SOLABS QM10: Audit Process P0044 User Guide

October 2022

Introduction

Starting with Core Software Release 10.9, the Audit Process is now part of the QM Essentials package and will be available to all clients.

This document provides instructions on the use of the **SOLABS QM10 Audit Process APP P0044** – 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 is available in the Process User Functional Design Specification (PUFDS) document that can be found in the Public folder of the SOLABS eRoom.

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 can be assigned to different roles and/or users in the system, as appropriate. You take action on the step assigned to you. In the Audit Process, many of the steps are assigned to the same user but still maintained as separate steps to formally capture the different activities. 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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Audit Process Flowcharts

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

The flowchart shown at the right is available as part of the Process User Functional Design Specification (PUFDS) document.

The Flowchart shown below is available within the Process APP. As the process moves along, the active step in that Flowchart is highlighted.
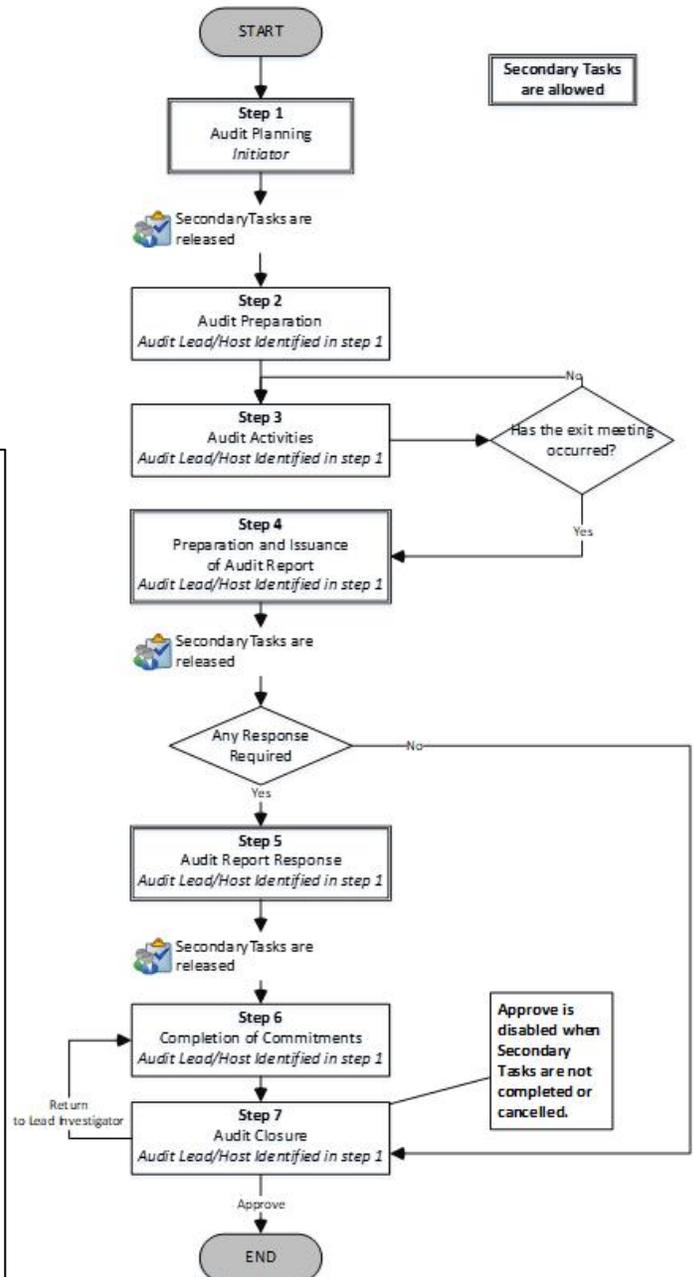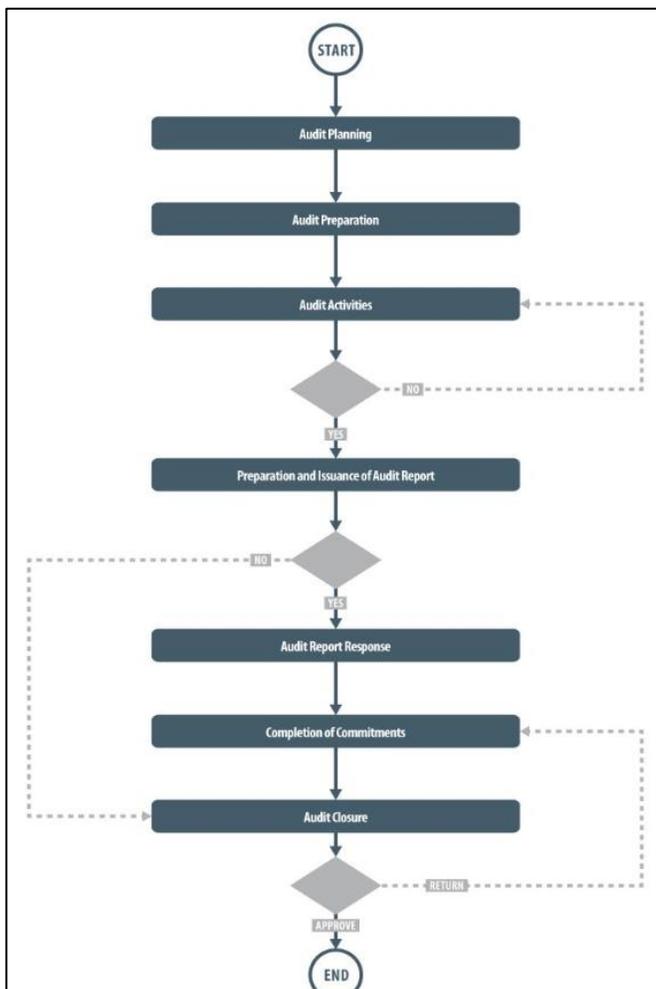
This User Guide is organized into sections for each of the Steps in the Audit Process. The flowchart section for each of those steps will be displayed in larger, more readable format within those sections.

Audit Process – Process Steps

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

Unlike other SOLABS QM Process APPs, there are no **Process Roles** to assign with the **Audit Process P0044.** An **Audit Lead/Host** is identified by the Initiator at Step 1 and will then be responsible for the remaining steps in the process. If the person initiating Step 1 will be the Audit Lead/Host, they can choose themselves.

Starting the Audit Process

From the PROCESS Section in SOLABS QM10, choose Start Process from the Quick Access Process Menu.
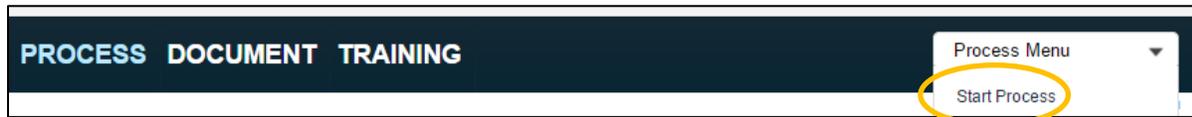
At the next screen, locate the listing for the Audit Process and click the blue START button.

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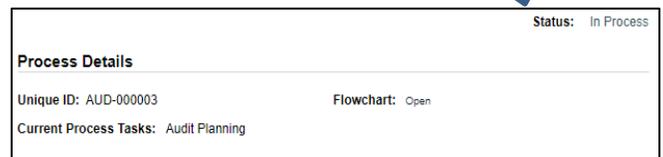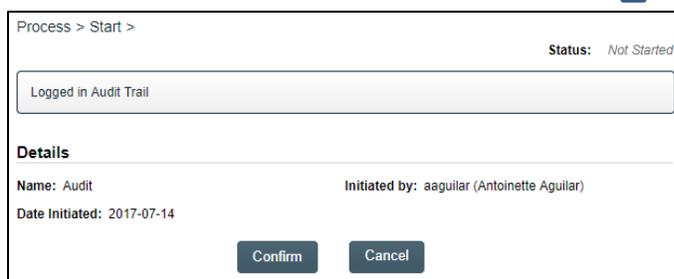
The first step on the **Process Flowchart** will now be highlighted when the flowchart is opened.

Step 1: Audit Planning

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

The fields on the **Process Task Form** are 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.

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

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

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

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

Completing the Process Task Form:

This sub-section covers the information required for each of the fields in the **Process Task Form** at **Audit Process Step 1**.

The **Audit Process ID** field will be automatically populated with the next available Audit number.

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

The **Audit Category** and **GxP Area** fields are mandatory. They are Single-item Selection fields with a pre-set list of values.

The **Audit Type** field is mandatory. It is a Multi-item Selection field populated from an **editable Custom List** of Audit Types that your SOLABS System Administrator can customize for your organization.

How will Audit be Conducted?, Site Being Audited and **Audit Performed By** are mandatory Single-item Selection fields populated from **editable Custom Lists** that your SOLABS System Administrator can customize for your organization.

Prior to Release 10.9 **How will Audit be Conducted?** allowed for just two set options – either *Questionnaire* or *On Site*. With Releases 10.9 those values and *Remote Audit* will be defaults but the values are editable.

Third Party Auditor is a Yes/No selection. If **Yes** is selected, additional mandatory free-text fields (up to 1024 characters) are displayed for the **Third Party Auditor Name** and the **Third Party Auditor Organization**.

The **Proposed Audit start Date** is a mandatory date field that can be populated directly or from a calendar. A Yes/No selection is then made for **Is Confirmation of the proposed audit date required?** If **Yes** is selected, a **Secondary Task** will automatically be created for that confirmation. See Page 7 below for information on Secondary Tasks.

The **Audit Lead/Host** field is mandatory. It is a Single-item Selection field that includes the list of SOLABS QM10 Active Users who have an Account Type of "Standard". The person chosen will be responsible for the remaining steps in the Audit Process. The initiator can choose themselves too.

The **Team Members** field is not mandatory. It is a Multi-item Selection field that includes the list of SOLABS QM10 Active Users who have an Account Type of "Standard". It also includes a selection of "Other". If "Other" is selected, then the field **Specify Team Member Name** is displayed.

The **Audit Purpose** and **Audit Scope** fields are mandatory text area fields (up to 4000 characters allowed) that can also be populated by **Quick Text.**

Quick Text lists are **editable Custom Lists** maintained by your SOLABS QM10 Administrator to be unique for your organization and provide consistency of related terminology.

Creating Secondary Tasks

The initiator of the Audit Process can create **Secondary Tasks** that will be associated with the Audit. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the Audit.

The **Secondary Task** section is underneath the Process Task Form, but still on the Audit Planning screen.

As mentioned above, if **Yes** was selected for the **Is Confirmation of the proposed audit date required?** field, a Secondary Task will automatically be created for that confirmation, with the **Originator** field defaulting to the person initiating Step 1 of the Audit Process. The mandatory fields for **Due Date**, **Assignee (Role)** and **Assignee (User)** will need to be populated with an appropriate date and assignee.

Another Secondary Tasks can be created be selecting **Secondary Task 1.**

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

Replace the text "Secondary Task 1" with an appropriate Title for the task.

The task **Type** can then be chosen from a drop-down list. Pre-Implementation tasks will need to be completed prior to Audit Closure.

The **Description** and **Due Date** fields are mandatory for each Task. Choose due dates appropriate to ensure tasks are completed in a time frame that supports on time Audit closure.

The **Originator** field will default to the User initiating the Audit 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 Audit closure.

To assign by **Role**, choose the appropriate Function Role from the list. All Users with that Role will then appear in the **Assignee (User)** drop-down list so that the appropriate person can be selected. To assign by **User**, choose the appropriate User from the list. Their Function Role will then appear in the **Assignee (Role)** drop-down list and must be selected.

The **+ADD** button can be used to create additional Secondary Tasks.

The Assignees will receive email Notifications and see the View/Act On options for their Secondary Tasks 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 Audit Step.

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Initiating a Related Process

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

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

Choose the **Process Relation** as either a **Dependent Process** (must be completed before the Audit 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 initiate both processes concurrently as the initiator.   The Audit process will then be the **Parent Process** of the new process being initiated.

If a Related Process was already initiated, separately from this Audit, 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.
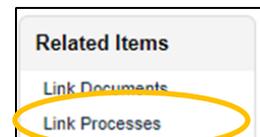
Whether linking an existing process or initiating a new one, the **Related Processes** will be listed in the **Related Items** section, along with any **Secondary Tasks** and **Related Documents**, when Audit **Step 1** is Submitted and Confirmed.

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Submit and Confirm

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

The Process Flowchart will highlight the next step of the process and the person chosen in **Step 1** as the **Audit Lead/Host** will be listed. The **Audit Lead/Host** will also receive an email Notification and will see the **Audit Preparation** task listed on their SOLABS QM10 HOME Page.

Step 2:   Audit Preparation

At this step in the Audit Process, the **Audit Lead/Host** chosen at Step 1 will receive an email Notification and will see their **Audit Preparation** task listed in the Process section of their SOLABS QM10 HOME Page. Even if the Lead Auditor was the one who initiated the process, they will receive a new email Notification so that activities for **Audit Preparation** are captured as a separate step.

Viewing the Audit Preparation Task

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

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

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In this example, clicking on View for a Secondary Task listed in AUD-000014 brings up the Task Details screen for that assigned Task.

AUD-000014 is listed as a **Related Item** for that Task. To get back to AUD-000014, the Reviewer can click on the **View** option.

Task Details

Name: Inform Internal Personnel of Planned Audit Date

Type: Task   **Unique ID:** Task-00000043

Description: Inform all internal personnel of this planned audit, since documentation is managed in all areas.

Reference Date: 09-Jul-2019

Location: Root\AUD-000014 Process Task Group\Audit Planning Task Group

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

Estimated Start Date: 09-Jul-2019   **Estimated End Date:** 12-Jul-2019

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

Status: Not Started

Comments:

Task Ownership

Originator: gdixson (Gretchen Dixson)

Assignee (Role): FCT_Documentation Coordinator

Assignee (User): jclark (Jaqueline Clark)

Related Items

Main Related Process
Unique ID: AUD-000014 **Date Initiated:** 16-Nov-2018 **Status:** In Process   View **Current Process Task:** Audit Preparation

Acting on the Audit Preparation Task

When the **Audit Lead/Host** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Audit Preparation** task.

As described above, the **Audit Lead/Host** can use the **Expand all** option under the Process Values table to see all information entered by the Initiator at Step 1.

The **Process Task Form** includes a multi-item selection field for **Completed Preparation Activities**, an editable text area for **Comments**, and a date field for the **Confirmed Audit Date**. Fields with an asterisk (*) are mandatory. More information on the use of these fields is provided starting on the next page.

The right-hand **Related Items** menu allows the **Audit Lead/Host** to **Link Documents** or **Link Processes**, if applicable. There is a section under the Process Task to initiate new **Related Processes**.

Process > Audit > Audit Preparation > Act on

Status: In Process

Process Details

Unique ID: AUD-000014   **Flowchart:** Open

Current Process Tasks: Audit Preparation

Process Values

Process Tasks
Name: Audit Planning   **Last Confirmation Date:** 09-Jul-2019 15:53:08
Name: Audit Preparation

Expand all   Print all

Process Task Form - Audit Preparation

* Completed Preparation Activities:

☐ Activities 1   Expand
☐ Activities 2

Comments:

* Confirmed Audit Date:

[   ] 📅   Clear

Secondary Tasks

☑ Obtain Audit Confirmation
  Due Date: 12-Jul-2019   Type: Task
  Originator: gdixson (Gretchen Dixson)
Modify Remove

☑ Inform Internal Personnel of Planned Audit Date
  Due Date: 12-Jul-2019   Type: Task
  Originator: gdixson (Gretchen Dixson)
Modify Remove

+ADD

Related Processes

☐ * Available Processes:
  ----- ▼

Process Actions
View
Get Link
Email Link
Move Out of Waiting

Act on
Audit Preparation

Related Items
Link Documents
Link Processes
Modify Description
Remove Links

Related Information
Summary Report

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

Initiation of Secondary Tasks or a Document Control Process is not allowed at Step 2.

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

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

Completed Preparation Activities is a Multi-item Selection field of values from an editable Custom List. The option "Other" is also included. If "Other" is selected, the mandatory **Specify Other Activity** text field (up to 1024 characters) is displayed.

There is an optional text area field for **Comments**, that allows up to 4000 characters.

The **Confirmed Audit Date** field is mandatory and is populated from a calendar.

When Step 2 is Submitted and Confirmed, the Audit Process moves to **Step 3: Audit Activities**.   It stays assigned to the **Audit Lead/Host**.

The Process Flowchart will highlight the next step of the process. The **Audit Lead/Host** will also receive an email Notification and will see the **Audit Activities** task listed on their SOLABS QM10 HOME Page.

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Step 3:   Audit Activities

At this step in the Audit Process, the **Audit Lead/Host** chosen at Step 1 will receive an email Notification and will see their **Audit Activities** task listed in the Process section of their SOLABS QM10 HOME Page. Even if the Lead Auditor was the one who initiated the process, they will receive a new email Notification so that activities for **Audit Activities** are captured as a separate step.
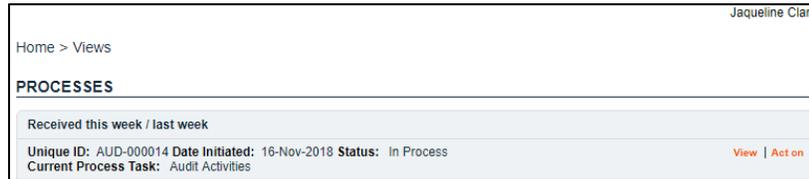
Viewing the Audit Activities Task

If the Audit Lead/Host 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 Audit Activities Task

When the **Audit Lead/Host** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Audit Activities** task.

As described above, the **Audit Lead/Host** 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 ability to add daily summaries and to indicate when the final exit meeting has occurred. These are described in more detail on the next page.

The right-hand **Related Items** menu allows the **Audit Lead/Host** to **Link Documents** or **Link Processes**, if applicable. There is a section under the Process Task to initiate new **Related Processes**.

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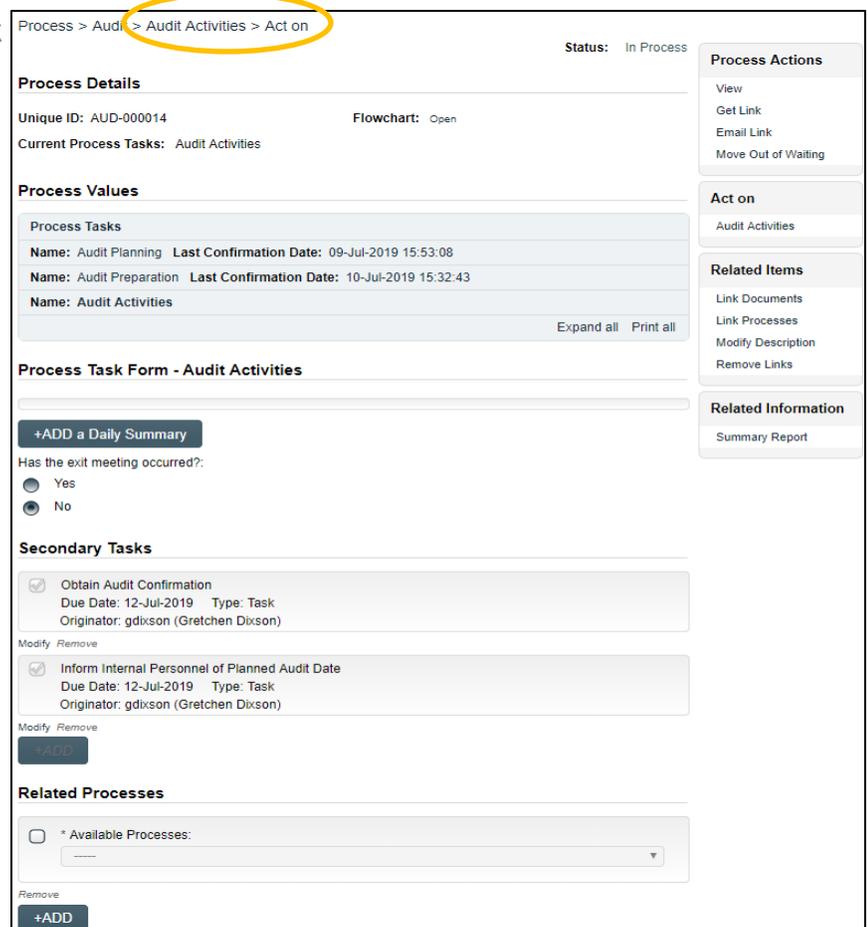
Refer to the separate document **SOLABS QM10: Introduction to PROCESS Section** for information on use of the **right-hand menus** since they are common to all SOLABS QM Process APPs.

Initiation of Secondary Tasks or a Document Control Process is not allowed at Step 3.

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

Submit	Save Draft	Cancel

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

The **Process Task Form** for the **Audit Activities** step includes a **+ADD a Daily Summary** button.   Each time the button is clicked, the following group of fields is displayed above it.

+ADD a Daily Summary

Date of the Daily Summary is a mandatory date field that is populated from a calendar.

Summary of the day is a mandatory text area allowing for 4000 characters.

Purpose of the meeting is a set of radio buttons allowing for choice of **Daily**, **Close** or **Other**. It defaults to Daily.

Summary of the meeting is a mandatory text area allowing for 4000 characters.

Preliminary Findings is an optional text area allowing for 4000 characters.

Has the exit meeting occurred? Is a set of radio buttons allowing for a **Yes** or **No** selection. It defaults to No.   If No is selected, the Audit Process will stay at **Step 3 – Audit Activities** to allow continued addition of Daily information.

If **Yes** is selected, the Audit Process will progress to **Step 4 – Preparation and Issuance of Audit Report** upon submission and confirmation of Step 3.

The process stays assigned to the **Audit Lead/Host** for Step 4.

The Process Flowchart will highlight the next step of the process. The **Audit Lead/Host** will also receive an email Notification and will see the **Preparation and Issuance of Audit Report** task listed on their SOLABS QM10 HOME Page.

Process Details

Name: Audit	Date Initiated: 16-Nov-2018 13:24:05
Unique ID: AUD-000014	Initiated by: gdixson (Gretchen Dixson)
Day(s) opened: 237	Date Closed : *<empty>*
Secondary Tasks Completion (%): 100 (2/2)	Dependent Processes Completion (%) : 0 (0/0)

Current Process Tasks	Currently with
Preparation and Issuance of Audit Report	jclark (Jaqueline Clark)

Flowchart: Open

Process Values

Process Tasks

Name: Audit Planning Last Confirmation Date: 09-Jul-2019 15:53:08

Name: Audit Preparation Last Confirmation Date: 10-Jul-2019 15:32:43

Name: Audit Activities Last Confirmation Date: 11-Jul-2019 16:05:22

Name: Preparation and Issuance of Audit Report

Expand all   Print all

Related Items

Secondary Tasks

Name: Obtain Audit Confirm[...] Unique ID: Task-00000042 Due: 12-Jul-2019 Status: Completed   View

Name: Inform Internal Pers[...] Unique ID: Task-00000043 Due: 12-Jul-2019 Status: Completed   View

Step 4:   Preparation and Issuance of Audit Report

At this step in the Audit Process, the **Audit Lead/Host** chosen at Step 1 will receive an email Notification and will see their **Preparation and Issuance of Audit Report** task listed in the Process section of their SOLABS QM10 HOME Page. Even if the Lead Auditor was the one who initiated the process, they will receive a new email Notification so that activities for **Preparation and issuance of Audit Report** are captured as a separate step.

Jaqueline Clark

Home > Views

PROCESSES

Received this week / last week

Unique ID: AUD-000014 Date Initiated: 16-Nov-2018 Status: In Process   View | Act on
Current Process Task: Preparation and Issuance of Audit Report

Viewing the Preparation and Issuance of Audit Report Task

If the Audit Lead/Host 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 Preparation and Issuance of Audit Report Task

When the **Audit Lead/Host** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Preparation and Issuance of Audit Report** task.

As described above, the **Audit Lead/Host** 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 summarize the outcome of the audit. These are described in more detail on the next page.

The right-hand **Related Items** menu allows the **Audit Lead/Host** 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 and Related Processes can be initiated at Step 4 but initiation of a Document Control Process is not allowed.

Process > Audit > Preparation and Issuance of Audit Report > Act on

Status: In Process

Process Details

Unique ID: AUD-000014   Flowchart: Open

Current Process Tasks: Preparation and Issuance of Audit Report

Process Values

Process Tasks
Name: Audit Planning   Last Confirmation Date: 09-Jul-2019 15:53:08
Name: Audit Preparation   Last Confirmation Date: 10-Jul-2019 15:32:43
Name: Audit Activities   Last Confirmation Date: 11-Jul-2019 16:05:22
Name: Preparation and Issuance of Audit Report

Expand all   Print all

Process Task Form - Preparation and Issuance of Audit Report

* Audit Report Attached:
----- ▼

* Audit Report Date:
[   ] 📅   Clear

Is Confirmation of the audit report reception required?:
◉ Yes
○ No

Are Responses Required?:
◉ Yes
○ No

* Date Responses Due:
[   ] 📅   Clear

* Executive Summary:
[   ]

Finding Summary
* Number of Critical Findings:
[   ]

* Number of Major Findings:
[   ]

* Number of Minor Findings:
[   ]

* Number of Comments:
[   ]

Comments:
[   ]

Process Actions
View
Get Link
Email Link
Move Out of Waiting

Act on
Preparation and Issuance of Au[...]

Related Items
Link Documents
Link Processes
Modify Description
Remove Links

Related Information
Summary Report

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* Audit Report Attached:

```
------                                                              ▼
```

* Audit Report Date:

```
[          ] [📅]   Clear
```

The **Audit Report Attached** field is a mandatory single-item selection field with values or **Yes** or **No**. If **No** is selected, a mandatory text area is displayed, allowing for up to 4000 characters. The Audit Report can be attached a a Related Items using the right-hand Link Documents menu option.

* Audit Report Attached:

```
No
```

* Justification:

```
[                    ]
```

The mandatory **Audit Report Date** field can be populated by a calendar.

Is Confirmation of the audit report reception required?:

◉ Yes

◯ No

Is Confirmation of the audit report reception required? is a radio button allowing for choices or **Yes** or **No**, and defaulting to **Yes**.   When the choice is **Yes**, a Secondary Task is automatically created for this activity.

☑ Obtain Confirmation of Audit Report Reception

Type:

```
Task                                                                ▼
```

* Description:

```
Send Letter confirming Audit Report Reception
```

* Due Date:

```
[          ] [📅]
```

Originator:

```
jclark (Jaqueline Clark)
```

* Assignee (Role):

```
------                                                              ▼
```

* Assignee (User):

```
------                                                              ▼
```

Are Responses Required?:

◉ Yes

◯ No

* Date Responses Due:

```
[          ] [📅]   Clear
```

Are Responses Required? is a radio button allowing for choices or **Yes** or **No**, and defaulting to **Yes**.   When the choice is **Yes**, a mandatory **Date Responses Due** field can be populated using a calendar.

When a **Yes** choice is selected, the Audit process will move to **Step 5 – Audit Report Responses** upon confirmation of Step 4. When **No** is selected, the process will move to **Step 7 – Audit Closure** upon confirmation of Step 4.

The following fields provide entry of information to summarize the Audit.   The **Executive Summary** is a text area allowing for up to 4000 characters. The **Finding Summary** section includes mandatory fields for **Number of Critical Findings**, **Number of Major Findings**, **Number of Minor Findings** and **Number of Comments**.   There is also an optional **Comments** field.

* Executive Summary:

Finding Summary
* Number of Critical Findings:

* Number of Major Findings:

* Number of Minor Findings:

* Number of Comments:

Comments:

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

Submit   Save Draft   Cancel

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

Since **Yes** was selected at Step 4 for **Audit Responses Required**, the Audit Process moves to **Step 5 – Audit Report Response**.

The Process Flowchart will highlight the next step of the process. The **Audit Lead/Host** will also receive an email Notification and will see the **Audit Report Response** task listed on their SOLABS QM10 HOME Page.

Step 5: Audit Report Response

At this step in the Audit Process, the **Audit Lead/Host** chosen at Step 1 will receive an email Notification and will see their **Audit Report Response** task listed in the Process section of their SOLABS QM10 HOME Page. Even though they have been assigned most steps in the process, they will receive a new email Notification so that activities for the **Audit Report Response** are captured as a separate step.

Viewing the Audit Report Response Task

If the Audit Lead/Host clicks on the View option to the right of the Process Task, they will get the same screen shown 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 Audit Report Response Task

When the **Audit Lead/Host** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Audit Report Response** task. As described above, the **Audit Lead/Host** 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 Audit Report Response. These are described in more detail on the next page.

The right-hand **Related Items** menu allows the **Audit Lead/Host** 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 and Related Processes can be initiated at Step 5 but initiation of a Document Control Process is not allowed.

Process > Audit > Audit Report Response > Act on

Status: In Process

Process Details

Unique ID: AUD-000014   Flowchart: Open

Current Process Tasks: Audit Report Response

Process Values

Process Tasks

Name: Audit Planning   Last Confirmation Date: 09-Jul-2019 15:53:08

Name: Audit Preparation   Last Confirmation Date: 10-Jul-2019 15:32:43

Name: Audit Activities   Last Confirmation Date: 11-Jul-2019 16:05:22

Name: Preparation and Issuance of Audit Report   Last Confirmation Date: 12-Jul-2019 15:56:53

Name: Audit Report Response

Expand all   Print all

Process Actions

View

Get Link

Email Link

Move Out of Waiting

Act on

Audit Report Response

Related Items

Link Documents

Link Processes

Modify Description

Remove Links

Related Information

Summary Report

Process Task Form - Audit Report Response

☐ * All Responses accepted

Date All Response Accepted:

[_____] [📅]   Clear

Date the Audit Response Letter Sent:

[_____] [📅]   Clear

Date the Acknowledgement Letter Received:

[_____] [📅]   Clear

Is tracking of any audit commitments required?:

◉ Yes

○ No

Create a Secondary task for each commitment

Is a CAPA required?:

◉ Yes

○ No

* Description of CAPA:

[_____]

* CAPA #:

[_____]

These two fields are displayed only if the **Audit Category at Step 1** was selected as one of the following:

- Regulatory Inspection
- Internal Audit
- Partner/Customer Audit

The field **Date Acceptability of Audit Response Letter Sent** is displayed instead if the **Audit Category at Step 1** was one of the following:

- Regulatory Inspection of Partner/Supplier
- Supplier Audit

Date Acceptability of Audit Response Letter Sent:

[_____] [📅]   Clear

When dates are entered, messages will appear in red as a reminder to attach the applicable letters.

Date Acceptability of Audit Response Letter Sent:

[25-Jul-2019] [📅]   Clear

Attach Acceptability of Audit Response Letter

Date the Audit Response Letter Sent:

[18-Jul-2019] [📅]   Clear

Attach Audit Response Letter

Date the Acknowledgement Letter Received:

[23-Jul-2019] [📅]   Clear

Attach Acknowledgement Letter

Is tracking of any audit commitments required? is a **Yes** or **No** radio button selection. The choice defaults to **Yes**. When **Yes** is selected, a message will appear in red below the radio buttons as a reminder to create Secondary Tasks for each commitment.

Is CAPA required? is a radio button selection with three possible selections. The choice defaults to **Yes, initiated in SOLABS QM10** if a CAPA Process is deployed in the instance of SOLABS QM.

If there is not a CAPA Process deployed in the instance of SOLABS QM, that option is grayed and the default is **Yes, initiated outside SOLABS QM.**

If **No** is selected, there are no other fields displayed.

When the selection is **Yes, initiated in SOLABS QM**, Step 5 will not be able to be Submitted until a CAPA is initiated from within the Audit Process using the **Related Processes** section. The Submit button will be grayed out:

The new CAPA can be chosen as **Dependent** or **Related**. The Audit Process will be the Parent Process to the new CAPA.

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

When Step 5 is Submitted and Confirmed, the Audit Process will progress to **Step 6 – Completion of Commitments.**

The Process Flowchart will highlight the next step of the process. The **Audit Lead/Host** will also receive an email Notification and will see the **Completion of Commitments** task listed on their SOLABS QM10 HOME Page.

Step 6: Completion of Commitments

At this step in the Audit Process, the **Audit Lead/Host** chosen at Step 1 will receive an email Notification and will see their **Completion of Commitments** task listed in the Process section of their SOLABS QM10 HOME Page. Even though they have been assigned most steps in the process, they will receive a new email Notification so that activities for the **Completion of Commitments** are captured as a separate step.

Jaqueline Clark
Home > Views
PROCESSES
Received this week / last week
Unique ID: AUD-000014 **Date Initiated:** 16-Nov-2018 **Status:** In Process   View │ Act on   **Current Process Task:** Completion of Commitments

Viewing the Completion of Commitments Task

If the Audit Lead/Host 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 Completion of Commitments Task

When the **Audit Lead/Host** clicks on the **Act on** option to the right of the Process Task, they will go immediately to the Act on screen for their **Completion of Commitments** task. As described above, the **Audit Lead/Host** can use the **Expand all** option under the Process Values table to see all information entered in prior steps.

There is a mandatory **Comments** field to provide any information on the progress of the commitments.

No Secondary Tasks or Document Control Process can be initiated at Step 6.

Upon Submission/Confirmation of step 6, the Audit Process moves to **Step 7 – Audit Closure**.

Process > Audit > Completion of Commitments > Act on

Status: In Process

Process Details

Unique ID: AUD-000014   **Flowchart:** Open

Current Process Tasks: Completion of Commitments

Process Values

Process Tasks
Name: Audit Planning **Last Confirmation Date:** 09-Jul-2019 15:53:08
Name: Audit Preparation **Last Confirmation Date:** 10-Jul-2019 15:32:43
Name: Audit Activities **Last Confirmation Date:** 11-Jul-2019 16:05:22
Name: Preparation and Issuance of Audit Report **Last Confirmation Date:** 12-Jul-2019 15:56:53
Name: Audit Report Response **Last Confirmation Date:** 26-Jul-2019 11:18:42
Name: Completion of Commitments
Expand all   Print all

Process Task Form - Completion of Commitments

* Comments:

The Process Flowchart will highlight the next step of the process. The **Audit Lead/Host** will also receive an email Notification and will see the **Audit Closure** task listed on their SOLABS QM10 HOME Page.

Step 7: Audit Closure

At this step in the Audit Process, the **Audit Lead/Host** chosen at Step 1 will receive an email Notification and will see the **Audit Closure** task listed in the Process section of their SOLABS QM10 HOME Page. Even though they have been assigned most steps in the process, they will receive a new email Notification so that activities for the **Audit Closure** are captured as a separate step.

Viewing the Audit Closure Task

If the Audit Lead/Host clicks on the View option to the right of the Process Task, they <u>will get the same screen shown above</u>.

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 Audit Closure Task

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

There is an optional **Comments** field to provide any information on the progress of the commitments.

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

If there are any Secondary Tasks that are not yet completed or cancelled, the **Approve** option will be grayed out and the statement *All prerequisite secondary tasks are not completed* will be displayed in red. In that case the only **Decision** option is **Return to Lead Auditor** and a mandatory **Reason** field is displayed.

When the **Return to Lead Auditor** decision is submitted/confirmed, the Audit Process will move back to **Step 6 – Completion of Commitments** (see Page 22).
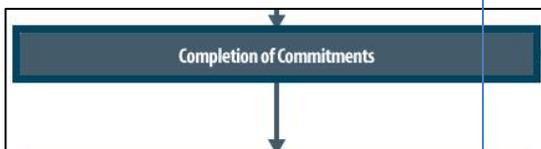
Process Details

Unique ID: AUD-000010   Flowchart: Open

Current Process Tasks: Audit Closure

Process Values

Process Tasks
Name: Audit Planning   **Last Confirmation Date:** 26-Jul-2019 13:02:09
Name: Audit Preparation   **Last Confirmation Date:** 26-Jul-2019 13:02:51
Name: Audit Activities   **Last Confirmation Date:** 26-Jul-2019 13:05:29
Name: Preparation and Issuance of Audit Report   **Last Confirmation Date:** 26-Jul-2019 13:10:04
Name: Audit Report Response   **Last Confirmation Date:** 29-Jul-2019 12:53:50
Name: Completion of Commitments   **Last Confirmation Date:** 29-Jul-2019 12:54:28
Name: Audit Closure

Expand all   Print all

Process Task Form - Audit Closure

Comments:

Decision:
- ○ Approve
- ● Return to Lead Auditor

All prerequisite secondary tasks are not completed.

* Reason:

Status: In Process

Process Details

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

Name: Audit   Date Initiated: 16-Nov-2018 13:24:05

Unique ID: AUD-000014   Initiated by: gdixson (Gretchen Dixson)

Day(s) opened: 255   Date Closed : *<empty>*

Secondary Tasks Completion (%): 33 (2/6)   Dependent Processes Completion (%) : 0 (0/0)

Act on
- Completion of Commitments

Current Process Tasks	Currently with
Completion of Commitments	jclark (Jaqueline Clark)

Flowchart: Open

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

Process Values

Process Tasks
Name: Audit Planning   **Last Confirmation Date:** 09-Jul-2019 15:53:08
Name: Audit Preparation   **Last Confirmation Date:** 10-Jul-2019 15:32:43
Name: Audit Activities   **Last Confirmation Date:** 11-Jul-2019 16:05:22
Name: Preparation and Issuance of Audit Report   **Last Confirmation Date:** 12-Jul-2019 15:56:53
Name: Audit Report Response   **Last Confirmation Date:** 26-Jul-2019 11:18:42
Name: Completion of Commitments
Name: Audit Closure   **Last Confirmation Date:** 29-Jul-2019 13:06:53

Related Information
- Summary Report

Expand all   Print all

Completion of Commitments

If all Secondary Tasks are completed when the Process moves from Step 6 to Step 7, the **Approve** option will be available in the **Decision** section. The Decision of **Return to Lead Auditor** is also available.

When the Decision of Approve is selected, no additional fields are required.

Process Task Form - Audit Closure

Comments:

Decision:
- ◉ Approve
- ○ Return to Lead Auditor

Decision:
- ○ Approve
- ◉ Return to Lead Auditor

* Reason:

The Audit Process will then move to a status of Completed.

Status: Completed

Viewing Details for a Completed Audit Process

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

PROCESS DOCUMENT TRAINING

Jaqueline Clark

Views | Navigation

Process Started
Reset filters

Recent Items | Expand
Pr: AUD-000014 ✗
Pr: CC-000031 ✗
Pr: DOC-000043 ✗
Pr: AUD-000007 ✗
Pr: AUD-000009 ✗
Pr: DOC-000038 ✗
F: Packaging Components ✗

Process > Navigation

Process Type:
All

Currently with:
any

Status:
any

Process Started:
- ◉ This week/last week
- ○ Last 3 months
- ○ Last 6 months
- ○ This year
- ○ Last year
- ○ Custom

Start Date:
from: to:

End Date:
from: to:

Filter

Using the Process Values Table

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

Status: Completed

Process Details

Name: Audit

Unique ID: AUD-000014

Day(s) opened: 255

Secondary Tasks Completion (%): 100 (6/6)

Current Process Tasks
N/A

Flowchart: Open

Date Initiated: 16-Nov-2018 13:24:05

Initiated by: gdixson (Gretchen Dixson)

Date Closed : 29-Jul-2019 13:21:46

Dependent Processes Completion (%) : 0 (0/0)

Currently with
N/A

Process Values

Process Tasks
Name: Audit Planning   Last Confirmation Date: 09-Jul-2019 15:53:08
Name: Audit Preparation   Last Confirmation Date: 10-Jul-2019 15:32:43
Name: Audit Activities   Last Confirmation Date: 11-Jul-2019 16:05:22
Name: Preparation and Issuance of Audit Report   Last Confirmation Date: 12-Jul-2019 15:56:53
Name: Audit Report Response   Last Confirmation Date: 26-Jul-2019 11:18:42
Name: Completion of Commitments   Last Confirmation Date: 29-Jul-2019 13:21:21
Name: Audit Closure   Last Confirmation Date: 29-Jul-2019 13:21:46

Expand all   Print all

Using the Related Items Table

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

Related Items

Secondary Tasks	
Name: Obtain Audit Confirm[...] Unique ID: Task-00000042 Due: 26-Jul-2019 Status: Completed	View
Name: Inform Internal Pers[...] Unique ID: Task-00000043 Due: 26-Jul-2019 Status: Completed	View
Name: Obtain Confirmation [...] Unique ID: Task-00000046 Due: 14-Aug-2019 Status: Completed	View
Name: Tracking of Audit Co[...] Unique ID: PRE-00000039 Due: 31-Aug-2019 Status: Completed	View

Task Details

Name: Tracking of Audit Commitment for Major Finding

Type: Pre-Implementation   Unique ID: PRE-00000039

Description: Tracking of Audit Commitment for Major Finding

Reference Date: 26-Jul-2019

Location: Root\AUD-000014 Process Task Group\Audit Report Response Task Group

Estimated Start Day Offset: 0   Estimated End Day Offset: 36

Estimated Start Date: 26-Jul-2019   Estimated End Date: 31-Aug-2019

Start Date: 29-Jul-2019   End Date: 29-Jul-2019

Status: Completed

Comments:

Task Ownership

Originator: jclark (Jaqueline Clark)

Assignee (Role): FCT_Auditor - QA Compliance

Assignee (User): csanders (Christina Sanders)

Related Items

Main Related Process	
Unique ID: AUD-000014 Date Initiated: 16-Nov-2018 Status: Completed	View
Current Process Task: *N/A*	

-2019 Status: Completed View
-2019 Status: Completed View
Expand all
& Effective   Open | View
Approved &   Open | View
Approved &   Open | View
Expand all
ss   View
Collapse all

October 2022

Creating a Summary Report

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

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

Related Information

Audit Trail

Summary Report

Status: Completed

Process Details

Name: Audit

Unique ID: AUD-000014

Day(s) opened: 0

Secondary Tasks Completion (%): 100 (6/6)

Current Process Tasks
N/A

Flowchart: Open

Date Initiated: 16-Nov-2018 13:24:05

Initiated by: gdixson (Gretchen Dixson)

Date Closed : 29-Jul-2019 13:21:46

Dependent Processes Completion (%) : 0 (0/0)

Currently with
N/A

Print Out Options

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

Generate Report

---

1 GDP Boulevard
Burlington, VT
05401
USA
1-802-123-4567
1-800-123-4567
www.gdpmp.com

:::GDP

AUD-000014

Name: Audit

Unique ID: AUD-000014

Day(s) opened: 255

Secondary Tasks Completion (%): 100 (6/6)

Current Process Tasks:
N/A

Date Initiated: 16-Nov-2018 13:24:05

Initiated by: gdixson (Gretchen Dixson)

Date Closed : 29-Jul-2019 13:21:46

Dependent Processes Completion (%) : 0 (0/0)

Currently with:
N/A

Process Values

Name: Audit Planning   **Last Confirmation Date:**09-Jul-2019 15:53:08

Audit Process ID:AUD-000014
Title: Internal Audit - Documentation Systems
Audit Category: Internal Audit
GxP Area: Good Manufacturing Practices (GMP)
Audit Type: Type 2
How will Audit be Conducted?: On Site
Site Being Audited: Site 1
Audit Performed By: Performed By 1
Third Party Auditor: Yes
Third Party Auditor Name: John Smith
Third Party Auditor Organization:JS Auditing, LLC
Proposed Audit Start Date: 31-Jul-2019
Is Confirmation of the proposed audit date required?: Yes
Audit Lead/Host: jclark (Jaqueline Clark)
Team Members: gdixson (Gretchen Dixson) ; csanders (Christina Sanders)
Audit Purpose: Purpose 1
Audit Scope: Scope 1
Sign-off by:gdixson (Gretchen Dixson)

Name: Audit Preparation   **Last Confirmation Date:**10-Jul-2019 15:32:43

Completed Preparation Activities: Activities 1; Activities 2
Comments: N/A
Confirmed Audit Date: 31-Jul-2019
Sign-off by:jclark (Jaqueline Clark)

Printed by: Gretchen Dixson on 29-Jul-2019 14:07:02 / © SOLABS 2010+   Page 1 of 6

Using the Audit Trail

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

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

Related Information

Audit Trail

Summary Report

Process > AUD-000014 > Audit Trail

Process Name: AUD-000014

Action Details: Process Completed   Print
Process Task Name: N/A
Date: 29-Jul-2019 13:21:46
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Audit Closure
Date: 29-Jul-2019 13:21:46
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Completion of Commitments
Date: 29-Jul-2019 13:21:21
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Audit Closure
Date: 29-Jul-2019 13:06:53
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Completion of Commitments
Date: 26-Jul-2019 16:45:51
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Audit Report Response
Date: 26-Jul-2019 11:18:42
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Preparation and Issuance of Audit Report
Date: 12-Jul-2019 15:56:53
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Audit Activities
Date: 11-Jul-2019 16:05:22
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Audit Preparation
Date: 10-Jul-2019 15:32:43
Role: FCT_Documentation Coordinator
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Audit Planning
Date: 09-Jul-2019 15:53:08
Role: FCT_QMS System Administrator
Username (Full Name): gdixson (Gretchen Dixson)
Reason for Change: N/A

Action Details: Process Started   Print
Process Task Name: N/A
Date: 16-Nov-2018 13:24:05
Role: N/A
Username (Full Name): gdixson (Gretchen Dixson)
Reason for Change: N/A

Expand all   Print all   View 1

Audit Process Notifications

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

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

There are no additional Custom Notifications or related Options available with Audit Process P0044.

Audit Process Reports

As described in the separate User Guide titled **QM APP Reports Breakdown** this list of SSRS Reports is available with all SOLABS Process APPs, along with various Excel datasets.

- CC Per Process Step
- CC Current Step Listing
- CC Listing
- CC Statistics per Month
- CC Statistics per Parameter
- CC Statistics per Year

A new macro-enabled Excel report will soon be available for the Audit Process to facilitate more advanced analytics and reporting:
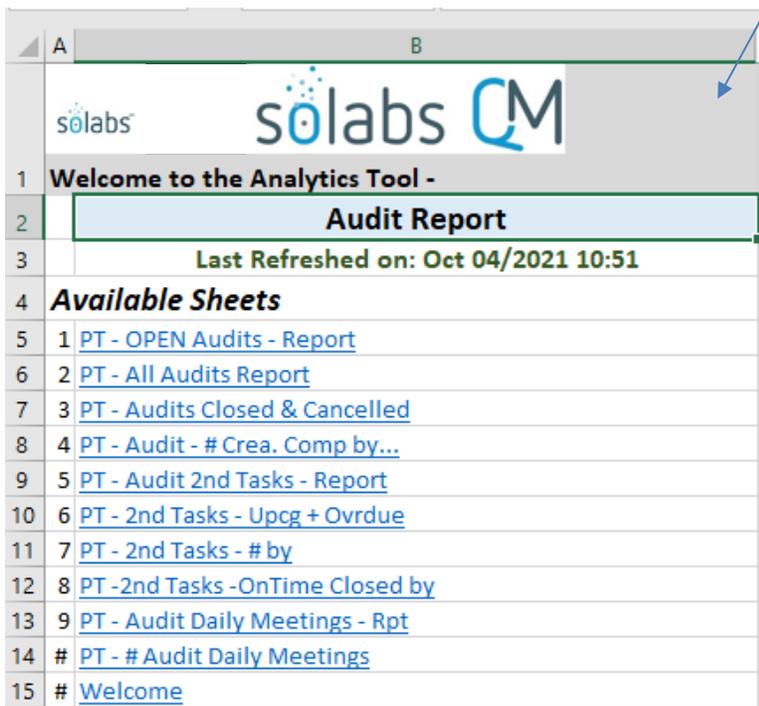
	A	B
		solabs QM
1	**Welcome to the Analytics Tool -**	
2		**Audit Report**
3		Last Refreshed on: Oct 04/2021 10:51
4	***Available Sheets***	
5	1	PT - OPEN Audits - Report
6	2	PT - All Audits Report
7	3	PT - Audits Closed & Cancelled
8	4	PT - Audit - # Crea. Comp by...
9	5	PT - Audit 2nd Tasks - Report
10	6	PT - 2nd Tasks - Upcg + Ovrdue
11	7	PT - 2nd Tasks - # by
12	8	PT -2nd Tasks -OnTime Closed by
13	9	PT - Audit Daily Meetings - Rpt
14	#	PT - # Audit Daily Meetings
15	#	Welcome

On the next page is an example of just one of the **Available Sheets** that will help you access, view, analyze and share information on the Audit process workflows.

solabs CM

Hide All Slicers **Send Item(s)** **Print Reports** **Broadcast Email** **Navigate System** **Show/Hide Cols**

Audit ID# Exp/Clps All
Audit Lead Exp/Clps Cols
Audit Title Exp/Clps Rows
Audit Category
GxPArea
Audit type
Audit Conducted
Site Audited
CAPANo
Audit Initiator
Audit PerformedBy
Closed Year
Cancelled Year

Group Data By:
- By Audit Category
- By Audit Lead
- By Audit Title
- By Audit Type
- By Audit ID
- By Site Audited
- By Performed By
- By Yr-Mth
- Multi-Select

Total Audits - Closed

Closed Year	Closed Month Name	# Closed Audits
2017	Sep	1
2017 Total		1
2018	Feb	1
2018	Apr	1
2018	Nov	1
2018 Total		3
2019	Apr	1
2019	Jun	1
2019	Jul	2
2019	Oct	1
2019 Total		5
2020	Feb	1
2020	Jun	1
2020	Aug	2
2020	Sep	1
2020	Oct	3
2020	Nov	3
2020	Dec	1
2020 Total		12
2021	Jan	1
2021	Feb	2
2021	Apr	4
2021	May	1
2021	Jun	1
2021 Total		9
Grand Total		30

Total Audits - Cancelled

Cancelled Year	Cancelled Month Name	# Cancelled Audits
2020	Sep	1
Grand Total		1

by Cancelled Date

 # Audits Closed - by Closure Date

Audit ID#

AUD-000...	AUD-000...	AUD-000...	AUD-000...
AUD-000...	AUD-000...	AUD-000...	AUD-000...
AUD-000...	AUD-000...	AUD-000...	AUD-000...
AUD-000...	AUD-000...	AUD-000...	AUD-000...
AUD-000...	AUD-000...	AUD-000...	AUD-000...
AUD-000...	AUD-000...	AUD-000...	AUD-000...

Audit Lead
	Brandon Gregory
Celia Pearson	Christina Sanders
Donald Barnes	Elizabeth Johnson
Emily Griffin	Ericka Moore

Audit Title
- 2018 Internal Audit
- 2018 Internal Audit - Documentation System
- 2018 Internal Audit - Documentation Systems
- 2021 CMO Site Audit
- 2021 Internal Audit
- Audit
- Audit for CC-000031
- Audit of Solabs
- Baker Chemicals

Audit Category
Internal Audit	Partner/Customer Audit
Regulatory Inspection	Regulatory Inspection of...
Supplier Audit	(blank)

GxPArea
- Good Clinical Practices (GCP)
- Good Laboratory Practices (GLP)
- Good Manufacturing Practices (GMP)
- (blank)

Audit type
	External
External; Supplier	Internal
Type 1	Type 2
Client Audit	Planned Internal Audit

Audit Conducted
On Site	Questionnaire
(blank)	

Site Audited
CMO	Manufacturing Site 1
Manufacturing Site 2	Site 1
Site 2	Supplier Site

CAPANo
Initiated as a ...	Initiated from ...	(blank)

Audit Initiator
Brandon Gregory	Corrina Dunn
Elizabeth Johnson	Ericka Moore
Gretchen Dixson	Kelly Allen

Audit PerformedBy
- ABC Consulting
- GDP Auditor
- JS Auditing, LLC
- Performed By 1

Closed Year
2017	2018	2019	2020
2021			

Cancelled Year
2020

This view of all the data available on the **PT - Audits Closed and Cancelled** Sheet give you an idea of how powerful this report can be in helping analze your audit process data.

October 2022