

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.



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Laboratory Investigation Request (LIR) Process Flowcharts

The LIR Process Flowcharts are displayed START Secondary Tasks allowed on this page for informational purposes tiation of Related Processes Step1 of Lab Investigation (Phase I) allowed only - to show that it is a multi-step process with related decision paths. Ţ 2 ndaryTasksare released Step 2 The flowchart shown at the right is Laborat hitigtor an / Share I available as part of the Process User . æ Secondary Tasks are released Functional Design Specification (UFDS) esses move out of waiting document that is provided with the Step 3 Reviewer Approval ed Reviewer Identified In step 1 Process App. A . Step 4 QA Review The Flowchart shown below is available QA Approver I dentfied in sep 1 within the Process App. As the process ocesses move out of waiting moves along, the active step in that Flowchart is highlighted. O "-Start Sta Step 5 Aanufacturing Investigation (Phase Step 6 vestigation (Phase Laboratory Assigned Manuf. Investig identified in step 4 Assigned Lab Investigator identified step 4 8 2 condary Tasks Secondary Tasks are released are release DOC Processes move out of waiting DOC Processes out of waiting esses m ov Step ExtApp la gra Execution Extension Request Approval (x) OR ssigned QA Approver identified step 1 QA Approval of investigation QA Approver I dentified in step 1 Step ExtApp Execut Approval (x) Assigned Q.A Approver identified o step 1 Additional Testing PR UR OC Additional ting Done nterpretation of investigation Resul and Release Decision QA Approver I dentified in step 1 Ť DOC Processe ove out of waiting ŧ END

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.



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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



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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.

Process > Start >			
		Status:	Not Started
Logged in Audit Trail			
Details			
Name: Laboratory Investigation Report	Initiated by: s	olabssupport (Default Admin)	
Date Initiated: 2019-07-30			
Confirm	Cancel		
		Status:	In Process
Process Details			
Unique ID: LIR-000003	Flowchart: c	Open	
Current Process Tasks: Initiation of Lab Investigation	n (Phase I)		
The first Step on the Process Flowchart wi nighlighted when the flowchart is opened.	ll now be	Step 1	tigation



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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**.



Process - Laboratory investigation (Phase I) Process Datails Unique ID: UR-000003 Process Task: Process Task: <th>-</th> <th></th> <th></th>	-		
Process Details Unique ID: LIR-20003 Corrent Process Tasks:	Process > Labora	lory Investigation Report > Initiation of Lab Investigation (Phase I) > Act on	
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Process Tasks Process Task Form - Initiation of Lab Investigation (Phase I) Uncould C Uncould C Uncould C Uncould C Testing Type:	Drocoss Values		Get Link
Process Tasks More Cut of Watering Name: Initiation of Lab Investigation (Phase I) Expand all Print all Process Tasks Form - Initiation of Lab Investigation (Phase I) Related Item Unique ID: Lin Occoss Lin Occoss Related Item * Tote: Investigation (Phase I) * Task: Related Item * Product/ Material: Related Item * Product/ Task: Related Item * Product/ Connect: * <t< td=""><td>Flocess values</td><td></td><td>Email Link</td></t<>	Flocess values		Email Link
Name: Initiation of Lab Investigation (Phase I) Process Task Form - Initiation of Lab Investigation (Phase I) Unique ID: Unique ID: Unique ID: ILR000003 * Tee: * Tee: * Tee: * Tee: * Tailing Type: * Tailing Type: * Product Mumber(s): * Product Mumber(s): <	Process Tasks		Move Out of Waiting
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Process Task Form - Initiation of Lab Investigation (Phase I) Related Items Unque ID: Related Items UR 000003 Tite * Testing Type: Item Comments * resing Type: Item Comments * Related Information Add Trail * Related Information Add Trail * Stage: Item Comments * Product/Material: Related Information * Product/Material: Item Product/Material:		Expand all Print all	Act on
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Unique ID: LIR-00003 - Tase: - Tase:	Process Task Fo	orm - Initiation of Lab Investigation (Phase I)	
Lik Documents Lik Monosense Li	Unique ID:		Related Items
* Toe: * Testing Type: * Lusk Transmitter * Luck 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 * Product	LIR-000003		Link Documents
Testing Type: Testing	* Title:		Link Processes
* Testing Type: ***********************************			Modify Description
Related Information Related Information Add Trail Summay Report Related Information Related Informat	* Testing Type:		Remove Links
Lot Number(s): Lot Number(s): Each of the fields in the Process Task Form will be displayed more clearly and described starting on the next page. * Part #: ** * Product/Material: * Part #: ** * Product/Material: * Part #: ** * Product/Material: * Product/Material: ** * Product/Material: * Product/Material: ** * Product/Material: ** * Name Product Name Name Name Name Name Name Name Name			
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	Site 2	*	
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* Assigned Reviewer: * Assigned QA Approver:	Comments:		
* Assigned Reviewer:			
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* Assigned Reviewer:			
* Assigned QA Approver:	* Assigned Reviewer	A	
* Assigned QA Approver:		• • • • • • • • • • • • • • • • • • •	
- Assigned QA Approver:			
	- Assigned QA Appro	-)	



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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 righthand 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.

Unique ID:	
LIR-000003	
* Title:	
* Testing Type:	
	Process
e-item Selection field with a set list of values.	Release Stability Accelerated Stability

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

Lot Numbers(s) is a	* Lot Number(s):]
mandatory text area field		
characters.		

Product/Material is a

mandatory Autocomplete, Delimited Values field base on the productname colun of the client-specific EDI Li EDI_Product.

* Product/Material:	
* Part #:	

Part # is a mandatory, customizable Single-item Selection field based on the codeNumber column of the clientspecific EDI List EDI_Product.

Stage is a mandatory Single-	* Stage:		
item Selection field. The			•
values are configurable using			
a shared Custom List called	Name: SOL169 Stage List Status: Active	* Stage:	
SOL169_Stage_List. There is	Values : Stage 1 : Stage 2 : Stage 2	Other	
also a value for Other .	values. Stage 1, Stage 2, Stage 5	* Specify Product Stage:	
When Other is selected, a mandat	ory field called Specify Product Stage is		

displayed, allowing for entry of up to 8000 characters.

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

* Strength/Dose:	

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_EDI_Material and the packagingConfiguration column of the client specific EDI list PR_EDI_Material.

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

* Description:								
	* D	ate	Result	Obta	ined:			
		Clear						
		August 2019 🔻						
	S	u	Мо	Tu	We	Th	Fr	Sa
						1	2	3
Date Result Obtained is a mandatory date field that can is		4	5	6	7	8	9	10
populated from a calendar. It does not allow input of future dates.		11	12	13	14	15	16	17
Testing Site is a mandatory Single-item Selection field. The values		18	19	20	21	22	23	24
are configurable using a shared Custom List called		25	26	27	28	29	30	31
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:	
- 0% d	Expand
Site 1	<u> </u>
Site 2	
→	

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

Comments:	
L	



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* 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 * Description: * Due Date: Originator: solabssupport (Default Admin)	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.
* Assignee (Role): * Assignee (User): *	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.



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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	View Act on

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></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 lasks	
Name: Initiation of Lab Investigation (Phase I) Last	Confirmation Date: 2019-08-06 13:54:30
Name. Laboratory investigation Conclusion (Pha	Expand all Print all
Related Items	
Secondary Tasks	
Name: Review Data from all[] Unique ID: Task-00	000001 Due: 2019-08-09 Status: Not Started View
	Expand all

Default Admin

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



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	Task > View			
Secondary Task listed in LIR-000003 brings up the Task Details screen for	Task Details			
	Name: Review Data from all previous Stability pulls			
that assigned Task.	Type: Task	Unique ID: Task-00000001		
LIR-00003 is listed as a Related Item	Description: Review Data from all previous Stability pu	Description: Review Data from all previous Stability pulls		
for that Task. To get healt to UD	Reference Date:			
for that lask. To get back to LIR-	Location: Root\LIR-000003 Process Task Group\Initiat	ion of Lab Investigation (Phase I) Task Group		
000003, the Reviewer can click on the	Estimated Start Day Offset: N/A	Estimated End Day Offset: N/A		
View option.	Estimated Start Date: N/A	Estimated End Date: 2019-08-09		
	Start Date: N/A	End Date: N/A		
	Status: Not Started			
	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 S Current Process Task: Laboratory Investigation Cor	Status: In Process nclusion (Phase I)	iew	

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.

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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**.



rocess > Laboratory Investigation Report > Laboratory Investigation Conclusion (Phase I) >	
Status: In Process	Process Actions
rocess Details	View
	Modify Values
hique ID: LIR-000003 Flowchart: Open	Reassign Tasks
Irrent Process Tasks: Laboratory Investigation Conclusion (Phase I)	Cancel
Welver	Email Link
rocess values	Move Out of Waiting
Process Tasks	
Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	Act on
Name: Laboratory Investigation Conclusion (Phase I)	Laboratory Investigation
Expand all Print all	Conci[]
rocess Task Form - Laboratory Investigation Conclusion (Phase I)	Related Items
	Link Documents
aboratory investigation Conclusion.	Link Processes
	Modify Description
	Remove Links
	Polated Information
as Lab Error Determined?:	
yes	Audit Irail
) No	Summary Report
Description of Error:	
Each of the fields in the Process Task F	orm
dentify Laboratory Probable will be displayed more clearly and	
will be displayed more clearly and	
described starting below.	
aboratory Root Cause Categories:	
Expand	
Niali 🔺	
- Material	
Material v	
Material	
Material	
Material	
Material	

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.

pratory Investigation Conclusion:	

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

Was Lab Error Determined?:	Was Lab Error Determined? is a Radio Button allowing for a selection of Yes or No, that
Yes	defaults to Yes . If No is selected, the following mandatory field is displayed and allows
O No	for up to 8000 characters.
	* Comment for Lab Error Not Determined:



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

* Description of Error:	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
Man Material Method Environment	Collapse 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.
* Laboratory Man Category:	Name: SOL095_Man_Category_List Status: Active ▼ Values: Man 1; Man 2; Man 3
* Laboratory Material Category:	▼ Name: SOL099_Material_Category_List Status: Active Values : Material 1 ; Material 2 ; Material 3
* Laboratory Method Category:	▼ Name: SOL102_Method_Category_List Status: Active Values: Method 1 ; Method 2 ; Method 3
* Laboratory Machine Category:	▼ Name: SOL094_Machine_Category_List Status: Active Values: Machine 1 ; Machine 2 ; Machine 3
* Laboratory Environment Category:	Name: SOL066_Environment_Category_List Status: Active Values : Environment 1 ; Environment 2 ; Environment 3

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

Secondary Tasks

annannan	плилаалавиллаалавиллаалавиллаалавиллаалавиллаалавиллаалавиллаалави
	Review Data from all previous Stability pulls
	Due Date: 2019-08-09 Type: Task
	Originator: solabssupport (Default Admin)
Modify	Remove
+A	DD

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

Initiating a Related Process

* Available Processes:	γ
Remove	
+ADD	
Related Processes	
Related Processes	
Available Processes:	\bigcirc
Available Processes:	
Related Processes Available Processes: * Initiator:	Related Processes
Related Processes:	Related Processes
Related Processes:	Related Processes
Related Processes:	Related Processes



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		
Secondary Tasks		
Name: Review Data from all[] Unique ID: Task-00000001 Due: 2019-08-09 Status: Not Starte	∍d	View
	Exp	pand all
Related Processes		
Unique ID: CAPA-000001 Date Initiated: 2019-08-07 Status: In Process Current Process Task: Initiation and CAPA Definition	View	Act on



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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**.

Document Control / Impacted Documents Document Control process required?: Yes No Document Control Process Relation: Dependent Process Related Process 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	
Secondary Tasks	
Name: Review Data from all[] Unique ID: Task-00000001 Due: 2019-08-09 Status: Not Sta	rted View
	Expand all
Related Processes	
Unique ID: CAPA-000001 Date Initiated: 2019-08-07 Status: In Process Current Process Task: Initiation and CAPA Definition	View Act on
Unique ID: DOC-000001 Date Initiated: 2019-08-07 Status: In Process Current Process Task: Change Request for Creation, Review or Withdrawal of Document	View Act on

Decision:

Advance to reviewer approval

Return to initiation

Comment:

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**.



		Page 16 01 41
The Process Details will list the Current Process Task		Status: In Process
and who it is Currently with	Process Details	
(the Assigned Reviewer selected at Step 1).	Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
	Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
he Process Flowchart will	Day(s) opened: 8	Date Closed : <empty></empty>
the process	Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
	Current Process Tasks Reviewer Approval	Currently with reviewer (reviewer)
	Flowchart: Open	
	Process Values	
	Process Tasks	
+	Initiation of Lab Investigation (Phase I) Las	t Confirmation Date: 2019-08-06 13:54:30
Step 3	Laboratory Investigation Conclusion (Phase	I) Last Confirmation Date: 2019-08-07 14:54:22
Assianed Reviewer identified in s	tep 1 - Reviewer Approval	
		Expand all Print all
	Related Items	
	Secondary Tasks	
	Name: Review Data from all[] Unique ID: Task-00	0000001 Due: 2019-08-09 Status: Not Started View
		Expand all
	Related Processes	
	Unique ID: CAPA-000001 Date Initiated: 2019-08- Current Process Task: Initiation and CAPA Definit	07 Status: In Process View Act on tion
	Unique ID: DOC-000001 Date Initiated: 2019-08-0 Current Process Task: Change Request for Creat	View Act on View Act on
		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.

ſ	Home > Views	
	PROCESSES	
	Received this week / last week	
	Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process Current Process Task: Reviewer Approval	View Act on



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.

Status: In Process	Process Actions
Process Details	View
- In the second se	Get Link
nique ID: LIR-000003 Flowchart: Open	Email Link
urrent Process Tasks: Reviewer Approval	Move Out of Waiting
Process Values	
	Act on
Process Tasks	Reviewer Approval
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	Related Items
Name: Reviewer Approval	Link Documents
Expand all Print all	Link Processes
Expand all Print all	Link Processes Modify Description
Expand all Print all Process Task Form - Reviewer Approval	Link Processes Modify Description Remove Links
Expand all Print all Process Task Form - Reviewer Approval	Link Processes Modify Description Remove Links
Expand all Print all Process Task Form - Reviewer Approval Decision:	Link Processes Modify Description Remove Links
Expand all Print all Process Task Form - Reviewer Approval Decision: Approve - Proceed to QA review	Link Processes Modify Description Remove Links Related Information Summary Report
Expand all Print all Process Task Form - Reviewer Approval Decision: Approve - Proceed to QA review Laboratory error confirmed (close process)	Link Processes Modify Description Remove Links Related Information Summary Report
Expand all Print all Process Task Form - Reviewer Approval Decision: Approve - Proceed to QA review Laboratory error confirmed (close process) Return for more information	Link Processes Modify Description Remove Links Related Information Summary Report
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?:	Link Processes Modify Description Remove Links Related Information Summary Report
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	Link Processes Modify Description Remove Links Related Informatic Summary Report
Expand all Print all Process Task Form - Reviewer Approval Decision: Approve - Proceed to QA review Laboratory error confirmed (close process) Return for more information Dese this potentially impact distributed product?: Yes No	Link Processes Modify Description Remove Links Related Informatic Summary Report
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:	Link Processes Modify Description Remove Links Related Informatic 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.



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Decision:

Approve - Proceed to QA review

- Laboratory error confirmed (close process)
- Return for more information

Does	this potentially impact distributed product?:
۲	Yes
\bigcirc	No
Com	ment:

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.





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	
PROCESSES	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process	View Act on

Process > Laboratory Investigation Report > QA Review > Act on-

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**.





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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.

'	* Event Type:		NOTE:	
		OOS OOT OOE	OOS = Out of Specification OOT = Out of Trend OOE = Out of Expectation	v

Is this a Recurring Event?:

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 #:		
	LIR	
Event Description:	LIR-000001 - ds - [In Process]	
	LIR-000002 - d - [In Process]	
	-	
Remove		
+ADD		

Event# is a mandatory, autocomplete, field that will bring up LIR processes that are present in the system with a status ≠ *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?:	
Yes	
No Assigned Manufacturing Investigator:	diane (Diane) gretchen (Gretchen) kathy (kathy)
	· · · · · · · · · · · · · · · · · · ·

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?:			
Yes	·		
○ No	erika (Erika)		
* Assigned Laboratory Investigator:	francis (Francis) karine (Karine)		
		יור	

I**s Laboratory** I**nvestigation 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.**





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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.

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

The Process Details will list the	Process Details			
Current Process Details with itst 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.	Name: Laboratory Investigation Unique ID: LIR-000003 Day(s) opened: 10 Secondary Tasks Completion Current Process Tasks Laboratory Investigation (Phase Manufacturing Investigation (Ph Flowchart: Open Process Values	Report Date Initia Date (%): 0 (0/1) Depe (%): 0 (0/1) Depe II) erika ase II) diane	Initiated: 2019-07-30 12:05:14 ted by: solabssupport (Default Admin) Closed : <empty> ndent Processes Completion (%) : 0 (0/ ently with (Erika) 9 (Diane)</empty>	/0)
TS Phase II Investigation Required? Yes	Process Tasks Name: Initiation of Lab Invest Name: Laboratory Investigation Name: Reviewer Approval L Name: QA Review Last Cor Name: Laboratory Investigat Name: Manufacturing Investigat	igation (Phase I) Last Confirm on Conclusion (Phase I) Last ast Confirmation Date: 2019 Ifirmation Date: 2019-08-09 1 tion (Phase II) tigation (Phase II)	mation Date: 2019-08-06 13:54:30 Confirmation Date: 2019-08-07 14:54:22 -08-08 17:03:14 14:27:29 Expand all	Print all
Step 5 Manufacturing Investigation (Phase II) Assigned Manuf, Investigator identified in step 4	Step 6 Laboratory Investigation (Phase II) Assigned Lab Investigator identified in step 4 Related Processes Unique ID: LIR-000001 Date Current Process Task: Labor Unique ID: CAPA-000001 Da Current Process Task: Initia Unique ID: DOC-000001 Date Current Process Task: Chai	.] Unique ID: Task-00000001 Initiated: 2019-07-15 Status: pratory investigation Conclusion te Initiated: 2019-08-07 Statu tion and CAPA Definition e Initiated: 2019-08-07 Status nge Request for Creation, Revi	Due: 2019-08-09 Status: Not Started Exp In Process n (Phase I) Is: In Process s: In Process ew or Withdrawal of Document Exp	View Dand all View View View Dand 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	
PROCESSES	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process Current Process Task: Manufacturing Investigation (Phase II)	View Act on

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.

-Tocess > Laboratory investigati	ion Repo <mark>rt > Manufacturing Investigation (Phase II) > Act on</mark>	
	Status: In Process	Process Actions
Process Details		View
Inique ID: LID: 000000	Elevebarti o	Get Link
	FlowChart. Open	Email Link
current Process Tasks: Laboratory	Investigation (Phase II); Manufacturing Investigation (Phase II)	Move Out of Waiting
Process Values		Act on
Process Tasks		Manufacturing
Name: Initiation of Lab Investigation	n (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	Investigation (P[]
Name: Laboratory Investigation Co	nclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22	Related Items
Name: Reviewer Approval Last C	onfirmation Date: 2019-08-08 17:03:14	Link Documents
Name: QA Review Last Confirma	ation Date: 2019-08-09 14:27:29	Link Processes
Name: Laboratory Investigation (Phase II)	Modify Description
Name: Manufacturing Investigation	on (Phase II)	Remove Links
	Expand all Print all	
		Related Informatio
Process Task Form - Manufa	acturing Investigation (Phase II)	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	icturing Investigation (Phase II)	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	ccturing Investigation (Phase II)	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Execution (Phase II)	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T	summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an	summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan: U Was Root Cause or Probable Roo Conclusion: Decision: Release tasks	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report
Process Task Form - Manufa Manufacturing Investigation Plan:	Each of the fields in the Process T Form is displayed more clearly an described on the next page.	Summary Report



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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:	
	 13

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

	•
* Manufacturing Cause Description:	
* Manufacturing Cause Categories:	
Man	Collapse
	Â
Method	
Machine	
Environment	
	Ψ
4	- F
Select all Deselect all	

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? is a Single-item Selection field with choices of Yes or No.

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

Decision:

Release tasks

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

- Request extension
- \bigcirc Investigation completed \cap
- 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.



```
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```

- 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:	
* 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.

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**.



Date Initiated: 2019-07-30 12:05:14 Initiated by: solabssupport (Default Admin) Date Closed: <empty> Dependent Processes Completion (%): 0 (0/0) Currently with erika (Erika</empty>
Initiated by: solabssupport (Default Admin) Date Closed : <empty> Dependent Processes Completion (%) : 0 (0/0) Currently with erika (Erika</empty>
Date Closed : <empty> Dependent Processes Completion (%) : 0 (0/0) Currently with erika (Erika</empty>
Dependent Processes Completion (%): 0 (0/0) Currently with erika (Erika)
Currently with erika (Erika)
qa (q a)
Confirmation Date: 2019-08-06 13:54:30
Last Confirmation Date: 2019-08-07 14:54:22
: 2019-08-08 17:03:14
08-09 14:27:29
Confirmation Date: 2010-08-13 00:51:10
Commution Date: 2013-00-13 03.31.10

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 Current Process Task: Manufacturing Extension Request Approval (1)	View Act on



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.

Process > Laboratory Act on	Investigation Report > Manufacturing Extension Request Approval (1) >	
	Status: In Process	Process Actions
Process Details		View
Jnique ID: LIR-000003	Flowchart: Open	Email Link
Current Process Tasks:	Laboratory Investigation (Phase II); Manufacturing Extension Request Approval (1)	Move Out of Waiting
Process Values		Act on
Process Tasks		Manufacturing Extension Reques[]
Name: Initiation of Lab	Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	
Name: Laboratory Inve	stigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22	Related Items
Name: Reviewer Appre	oval Last Confirmation Date: 2019-08-08 17:03:14	Link Documents
Name: QA Review La	st Confirmation Date: 2019-08-09 14:27:29	Link Processes
Name: Laboratory Inv	estigation (Phase II)	Modify Description
Name: Manufacturing	nvestigation (Phase II) Last Confirmation Date: 2019-08-13 09:51:10	Remove Links
Name: Manufacturing	Extension Request Approval (1)	Related Information
	Expand all Print all	Summary Report
Process Task Form	- Manufacturing Extension Request Approval (1)	
QA Extension Request A	pproval Decision:	
Approve		
Return for more in	formation	
Denied	to is to be undefed to the following date:	
2019-10-09		
Comments:		

• 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).



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

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 <u>will get</u> 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.

	Status: In Process	Process Actions
Process Details		View
	Floure and a	Get Link
Inique ID: LIR-000003	Flowchart: Open	Email Link
urrent Process Tasks: Laborate	ry Investigation (Phase II); Manufacturing Investigation (Phase II)	Move Out of Waiting
Process Values		Act on
Process Tasks		Laboratory Investigatio
Name: Initiation of Lab Investiga	tion (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	(Phas[]
Name: Laboratory Investigation	Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22	Related Items
Name: Reviewer Approval Las	t Confirmation Date: 2019-08-08 17:03:14	Link Documents
Name: QA Review Last Confin	mation Date: 2019-08-09 14:27:29	Link Processes
Name: Laboratory Investigation (Phase II)		Modify Description
Name: Manufacturing Investiga	ation (Phase II)	Remove Links
Name: Manufacturing Extension	Request Approval (1) Last Confirmation Date: 2019-08-13 11:07:35	
	Expand all Print all	Related Information
		Summary Report
Process Task Form - Labo	ratory Investigation (Phase II)	
Laboratory Investigation Plan:		
Laboratory Investigation Plan: Was Root Cause or Probable Ro	The Process Task Form fields will be displayed more clearly and describe starting on the next page.	e ed



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•

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:	For each category
	selected, another Single-
	item Selection field will
	be displayed for a more
	detailed Root Cause.
	The values for those
* Laboratory Cause Categories:	fields are configurable
Man	from shared Custom
Material	Lists maintained by the
Method	System Administrator
Machine	(refer to Page 13).
Environment	
4	
Select all Deselect all	A mandatory Conclusion
* Conclusion:	field (text area allowing
	up to 8000 characters) is
	up to about characters) is
	available when the
	Assigned Laboratory
	Investigator is ready.

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Decision:		
۲	Release tasks	
0	Request extension	
0	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	
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></empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks QA Approval of Investigation	Currently with 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) Last Co	nfirmation 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	
	Expand all Print all



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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	
PROCESSES	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process Current Process Task: QA Approval of Investigation	View Act on

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.



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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 Actions
Process Details		View
Unique ID: LIR-000003	Flowchart: Open	Get Link
Current Process Tasks: OA Anno	nval of Investigation	Email Link
current rocess tasks. Comppi	oval of investigation	Move Out of Waiting
Process Values		Act on
Process Tasks		QA Approval of
Name: Initiation of Lab Investigat	ion (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	investigation
Name: Laboratory Investigation C	Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22	Related Items
Name: Reviewer Approval Last	Confirmation Date: 2019-08-08 17:03:14	Link Documents
Name: QA Review Last Confirm	mation Date: 2019-08-09 14:27:29	Link Processes
Name: Laboratory Investigation (Phase II) Last Confirmation Date: 2019-08-13 11:48:49	Modify Description
Name: Manufacturing Investigation	on (Phase II) Last Confirmation Date: 2019-08-13 11:52:28	Remove Links
Name: Manufacturing Extension I	Request Approval (1) Last Confirmation Date: 2019-08-13 11:07:35	
Name: Laboratory Extension Reg	uest Approval (1) Last Confirmation Date: 2019-08-13 11:45:54	Related Informatio
Name: QA Approval of Investig	ation	Summary Report
	Expand all Print all	
	The Process Task Form fields will displayed more clearly and descr	be ibed
	The Process Task Form fields will displayed more clearly and descr	be ibed
Additional Lab Testing Needed?:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment: Decision:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment: Decision: Approve	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment: Decision: Approve Return for more information	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment: Decision: Approve Return for more information Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment: Decision: Approve Return for more information Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed
Additional Lab Testing Needed?: Yes No Lab Testing Comment: Decision: Approve Return for more information Comment:	The Process Task Form fields will displayed more clearly and descr starting on the next page.	be ibed

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.



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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 Need	ed?:
Yes	* Lab Testing Comment:
O No	

Additional Lab Testing Needed?:

Ves

Approve

Comment:

Return for more information

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.

\bigcirc	Yes	* Rationale for No Additional Lab Testing:
۲	No	
		•
Deci	sion:	

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 0 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)
 - o 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.

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.

<u>Home</u> > Views	
PROCESSES	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process Current Process Task: Additional Testing	View Act on

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.



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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**.

Cancel

Save Draft

Process > Laboratory Investigation Report > Additional Testing > Act on Status: In Process **Process Actions** Process Details View Modify Values Unique ID: LIR-000003 Flowchart: Open Reassion Tasks Current Process Tasks: Additional Testing Cancel Get Link Process Values Email Link Move Out of Waiting Process Tasks Name: Initiation of Lab Investigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30 Act on Name: Laboratory Investigation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22 Additional Testing Name: Reviewer Approval Last Confirmation Date: 2019-08-08 17:03:14 Name: QA Review Last Confirmation Date: 2019-08-09 14:27:29 Related Items Name: Laboratory Investigation (Phase II) Last Confirmation Date: 2019-08-13 11:46:49 Link Documents Name: Manufacturing Investigation (Phase II) Last Confirmation Date: 2019-08-13 11:52:28 Link Processes Name: Manufacturing Extension Request Approval (1) Last Confirmation Date: 2019-08-13 11:07:35 Modify Description Name: Laboratory Extension Request Approval (1) Last Confirmation Date: 2019-08-13 11:45:54 Remove Links Name: QA Approval of Investigation Last Confirmation Date: 2019-08-14 12:23:00 Name: Additional Testing Related Information Expand all Print all Audit Trail Summary Report Process Task Form - Additional Testing Attach Additional Testing Procotol(s) **Process Task Form fields are** Attach Additional Testing Report(s) Summary of Additional Testing Resu displayed more clearly and described T starting on the next page. Was Original Result(s) Confirmed?: Yes No Was Root Cause Identified? Decision Additional testing completed Request extension

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.

Submit



Summary of Additional Testing Results:

Page **34** of **41 Summary of Additional Testing Results** is a mandatory text area field allowing up to 8000 characters.

Was	Original Result(s) Confirmed?:
۲	Yes
\bigcirc	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	If Yes is selected, then Has root cause already been described? is
Has root cause already been described? : Yes	displayed. It is a Yes or No radio button selection that defaults to No .
* Additional Testing Root Cause Description:	With a selection of No , additional mandatory fields are displayed for Additional Testing Root Cause Description (8000-character text
* Additional Testing Root Cause Categories:	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).
Material Method Machine	A selection Yes for Has root cause already been described? requires no additional entries.
4 Select all Deselect all	
Decision: The Decis	ion 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.

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Additional testing completed

Request extension



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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 ExtApp6: 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

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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	
Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14
Unique ID: LIR-000003	Initiated by: solabssupport (Default Admin)
Day(s) opened: 16	Date Closed : <empty></empty>
Secondary Tasks Completion (%): 0 (0/1)	Dependent Processes Completion (%): 0 (0/0)
Current Process Tasks Interpretation of Investigation Results and R[]	Currently with qa (q a)
Flowchart: Open	
Process Values	Step 9 Interpretation of Investigation Results and Release Decision
Process Tasks	QA Approver Identified in step 1
Name: Initiation of Lab Investigation (Phase I)	•
Name: Laboratory Investigation Conclusion (Pha	DOC Processes move out of waiting 54:22
Name: Reviewer Approval Last Confirmation	
Name: QA Review Last Confirmation Date: 2	END
Name: Laboratory Investigation (Phase II) Last	Confirmation Date: 2019-08-13 11:46:49
Name: Manufacturing Investigation (Phase II) La	ast Confirmation Date: 2019-08-13 11:52:28
Name: Manufacturing Extension Request Approv	al (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 Confi	rmation Date: 2019-08-14 12:23:00
Name: Additional Testing Last Confirmation Da	ate: 2019-08-15 11:19:30
Name: Interpretation of Investigation Results a	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

Home > Views	
PROCESSES	
Received this week / last week	
Unique ID: LIR-000003 Date Initiated: 2019-07-30 Status: In Process Current Process Task: Interpretation of Investigation Results and Release Decision	View Act on

Page.



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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.

	Status: In Process	Process Actions
Process Details		View
rocess beaus		Get Link
Unique ID: LIR-000003	Flowchart: Open	Email Link
Current Process Tasks: I	nterpretation of Investigation Results and Release Decision	Move Out of Waiting
Process Values		Act on
Process Tasks		Interpretation of Investigatio[]
Name: Initiation of Lab In	vestigation (Phase I) Last Confirmation Date: 2019-08-06 13:54:30	
Name: Laboratory Investi	gation Conclusion (Phase I) Last Confirmation Date: 2019-08-07 14:54:22	Related Items
Name: Reviewer Approva	Last Confirmation Date: 2019-08-08 17:03:14	Link Documents
Name: QA Review Last	Confirmation Date: 2019-08-09 14:27:29	Link Processes
Name: Laboratory Investi	gation (Phase II) Last Confirmation Date: 2019-08-13 11:46:49	Modify Description
Name: Manufacturing Inv	estigation (Phase II) Last Confirmation Date: 2019-08-13 11:52:28	Remove Links
Name: Manufacturing Ex	ension Request Approval (1) Last Confirmation Date: 2019-08-13 11:07:35	Delated Information
Name: Laboratory Extens	ion Request Approval (1) Last Confirmation Date: 2019-08-13 11:45:54	Related Information
Name: QA Approval of In	vestigation Last Confirmation Date: 2019-08-14 12:23:00	Summary Report
Name: Additional Testing	Last Confirmation Date: 2019-08-15 11:19:30	
Name: Interpretation of	Investigation Results and Release Decision	
Name: Interpretation of	Investigation Results and Release Decision Expand all Print all	
Process Task Form - MRB Input Required?:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[]	
Process Task Form - MRB Input Required?: Yes No	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are	
Mame: interpretation of Process Task Form - MRB Input Required?: Yes No * MRB Summary:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are	
Mame: interpretation of Process Task Form - MRB Input Required?: Yes No MRB Summary:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described	
Mame: interpretation of Process Task Form - MRB Input Required?: Yes No * MRB Summary:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Mame: Interpretation of Process Task Form - MRB Input Required?: • Yes No * MRB Summary:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Mame: interpretation of Process Task Form - MRB Input Required?: • Yes • No • MRB Summary:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Name: Interpretation of Process Task Form - MRB Input Required?: Yes No MRB Summary: Result Type:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Anne: Interpretation of Process Task Form - MRB Input Required?: Yes No MRB Summary: Result Type:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Name: Interpretation of Process Task Form - MRB Input Required?: Yes No * MRB Summary: Result Type: Result Type: Release Decision:	Investigation Results and Release Decision Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Name: Interpretation of Process Task Form - MRB Input Required?: Yes No * MRB Summary: Result Type: * Release Decision:	Investigation Results and Release Decision Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	
Arme: interpretation of Process Task Form - MRB Input Required?: Yes No MRB Summary: Result Type: Release Decision:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page. v	
Name: Interpretation of Process Task Form - MRB Input Required?: Yes No * MRB Summary: Result Type: Release Decision:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page. v	
Name: Interpretation of Process Task Form - MRB Input Required?: Yes No * MRB Summary: Result Type: * Release Decision: * Rationale:	Investigation Results and Release Decision Expand all Print all Interpretation of Investigation Results and Release Dec[] Process Task Form fields are displayed more clearly and described starting on the next page.	



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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.



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.



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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.

Items section.	sõlabs CM	PROCESS DOCUME	ENT TRAINING		Process Menu
	Views Navigation	Process > Navigation			[
	Process Started Reset filters	Process Type:		•	
	Recent Items Expand	Currently with:		•	
	Pr: LIR-000003 X Pr: CAPA-000001 X Pr: DOC-000001 X	Status: any		T	
Pr: PC-000001 Pr: LIR-000002 Pr: LIR-000001	Pr: PC-000001 X Pr: LIR-000002 X Pr: LIR-000001 X	Process Started: This week/last week Last 3 months Last 6 months This weer			
		Custom Start Date:		End Date:	
		from: Filter	to:	from: to:	
Using the Pro	cess Values Table	Process Details		Stat	tus: Completed
Process Tasks can	be viewed by using	Name: Laboratory Inves	tigation Report	Date Initiated: 2019-07-30 12:05:14	
the Expand all or	Print all options at the	Unique ID: LIR-000003		Initiated by: solabssupport (Default Ad	min)
bottom of the Pro	ocess Values table.	Day(s) opened: 16		Date Closed: 2019-08-15 12:05:22	
An individual Proc	cess Task can be	Secondary Tasks Com	pletion (%): 100 (1/1)	Dependent Processes Completion (%): 0 (0/0)
expanded by click Process Values ta	ing on it within the ble.	Current Process Tasks		Currently with N/A	
Name: Reviewer Appr	oval Last Confirmation Dat	te: 2019-08-08 17:03:14			
Decision: Approve - Does this potentially Comment: N/A	Proceed to QA review impact distributed product?	?: No			
Sign-off by: reviewer	r (reviewer)		Investigation (Phase I) La	et Confirmation Date: 2019-08-06 13:54:30)
		Name: Reviewer Ann	roval Last Confirmation D	ate: 2019-08-08 17:03:14	4.04.22
		Name: QA Review L	ast Confirmation Date: 20	19-08-09 14:27:29	
		Name: Laboratory Inv	estigation (Phase II) Last C	Confirmation Date: 2019-08-13 11:46:49	
		Name: Manufacturing	Investigation (Phase II) La	st Confirmation Date: 2019-08-13 11:52:28)
		Name: Manufacturing	Extension Request Approva	al (1) Last Confirmation Date: 2019-08-13	11:07:35
		Name: Laboratory Ext	tension Request Approval (1) Last Confirmation Date: 2019-08-13 11:	45:54
		Name: QA Approval o	f Investigation Last Confin	mation Date: 2019-08-14 12:23:00	
		Name: Additional Test	ting Last Confirmation Da	te: 2019-08-15 11:19:30	
		Name: Interpretation	of Investigation Results and I	Releas Last Confirmation Date: 2019-0	08-15 12:05:22
November 2021				Expa	and all Print all

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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.

elated ite	ms	
Secondary	Tasks	
Name: Rev	iew Data from all[] Unique ID: Task-00000001 Due: 2019-08-09 Status: Completed	View
	Task Details	all
Related Do	Name: Review Data from all previous Stability pulls	
Namo: Tost	Type: Task Unique ID: Task-00000001	
Name. Test	Description: Review Data from all previous Stability pulls	ew
Name: Test	Reference Date:	ew
	Location: Root\LIR-000003 Process Task Group\Initiation of Lab Investigation (Phase I) Task Group	all
Related Pro	Estimated Start Day Offset: N/A Estimated End Day Offset: N/A	
	Estimated Start Date: N/A Estimated End Date: 2019-08-09	
Onique ID: Current Pro	Start Date: 2019-08-15 End Date: 2019-08-15	~
Unique ID:	Status: Completed	
Current Pro	Comments:	
Unique ID:		on
Current Pro	lask 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	iew

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.



Process Details		SOLARS de la Commune Osest State 330 Morrero, Quebo: 153 UYL, Cano 20 514 257, 1368 etc. 219 www.sciabh.com	solabs curring Present	
FIGUESS Details		LIR-000003		
Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:	Name: Laboratory Investigation Report	Date Initiated: 2019-07-30 12:05:14	
Unique ID: LIR-000003	Initiated by: solabssupport (De	Unique ID: LIR-000003 Day(s) opened: 16	Initiated by: solabssupport (Default Admin) Date Closed : 2019-08-15 12:05:22	
Day(s) opened: 0	Date Closed : 2019-08-15 12	Current Process Tasks:	Currently with:	
Secondary Tasks Completion (%): 100 (1/1)	Dependent Processes Compl			
Current Process Tasks	Currently with	Process Values		
N/A	N/A	Name:Initiation of Lab Investigation (Phase I) Last	t Confirmation Date: 2019-08-06 13:54:30	
Flowchart: Open		Unique ID: LIR-000003 Title: OOS Content Uniformity Testing Type: Sability Lot Number(p): A12345 Product/Matrial: p2 Part #: c2		
Process Details Process Values Table – Step 1 Only		Mater: Stage 3 Material Type 1 Strength/Dose: Strength 2 Packaging Configuration: Package 2 Description: Out of specification result for P2 Lot A	12345 at 15 month stability pull.	
		Date Result Obtained: 2019-08-05 Testing Site: Site 1		
Process values Table – All Steps		Manufacturing Stie; Stie; Z Comments: N/A Assigned Reviewer: reviewer (reviewer) Assigned QA Approver: qa (a)		
Process Secondary Tasks				
Dependent Processes		Sign-off by:solabssupport (Default Admin)		
Process Relationships (Other Related Items)		Name:Laboratory Investigation Conclusion (Phase I) Last Confirmation Date:2019-08-07 14:54:22	
Generate Repo	Cancel	Laboratory Investigation Conclusion: No lab error Was Lab Error Determined?: No Comment for Lab Error Not Determined: Laborat Decision: Advance to reviewer approval Comment: N/A	s - Phase II investigation will be required. tory data was reviewed and no laboratory errors were identified.	
November 2021		Sign-off by:solabssupport (Default Admin)		



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Using the Audit Trail

Users with the **SOLABS System Administrator** role assignment, will also see the **Audit Trail** option on the righthand **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 Irali		
Action Details: Process Completed Process Task Name: N/A Date: 2019-08-15 12:05:22 Role: N/A Username (Full Name): qa (qa) Reason for Change: N/A		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed Process Task Name: Laboratory Investigation (Phase II) Date: 2019-08-13 11:48:49 Role: N/A Username (Full Name): erika (Erika) Reason for Change: N/A		Print
Action Details: Task Performed Process Task Name: Laboratory Extension Request Approval (1) Date: 2019-08-13 11:45:54 Role: N/A Username (Full Name): qa (qa) Reason for Change: N/A		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed 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		Print
Action Details: Task Performed Process Task Name: Initiation of Lab Investigation (Phase I) Date: 2019-08-08 13:54:30 Role: N/A Username (Full Name): solabssupport (Default Admin) Reason for Change: N/A		Print
Action Details: Process Started Process Task Name: N/A Date: 2019-07-30 12:05:14 Role: N/A Username (Full Name): solabssupport (Default Admin)		Print
Reason for Change: N/A	Evened ell. Driet - "	16



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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

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-XXXXXXX 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-XXXXXXX 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
November 2021	Regards,
	Where LIR-XXXXXX is a hyperlink to the process