the **QC User** can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

The **Process Task Form** includes the fields necessary to enter the details regarding the results of the additional testing. These are described in more detail starting below.

The right-hand **Related Items** menu allows the **Assigned Laboratory Investigator** 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.

As with previous steps, 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**.



No Secondary Tasks, Related Processes or Document Control Process can be initiated at Step 8.

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

The following sentences are displayed in red at the top of the Process Task Form section:

**Attach Additional Testing Protocol(s)**  
**Attach Additional Testing Report(s)**

Documents can be attached using the **Link Documents** option in the right-hand **Related Items** menu.

Process > Laboratory Investigation Report > Additional Testing > Act on Status: In Process

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: Additional Testing

**Process Values**

**Process Tasks**

- Name: Initiation of Lab Investigation (Phase I) **Last Confirmation Date:** 2019-08-06 13:54:30
- Name: Laboratory Investigation Conclusion (Phase I) **Last Confirmation Date:** 2019-08-07 14:54:22
- Name: Reviewer Approval **Last Confirmation Date:** 2019-08-08 17:03:14
- Name: QA Review **Last Confirmation Date:** 2019-08-09 14:27:29
- Name: Laboratory Investigation (Phase II) **Last Confirmation Date:** 2019-08-13 11:46:49
- Name: Manufacturing Investigation (Phase II) **Last Confirmation Date:** 2019-08-13 11:52:28
- Name: Manufacturing Extension Request Approval (1) **Last Confirmation Date:** 2019-08-13 11:07:35
- Name: Laboratory Extension Request Approval (1) **Last Confirmation Date:** 2019-08-13 11:45:54
- Name: QA Approval of Investigation **Last Confirmation Date:** 2019-08-14 12:23:00
- Name: Additional Testing

Expand all Print all

**Process Task Form - Additional Testing**

Attach Additional Testing Protocol(s)  
 Attach Additional Testing Report(s)  
 \* Summary of Additional Testing Results

**Process Task Form fields are displayed more clearly and described starting on the next page.**

Was Original Result(s) Confirmed?:  
 Yes  
 No

\* Was Root Cause Identified?:

Decision:  
 Additional testing completed  
 Request extension

Audit Trail  
Summary Report

\* Summary of Additional Testing Results:

**Summary of Additional Testing Results** is a mandatory text area field allowing up to 8000 characters.

Was Original Result(s) Confirmed?:

Yes

No

**Was Original Result(s) Confirmed?** is a **Yes** or **No** radio button selection that defaults to **Yes**.

**Was Root Cause Identified?** is a mandatory Single-item Selection field with choices of **Yes** or **No**.

\* Was Root Cause Identified?:

----- ▾

\* Was Root Cause Identified?:

Yes

---

Has root cause already been described? :

Yes

No

If **Yes** is selected, then **Has root cause already been described?** is displayed. It is a **Yes** or **No** radio button selection that defaults to **No**.

\* Additional Testing Root Cause Description:

\* Additional Testing Root Cause Categories:

Man

Material

Method

Machine

Environment

Select all Deselect all

With a selection of **No**, additional mandatory fields are displayed for **Additional Testing Root Cause Description** (8000-character text area field) and **Additional Testing Root Cause Categories** (Multi-item Selection field with five set choices). 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 (refer to Page 13).

A selection **Yes** for **Has root cause already been described?** requires no additional entries.

Decision:

Additional testing completed

Request extension

The **Decision** at Step 8 has two choices:

The default is **Additional testing completed**. Confirmation of this decision will move the LIR Process to **Step 9 – Interpretation of Investigation Results and Release Decision**.

Confirming a decision of **Request extension** will move the LIR Process to **Step ExApp8 – Additional Testing Extension Request Approval**. The options, fields and decisions are the same as Extension Request Approvals at Steps 5 and 6. See Pages 24-25 for completing the step.

## Step ExtApp 8: Additional Testing Extension Request Approval (x)

At this step in the LIR Process, the Assigned **QA Approver** chosen at Step 1 will receive an email Notification and will see their **Additional Testing Extension Request Approval (x)** task listed in the Process section of their SOLABS QM10 HOME Page. The number in parenthesis will indicate the number of extensions requested so far for Step 8. Although the Step Name is different, the options, fields and decisions for this step are exactly the same as for **Step ExtApp 5: Manufacturing Extension Request Approval (x)** and **Step ExtApp 6: Laboratory Extension Request Approval (x)**. Refer to Page 24-25.

All decisions will move the LIR Process back to **Step 8 – Additional Testing** upon confirmation so that the Assigned Investigator can continue to complete their investigation against the new due date. Refer to Page 32 for **Step 6 – Laboratory Investigation (Phase II)**.

## Step 9: Interpretation of Investigation Results and Release Decision

The **Process Details** will list the **Current Process Task** and who it is **Currently with** – the Assigned **QA Approver** selected at Step 1.

The **Process Flowchart** will highlight the next step of the process.

Secondary Tasks cannot be added at Step 9. Related Processes and a Document Control Process can be initiated at Step 9. Any Document Control Process initiated will move out of waiting upon confirmation of this step.

**Process Details**

<b>Name:</b> Laboratory Investigation Report	<b>Date Initiated:</b> 2019-07-30 12:05:14
<b>Unique ID:</b> LIR-000003	<b>Initiated by:</b> solabssupport (Default Admin)
<b>Day(s) opened:</b> 16	<b>Date Closed:</b> <empty>
<b>Secondary Tasks Completion (%):</b> 0 (0/1)	<b>Dependent Processes Completion (%):</b> 0 (0/0)

**Current Process Tasks**      **Currently with**  
 Interpretation of Investigation Results and R[...]      qa (q a)

Flowchart: [Open](#)

**Process Values**

Process Tasks	Last Confirmation
Name: Initiation of Lab Investigation (Phase I)	
Name: Laboratory Investigation Conclusion (Phase I)	2019-08-13 11:54:22
Name: Reviewer Approval	Last Confirmation
Name: QA Review	Last Confirmation Date: 2019-08-13 11:46:49
Name: Laboratory Investigation (Phase II)	Last Confirmation Date: 2019-08-13 11:52:28
Name: Manufacturing Investigation (Phase II)	Last Confirmation Date: 2019-08-13 11:07:35
Name: Manufacturing Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:45:54
Name: Laboratory Extension Request Approval (1)	Last Confirmation Date: 2019-08-14 12:23:00
Name: QA Approval of Investigation	Last Confirmation Date: 2019-08-15 11:19:30
Name: Additional Testing	
Name: Interpretation of Investigation Results and Release Decision	

[Expand all](#)   [Print all](#)

At this step in the LIR Process, the **QA Approver** will receive an email Notification and will see the **Interpretation of Investigation Results and Release Decision** task listed in the Process section of their SOLABS QM10 HOME Page.

Home > Views

**PROCESSES**

Received this week / last week

<b>Unique ID:</b> LIR-000003	<b>Date Initiated:</b> 2019-07-30	<b>Status:</b> In Process	<a href="#">View</a>   <a href="#">Act on</a>
<b>Current Process Task:</b> Interpretation of Investigation Results and Release Decision			

## Viewing the Interpretation of Investigation Results and Release Decision Task

If the QA Approver clicks on the **View** option to the right of the Process Task, they will get the same screen shown at the end of Page 33.

From the View screen, 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** (Secondary Tasks, Linked Documents, Linked Processes) to go to the **Task Details**, **Document Details** or **Process Details** screens associated with those Related Items. From any of those screens they can quickly return to the Process since it will be listed as a **Related Item** on all of those screens.

## Acting on the Interpretation of Results and Release Decision Task

When the QA Approver clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Interpretation of investigation Results and Release Decision** task. As described above, the QA Approver can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

The **Process Task Form** includes the fields necessary to enter the details regarding the interpretation of results and related release decisions. These fields are described in more detail starting on the next page.

The right-hand **Related Items** menu allows the **Assigned Laboratory Investigator** 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.

Process > Laboratory Investigation Report > Interpretation of Investigation Results and Release Decision > Act on

Status: In Process

**Process Actions**

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

**Act on**

- Interpretation of Investigatio[...]

**Related Items**

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

**Related Information**

- Summary Report

**Process Details**

Unique ID: LIR-000003 Flowchart: Open

Current Process Tasks: Interpretation of Investigation Results and Release Decision

**Process Values**

Process Tasks	
Name: Initiation of Lab Investigation (Phase I)	Last Confirmation Date: 2019-08-06 13:54:30
Name: Laboratory Investigation Conclusion (Phase I)	Last Confirmation Date: 2019-08-07 14:54:22
Name: Reviewer Approval	Last Confirmation Date: 2019-08-08 17:03:14
Name: QA Review	Last Confirmation Date: 2019-08-09 14:27:29
Name: Laboratory Investigation (Phase II)	Last Confirmation Date: 2019-08-13 11:46:49
Name: Manufacturing Investigation (Phase II)	Last Confirmation Date: 2019-08-13 11:52:28
Name: Manufacturing Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:07:35
Name: Laboratory Extension Request Approval (1)	Last Confirmation Date: 2019-08-13 11:45:54
Name: QA Approval of Investigation	Last Confirmation Date: 2019-08-14 12:23:00
Name: Additional Testing	Last Confirmation Date: 2019-08-15 11:19:30
Name: Interpretation of Investigation Results and Release Decision	

Expand all Print all

**Process Task Form - Interpretation of Investigation Results and Release Dec[...]**

MRB Input Required?:

Yes

No

\* MRB Summary:

\* Result Type:

-----

\* Release Decision:

-----

\* Rationale:

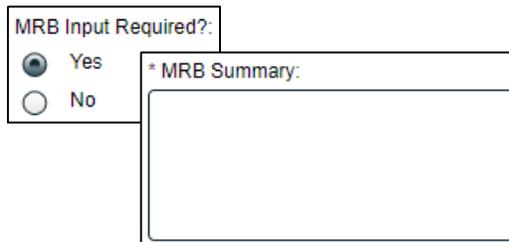
**Process Task Form fields are displayed more clearly and described starting on the next page.**

As with previous steps, 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**.



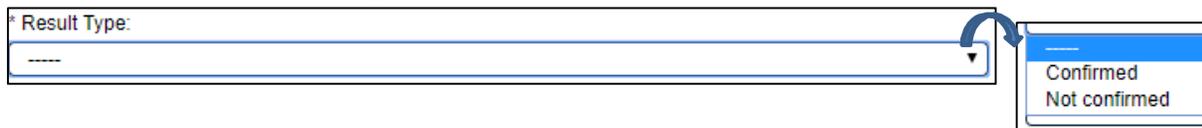
No Secondary Tasks can be initiated at Step 9. Related Processes and a Document Control Process can be initiated at this step.

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



**MRB Input Required?** is a **Yes** or **No** radio button selection that defaults to **Yes**. When **Yes** is selected, a mandatory text area field (allows up to 8000 characters) is displayed for **MRB Summary**. When **No** is selected, no additional information is required.

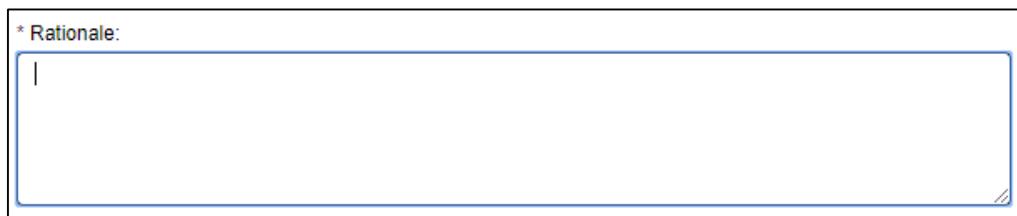
**Result Type** is a mandatory Single-item Selection field with 2 set choices.



**Release Decision** is a mandatory Single-item Selection field with 5 set choices.



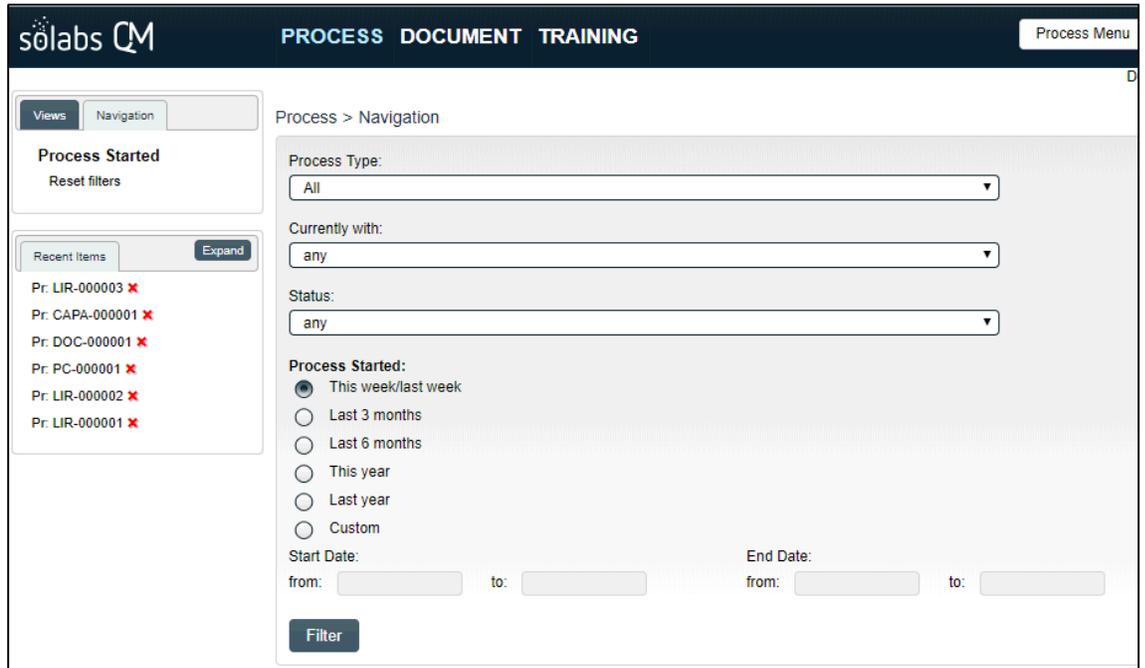
**Rationale** is a mandatory text area field allowing for up to 8000 characters.



The Laboratory Investigation Request (LIR) Process closes up on confirmation of Step 9. Any Document Control Process initiated at this step will move out of waiting. Any Secondary Tasks that may not have been completed by this point in the process will be removed.

## Viewing Details for a Completed Laboratory Investigation Request (LIR) 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> Laboratory Investigation Report	<b>Date Initiated:</b> 2019-07-30 12:05:14											
<b>Unique ID:</b> LIR-000003	<b>Initiated by:</b> solabssupport (Default Admin)											
<b>Day(s) opened:</b> 16	<b>Date Closed :</b> 2019-08-15 12:05:22											
<b>Secondary Tasks Completion (%) :</b> 100 (1/1)	<b>Dependent Processes Completion (%) :</b> 0 (0/0)											
<b>Current Process Tasks</b> N/A	<b>Currently with</b> N/A											
<table border="1"> <tbody> <tr> <td><b>Name:</b> Reviewer Approval</td> <td><b>Last Confirmation Date:</b> 2019-08-08 17:03:14</td> </tr> <tr> <td><b>Decision:</b> Approve - Proceed to QA review</td> <td></td> </tr> <tr> <td><b>Does this potentially impact distributed product?:</b> No</td> <td></td> </tr> <tr> <td><b>Comment:</b> N/A</td> <td></td> </tr> <tr> <td><b>Sign-off by:</b> reviewer (reviewer)</td> <td></td> </tr> </tbody> </table>			<b>Name:</b> Reviewer Approval	<b>Last Confirmation Date:</b> 2019-08-08 17:03:14	<b>Decision:</b> Approve - Proceed to QA review		<b>Does this potentially impact distributed product?:</b> No		<b>Comment:</b> N/A		<b>Sign-off by:</b> reviewer (reviewer)	
<b>Name:</b> Reviewer Approval	<b>Last Confirmation Date:</b> 2019-08-08 17:03:14											
<b>Decision:</b> Approve - Proceed to QA review												
<b>Does this potentially impact distributed product?:</b> No												
<b>Comment:</b> N/A												
<b>Sign-off by:</b> reviewer (reviewer)												
<b>Name:</b> Laboratory Investigation (Phase I)		<b>Last Confirmation Date:</b> 2019-08-06 13:54:30										
<b>Name:</b> Laboratory Investigation Conclusion (Phase I)		<b>Last Confirmation Date:</b> 2019-08-07 14:54:22										
<b>Name:</b> Reviewer Approval		<b>Last Confirmation Date:</b> 2019-08-08 17:03:14										
<b>Name:</b> QA Review		<b>Last Confirmation Date:</b> 2019-08-09 14:27:29										
<b>Name:</b> Laboratory Investigation (Phase II)		<b>Last Confirmation Date:</b> 2019-08-13 11:46:49										
<b>Name:</b> Manufacturing Investigation (Phase II)		<b>Last Confirmation Date:</b> 2019-08-13 11:52:28										
<b>Name:</b> Manufacturing Extension Request Approval (1)		<b>Last Confirmation Date:</b> 2019-08-13 11:07:35										
<b>Name:</b> Laboratory Extension Request Approval (1)		<b>Last Confirmation Date:</b> 2019-08-13 11:45:54										
<b>Name:</b> QA Approval of Investigation		<b>Last Confirmation Date:</b> 2019-08-14 12:23:00										
<b>Name:</b> Additional Testing		<b>Last Confirmation Date:</b> 2019-08-15 11:19:30										
<b>Name:</b> Interpretation of Investigation Results and Releas...		<b>Last Confirmation Date:</b> 2019-08-15 12:05:22										

## Using the Related Items Table

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

**Related Items**

**Secondary Tasks**

Name: Review Data from all[...] Unique ID: Task-00000001 Due: 2019-08-09 Status: Completed View

---

**Task Details**

Name: Review Data from all previous Stability pulls  
 Type: Task Unique ID: Task-00000001  
 Description: Review Data from all previous Stability pulls  
 Reference Date:  
 Location: Root\LIR-000003 Process Task Group\Initiation of Lab Investigation (Phase I) Task Group  
 Estimated Start Day Offset: N/A Estimated End Day Offset: N/A  
 Estimated Start Date: N/A Estimated End Date: 2019-08-09  
 Start Date: 2019-08-15 End Date: 2019-08-15  
 Status: Completed  
 Comments:

**Task Ownership**

Originator: solabssupport (Default Admin)  
 Assignee (Role): any  
 Assignee (User): qc (q c)

**Related Items**

**Main Related Process**

Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: Completed View  
 Current Process Task: N/A

## Creating a Summary Report

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

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: Laboratory Investigation Report Date Initiated: 2019-07-30 12:05:14  
 Unique ID: LIR-000003 Initiated by: solabssupport (Default Admin)  
 Day(s) opened: 0 Date Closed: 2019-08-15 12:05:22  
 Secondary Tasks Completion (%): 100 (1/1) Dependent Processes Completion (%): 0 (0/0)  
 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

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 www.solabs.com

solabs quality@heart

LIR-000003

Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
Days opened: 16	Date Closed: 2019-08-15 12:05:22
Secondary Tasks Completion (%): 100 (1/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks: N/A	Currently with: N/A

**Process Values**

Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30

Unique ID: LIR-000003  
 Title: OOS Content Uniformity  
 Testing Type: Stability  
 Lot Number(s): A12345  
 Product/Material: p2  
 Part #: c2  
 Stage: Stage 3  
 Material Type: Type 1  
 Strength/Dose: Strength 2  
 Packaging Configuration: Package 2  
 Description: Out of specification result for P2 Lot A12345 at 15 month stability pull.  
 Date Result Obtained: 2019-08-05  
 Testing Site: Site 1  
 Manufacturing Site: Site 2  
 Comments: N/A  
 Assigned Reviewer: reviewer (reviewer)  
 Assigned QA Approver: qc (q a)  
 Sign-off by: solabssupport (Default Admin)

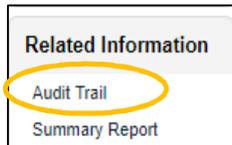
---

Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22

Laboratory Investigation Conclusion: No lab errors - Phase II investigation will be required.  
 Was Lab Error Determined?: No  
 Comment for Lab Error Not Determined: Laboratory data was reviewed and no laboratory errors were identified.  
 Decision: Advance to reviewer approval  
 Comment: N/A  
 Sign-off by: solabssupport (Default Admin)

## 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 LIR Process, from **Process Completed** all the way down to **Process Started**, with options to expand or print the entire process or any individual steps.

Process > LIR-000003 > Audit Trail

Process Name: LIR-000003	
<b>Action Details: Process Completed</b> Process Task Name: N/A Date: 2019-08-15 12:05:22 Role: N/A Username (Full Name): qa (q a) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Interpretation of Investigation Results and Release Decision Date: 2019-08-15 12:05:22 Role: N/A Username (Full Name): qa (q a) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Additional Testing Date: 2019-08-15 11:19:30 Role: N/A Username (Full Name): qc (q c) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: QA Approval of Investigation Date: 2019-08-14 12:23:00 Role: N/A Username (Full Name): qa (q a) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Manufacturing Investigation (Phase II) Date: 2019-08-13 11:52:28 Role: N/A Username (Full Name): diane (Diane) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Laboratory Investigation (Phase II) Date: 2019-08-13 11:46:49 Role: N/A Username (Full Name): erika (Erika) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Laboratory Extension Request Approval (1) Date: 2019-08-13 11:45:54 Role: N/A Username (Full Name): qa (q a) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Laboratory Investigation (Phase II) Date: 2019-08-13 11:35:09 Role: N/A Username (Full Name): erika (Erika) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Manufacturing Extension Request Approval (1) Date: 2019-08-13 11:07:35 Role: N/A Username (Full Name): qa (q a) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Manufacturing Investigation (Phase II) Date: 2019-08-13 09:51:10 Role: N/A Username (Full Name): diane (Diane) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: QA Review Date: 2019-08-09 14:27:29 Role: N/A Username (Full Name): qa (q a) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Reviewer Approval Date: 2019-08-08 17:03:14 Role: N/A Username (Full Name): reviewer (reviewer) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Laboratory Investigation Conclusion (Phase I) Date: 2019-08-07 14:54:22 Role: N/A Username (Full Name): solabssupport (Default Admin) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Task Performed</b> Process Task Name: Initiation of Lab Investigation (Phase I) Date: 2019-08-06 13:54:30 Role: N/A Username (Full Name): solabssupport (Default Admin) Reason for Change: N/A	<a href="#">Print</a>
<b>Action Details: Process Started</b> Process Task Name: N/A Date: 2019-07-30 12:05:14 Role: N/A Username (Full Name): solabssupport (Default Admin) Reason for Change: N/A	<a href="#">Print</a>

## Laboratory Investigation Request (LIR) 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, which 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 Laboratory Investigation Request (LIR) Process P0055.

### Custom Notifications

If Step 1 field **Date Result Obtained** < Today – 2 days, the following notification is sent on confirmation of step 1.

To: all users in the role of PR\_LIR\_QA\_Approver.

Subject: LIR process belatedly initiated

Body:

A Laboratory Investigation Report – LIR process has been initiated more than 2 days following the result.

Product/Material: *[Product/Material from step 1]*

Refer to *LIR-XXXXXX*

Regards,

Where *LIR-XXXXXX* is a hyperlink to the process

If Step 3 field **Does this potentially impact distributed product?** = Yes, the following notification is sent on confirmation of step 3.

To: all users in the role of PR\_LIR\_QA\_Approver and their manager.

Subject: LIR process impacting distributed product

Body:

A Laboratory Investigation Report – LIR process has been initiated regarding this distributed product.

Product/Material: *[Product/Material from step 1]*

Refer to *LIR-XXXXXX*

Regards,

Where *LIR-XXXXXX* is a hyperlink to the process

On process closure, the following notification is sent.

To: all users that confirmed a step in the process.

Subject: LIR process closed

Body:

A Laboratory Investigation Report – LIR process, in which you have participated, is closed.

Product/Material: *[Product/Material from step 1]*

Refer to *LIR-XXXXXX*

Regards,

Where *LIR-XXXXXX* is a hyperlink to the process