SOLABS QM10
Change Control Process P0036 User Guide

Introduction

This document provides instructions on the use of the **SOLABS QM10 Change Control Process APP P0036** – by guiding you through each step in the process and providing information on the activities, settings and options associated with each step.

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 to Proceed** step in a **Change Control** 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.

Detailed information on this process is available in the User Functional Design Specification (UFDS) document that comes with deployment of the Process in your instance of SOLABS QM10.

Change Control Process Flowcharts

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

There is a Flowchart available within the Process App. As the process moves along, the active step in that Flowchart is highlighted.

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

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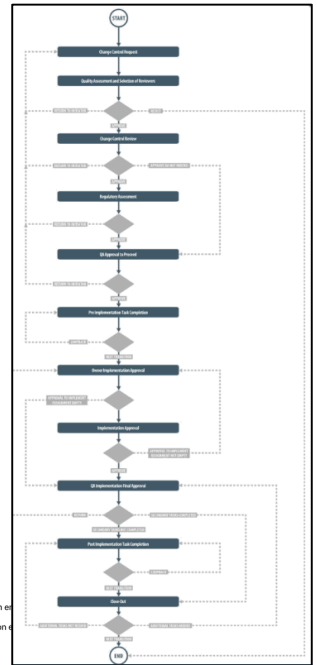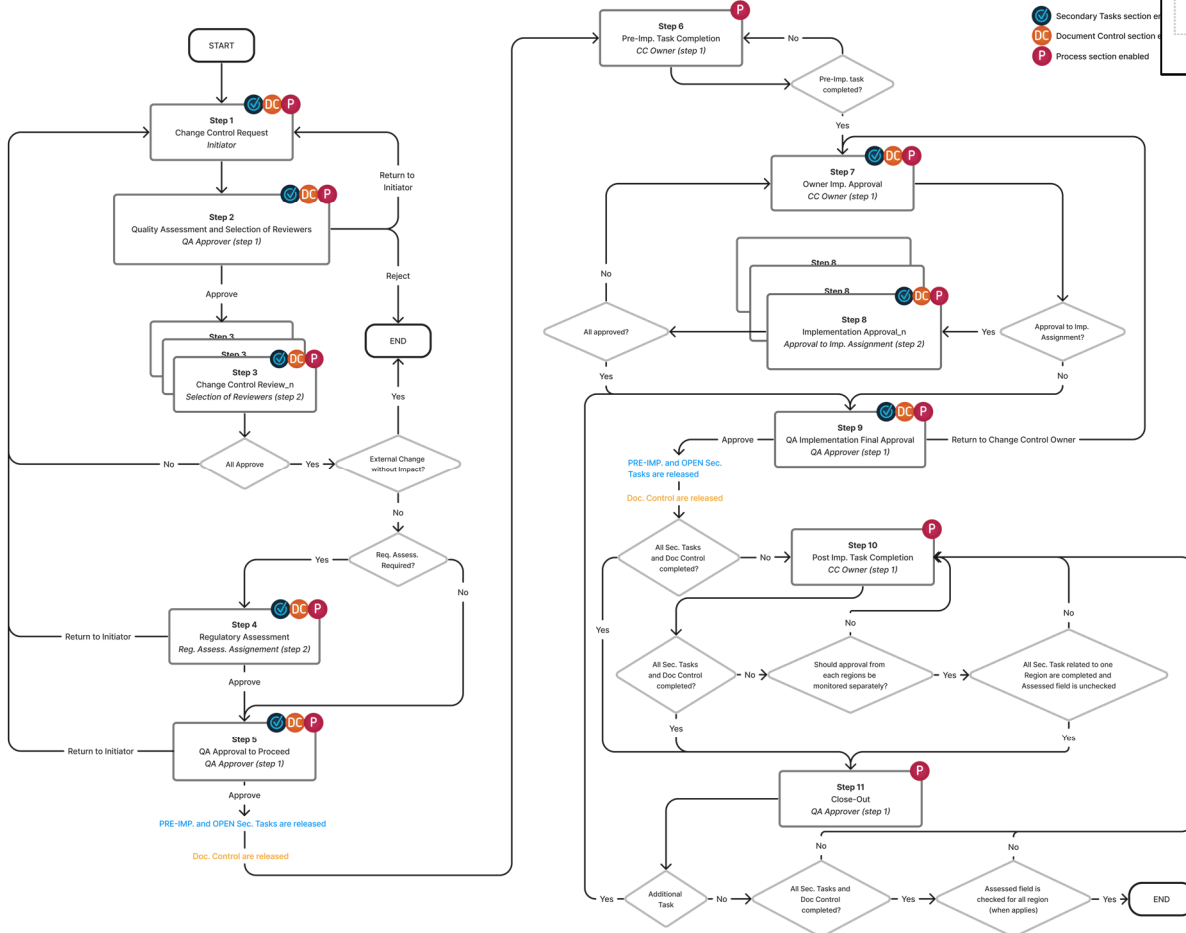
Change Control Process – Process Roles

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 **Change Control Process Roles** are associated with the **Change Control Process P0036** and must be assigned to the Users in **SOLABS QM10** who will make the related decisions and need to receive email Notifications related to the ongoing process.

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/Primary Task.   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 Change Control Process Roles need to be assigned to additional Users. If these Process Roles are not assigned to any Users, the related process tasks will instead go to Users who have the System Role assignment of SOLABS Documentation Administrator.   If that role is not assigned, the process tasks would go to the SOLABS System Administrator.

PR_CC_Approver:

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

- Step 2: Quality Assessment and Selection of Reviewers
- Step 5: QA Approval to Proceed
- Step 9: QA Implementation Final Approval
- Step 11: Close-Out

PR_CC_Owner:

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

- Step 6: Pre Implementation Task Completion
- Step 7: Owner Implementation Approval
- Step 10: Post Implementation Task Completion

The User with this role assignment that is selected at Step 1 will receive email Notifications for the following events. Specific details on these Notifications can be found in the Notifications section of this User Guide.

- Step 1 is confirmed
- The implementation date is approaching and there are some Pre-Implementation Secondary Tasks or Dependent Document Control Processes that are not complete
- All Pre-Implementation Secondary Tasks are complete
- All Open Secondary Tasks, Post-Implementation Secondary Tasks and Dependent Document Control Processes are complete
- All Secondary Tasks for a particular Region are complete and it was decided at Step 9 that approvals for each Region (where multiple Regions) should be monitored separately

PR_CC_RA:

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

- Step 4: Regulatory Assessment

Starting a Change Control 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 Change Control 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 Change Control Process.
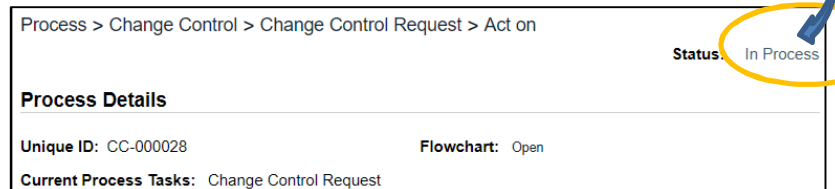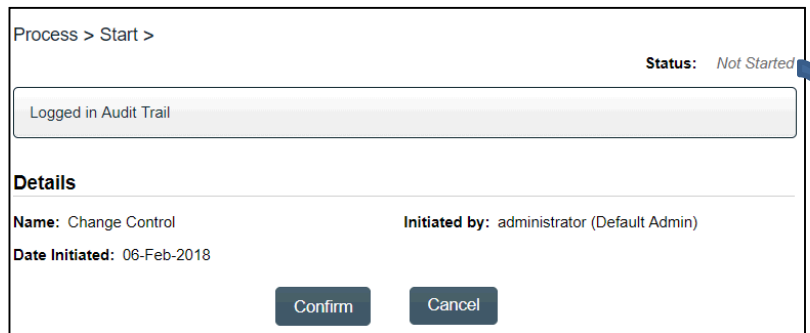
The first Primary Task box on the **Process Flowchart** will now be highlighted when it is opened: Change Control Request.

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Step 1 - Change Control Request

At Step 1 the user initiating the Change Control enters all the required information and metadata into the **Process Task Form**.

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

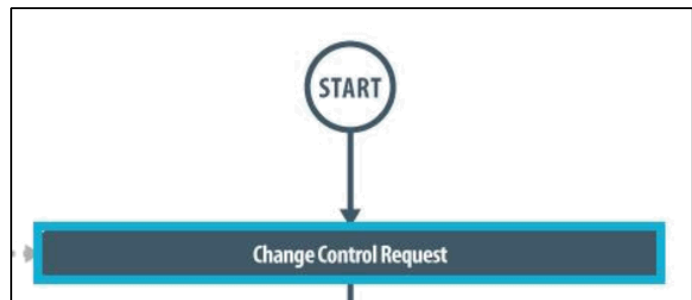Some of the fields on the **Process Task Form** are editable text fields or text areas. Others are single-select drop-down lists or multi-select fields. Fields with an asterisk (*) are mandatory.

The right-hand **Related Items** menu allows the initiator to **Link Documents** or **Link Processes**, if applicable. There are also sections to initiate **Secondary Tasks** and initiate new **Related Processes**, including a **Document Control Process**.

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

There is a **Save Draft** option at the bottom if you cannot complete the required fields at one time or when you need to use the right-hand menus to **Link Processes** or **Link Documents.**
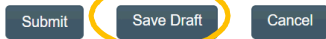
CAUTION: If you navigate away from this page without clicking on either **Submit** or **Save Draft**, all entries will be lost. To complete the information after the **Save Draft** option, you can either choose the **Act On** option from the Process section of your HOME Page, or search for the In-Process Change control and then use the right-hand **Act on Menu** to open the Process Task Form fields.

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

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Completing the Process Task Form:

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

The **Change Control Request No.** field will be automatically populated with the next available Change Control process number. The **Title** field is mandatory. Choose a clear, concise and intuitive title for the Change Control that will quickly communicate the subject. Titles will appear in Change Control Process Reports.

Change Control Request No.:

CC-000028

* Title:

---

* Change Type:

Name: CC_Change_Type_List

Values : List 1 ; List 2 ; List 3

* Change Type:

——

Packaging - Primary
Packaging - Secondary
Supplier
Active Ingredient
Excipient
Compendial Change
Continuous Improvement
Equipment Change
Other

The **Change Type** field is a mandatory field. It is a Single-item selection drop-down list populated by values from an **editable Custom List** maintained by your SOLABS System Administrator, with terminology unique to your organization. Example:

* ID (Product/System/Equipment):

Name: CC_ID_List **Status:** Active

Values : ID_List 1 ; ID_List 2 ; ID_List 3

The **ID (Product/System/Equipment)** field is a mandatory field. It is also a Single-item selection drop-down list populated by values from an **editable Custom List** maintained by your SOLABS System Administrator, with terminology unique to your organization.

Lot Number(s) Impacted:

The **Lot Number(s) Impacted** field is an optional text field allowing for up to 1024 characters.

* Stage:

Name: CC_Stage_List **Status:** Active

Values : Product Stage 1 ; Product Stage 2 ; Product Stage 3

* Specify Stage:

The **Stage** field is a mandatory single-item selection field populated by values from an **editable Custom List** maintained by your SOLABS System Administrator, with terminology unique to your organization. It also includes the option of **Other.** When "Other" is selected, another field will appear to **Specify Stage.**

* Initiation Type:

The **Initiation Type** field is a mandatory single-item selection field with two choices: **Internal** or **External**. If **External** is selected, additional mandatory fields will be displayed.

External Change Control # is a mandatory free-text field allowing for up to 1024 characters.

External Change Control Description is an optional free-text area allowing for up to 4000 characters.

External Change Control with Impact? is a single-item selection field with **Yes** or **No** as options.

* Initiation Type:

> External ▼

* External Change Control #:

[   ]

External Change Control Description:

[   ]

* External Change Control with Impact?:

> ----- ▼

---

* Impacted Site:

☐ Site 1
☐ Site 2

Name: Site_List **Status:** Active

Values : Site 1 ; Site 2 ; Site 3

Expand

Impacted Site is a mandatory multi-item selection field populated by values from an **editable Shared Custom List** maintained by your SOLABS System Administrator, with terminology unique to your organization.

General Information Fields

For any Change Type selected, the next fields on the Process Task Form are mandatory free-text fields to enter the **Current State**, the **Future State**, the **Justification** and the **Change Assessment**.

These fields allow up to 4000 characters each, or can be populated by Quick Text.

Quick Text is an **editable Custom List** of standardized phrases/terms that can be created as values for these fields.

* Current State:

[   ]

[Quick Text]

* Future State:

[|]

[Quick Text]

* Justification:

[   ]

[Quick Text]

* Change Assessment:

[   ]

[Quick Text]

The mandatory **Proposed Implementation Date** field can be populated from a Calendar.

The mandatory **Change Control Owner** field is a Single-select drop-down populated by the list of Users to whom the Process Role **PR_CC_Owner** is assigned. It will default to the Initiator, if that person is included in the list. The person chosen in this field will be assigned the following Steps in the Change Control Process and will receive various email Notifications regarding status of Secondary Tasks and the impact on the Proposed Implementation Date:

- **Step 6 - Pre Implementation Task Completion**
- **Step 7 – Owner Implementation Approval**
- **Step 10 – Post Implementation Task Completion**

The mandatory **QA Approver** field is a Single-select drop-down populated by the list of Users to whom the Process Role **PR_CC_Approver** is assigned. The person chosen in this field will be assigned the following steps in the Change Control Process:

- **Step 2: Quality Assessment and Selection of Reviewers**
- **Step 5: QA Approval to Proceed**
- **Step 9: QA Implementation Final Approval**
- **Step 11: Closeout**

Creating Secondary Tasks

The initiator of the Change Control Process can create **Secondary Tasks** that will be associated with the Change Control. These Secondary Tasks can be assigned to appropriate Users for activities required to support completion of the Change Control but that are not part of the Primary Tasks.

The **Secondary Task** section is under the Process Task Form, but still on the Change Control Request screen. This section is available at various Primary Task Steps of the Change Control Process, allowing others involved in the review, implementation and approval of the Change Control to assign additional Secondary Tasks.

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

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

The task **Type** can then be chosen from a drop-down list of Task Types. These Task Types are available in Steps 1-5. Pre-Implementation Task Type is not available in Steps 7-9. If a task Type is chosen that is not applicable at this Step, the message **This type of task is not allowed at current step** will be displayed. `This type of task is not allowed at current step`

Enter a **Description** and a **Due Date** for the Task. Choose due dates appropriate to ensure tasks are completed in a time frame that supports on time Change Control completion.

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

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

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.

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 Roles will then appear in the **Assignee (Role)** drop-down list and an appropriate option must be selected.

The Assignees of Secondary Tasks of Task Type = Open or Task Type = Pre-Implementation will receive email Notifications and see the View/Act On options for their Secondary Tasks only **after QA Approval to Proceed is completed at Step 5**. Until then the Task status is *Not Started*. Secondary Tasks of Task Type = Post Implementation are not released to assignees until after Step 9. The **Secondary Tasks** are listed under **Related Items** at the bottom of the screen for any Change Control Step.

Secondary Tasks (Post-Implementation and Open) can also be initiated in Steps 7-9.   In that case they are released after **QA Implementation Final Approval is completed at Step 9**, along with all Post Implementation Secondary Tasks initiated during Steps 1-5.

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 that lists Process Apps deployed for your organization.

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

If the **Process Relation** is selected as **Dependent Process**, the process it was initiated from is considered the **Parent Process.** Dependent Processes will be in a status of "Waiting for Parent Process" until **after QA Approval to Proceed is completed at Step 5**. Dependent Processes initiated after Step 5 will be "Waiting for Parent Process" until **QA Implementation Final Approval is completed at Step 9**.

The mandatory **Initiator** to field is a Single-item selection field that displays the Active User list for your organization.   The person chosen in this field will be the person who will be assigned Step 1 of the process you are choosing to initiate.   There is also an option to choose **myself**, if you would like to initiate both processes concurrently as the initiator.   This process will be the **Parent Process** of the new process being initiated.

If a Related Process was already initiated in SOLABS QM10, separately from this Change Control, 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 Process will be listed in the **Related Items** section when CCR Step 1 is Submitted and Confirmed.

The Related Processes will be released to the assignees only **after QA Approval to Proceed is completed at Step 5**. Related Processes initiated after Step 5 will be released after **QA Implementation Final Approval is completed at Step 9**.
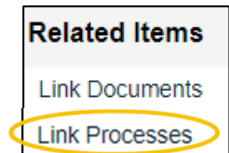
Initiating a Document Control Process

To initiate a new **SOLABS QM10 Document Control Process** to manage any document updates required for this Change Control, 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 Change Control is closed), or a **Related Process**.

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

If a Document Control Process was already initiated in SOLABS QM10, separately from this Change Control, 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 1 – Change Control Request, so that the person initiating the Change Control Process can also concurrently initiate the Document Control Process. The Change Control 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 CCR Step 1 is Submitted and Confirmed.

Dependent Document Control Processes will be in a status of "Waiting for Parent Process" until **after QA Approval to Proceed is completed at Step 5**. Dependent Document Control Processes initiated after Step 5 will be "Waiting for Parent Process" until **QA Implementation Final Approval is completed at Step 9**.

Submit and Confirm

When all information has been entered in the **Process Task Form**, and any **Secondary Tasks**, **Linked Documents, Linked Processes, Related Processes or Document Control Processes** have been added, click **Submit** and then **Confirm.** This will change the **Status to** *In Process* and to progress the process to **Step 2 – Quality Assessment and Selection of Reviewers**.

The Process Flowchart will highlight the next step of the process and the person chosen in Step 1 in the **QA Approver** field will be listed. This person will also receive an email Notification and will see the **Step 2 – Quality Assessment and Selection of Reviewers** task listed on their SOLABS QM10 HOME Page.
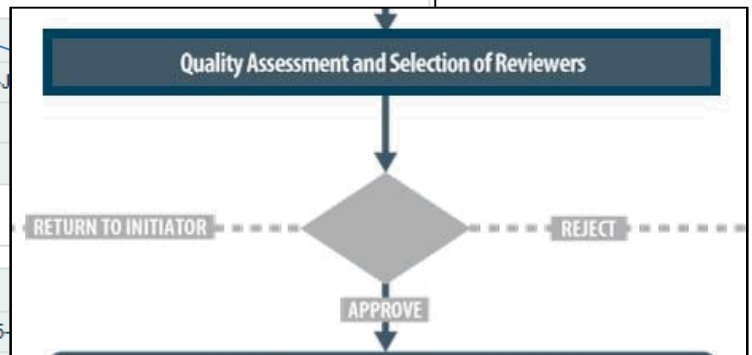
Step 2 – Quality Assessment and Selection of Reviewers

At this step in the Change Control Process, the person chosen at Step 1 will receive an email Notification and will see the **Step 2 – Quality Assessment and Selection of Reviewers** task listed in the Process section of their SOLABS QM10 HOME Page.

Viewing a Quality Assessment and Selection of Reviewers Task

If the User clicks on the View option to the right of the Process Task on their HOME Page, they will get the same screen shown on the previous page.

From that 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.

In this example, clicking on View for the Secondary Task listed in CC-000028 brings up the **Task Details** screen for that assigned Task.

Secondary Task PRE-00000034 is listed as a **Related Item** for that Task. To get back to CC-000028, the User can click on the **View** option.

This makes it easy to toggle between the Process and any Related Items.

Process Values

Process Tasks

Name: Change Control Request   **Last Confirmation Date:** 04-Jun-2019 10:17:49

Change Control Request No.: CC-000028
Title: Implement SOLABS QM for Document, Training and Quality Event Management
Change Type: Continuous Improvement
ID (Product/System/Equipment): SOLABS QM
Lot Number(s) Impacted: None
Stage: Other
Specify Stage: Not product-related.
Initiation Type: Internal
Impacted Site: Manufacturing Site 1
Current State: Paper based systems for Document Management, Training Management, Change Control, Deviation and CAPA management.
Future State: Electronic systems
Justification: Efficiency
Change Assessment: Computer Systems Validation
Proposed Implementation Date: 31-Dec-2019
Change Control Owner: mwagner (Margarita Wagner)
QA Approver: mturner (Marilyn Turner)
Sign-off by: gdixson (Gretchen Dixson)

Name: Quality Assessment and Selection of Reviewers

Expand all   Print all

Related Items

Secondary Tasks

Name: Identify list of int[...] **Unique ID:** PRE-00000034 **Due:** 05-Jul-2019 **Status:** Not Started   View

Main Related Process: CC-000028 Preview View
Name: Identify list of internal SOPs that will require update to reflect this change
Description: Identify list of internal SOPs that will require update to reflect this chang.

Task Details

Name: Identify list of internal SOPs that will require update to reflect this change

Type: Pre-Implementation   **Unique ID:** PRE-00000034

Description: Identify list of internal SOPs that will require update to reflect this chang.

Reference Date:

Location: Root\CC-000028 Process Task Group\Change Control Request Task Group

Estimated Start Day Offset: N/A   **Estimated End Day Offset:** N/A

Estimated Start Date: N/A   **Estimated End Date:** 05-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: CC-000028 **Date Initiated:** 22-Mar-2019 **Status:** In Process   View
Current Process Task: Quality Assessment and Selection of Reviewers

---

Acting on the Quality Assessment and Selection of Reviewers Task

When the assigned 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 **Quality Assessment and Selection of Reviewers** task.

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

As seen on the screen shot to the right, there are a number of fields to be completed by the assigned User at this step.

As with Step 1, there are different field types on the **Process Task Form**, including date fields, Single-select drop-down lists and free text fields/areas. Fields with an asterisk (*) are mandatory.

The right-hand **Related Items** menu allows the initiator to **Link Documents** or **Link Processes**, if applicable. There are also sections to initiate **Secondary Tasks** and initiate new **Related Processes**, including a **Document Control Process**.

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

Use the Save Draft option at the bottom if you cannot complete all the required fields at one time or when you use the right-hand menus to **Link Documents** or **Link Processes**.

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

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

Completing the Process Task Form

This sub-section covers the information required for each field in the **Process Task Form** at Change Control Process **Step 2: Quality Assessment and Selection of Reviewers.**

* Change Category Assessment:

| Critical |
| Major |
| Minor |

* Quality Assessment:

[Quick Text]

Change Category Assessment field is a mandatory single-item selection field with three choices: Critical, Major and Minor.

Quality Assessment is a mandatory free-text area that allows up to 4000 characters to describe the Quality Assessment. It can also be populated by Quick Text. **Quick Text** is an **editable Custom List** of standardized phrases/terms that can be created as values for these fields.

* Is a regulatory assessment required?:

-----

* Is a regulatory assessment required?:

Yes

* Regulatory Assessment Assignment:

Is a regulatory assessment required? is a single-item selection with just **Yes** or **No** options.

If **Yes** is selected, an additional mandatory single-item selection field will appear to identify the **Regulatory Assessment Assignment**. It is populated with names of the Users who are assigned the Process Role **PR_CC_RA**.

* Client Notification or Approval Required?:

| ----- |
| Approval Required |
| Notification Required |
| Not Required |

Client Notification or Approval Required? is a mandatory single-item selection field with three possible choices.

If either **Approval Required** or **Notification Required** is selected, an additional mandatory free-text field is displayed. It allows up to 1024 characters to provide the related details.

* Provide Details for Client Approval/Notification:

Lot Number(s) Impacted:

Lot Number(s) Impacted is an optional free-text field allowing up to 1024 characters. It will be pre-populated with any Lot Numbers entered at Step 1 and is editable as needed.

* Number of days to be notified prior to proposed implementation/close-out date:

7

Number of days to be notified prior to proposed implementation/close-out date is a mandatory numeric field that defaults to "7" but is editable as needed.

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Selection of Reviewers is mandatory to select people in the organization who should provide additional review of the proposed Change Control. There are choices to filter by either Active Users or by Department to find and select the appropriate people.

A filter choice of **Active users** will display a multi-select **Available** field populated with the SOLABS QM10 Active Users list. Selection of one or more Usernames followed by the **+ADD** button will place those names in the **Assigned** field.
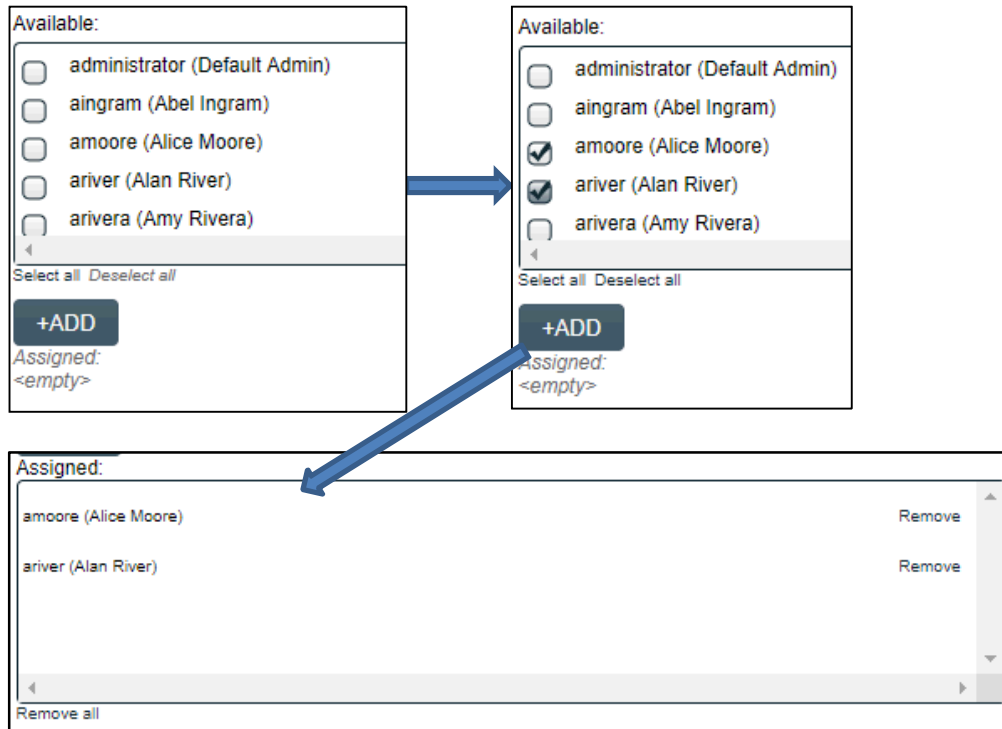
A filter choice of **Department** will display a multi-select **Available sub-filters** field populated with the list of SOLABS QM10 Departmental Security Roles. Selection of one or more departments will then display a multi-select **Available** field populated with the list of Users associated with those Departments. Selection of one or more Usernames followed by the **+ADD** button will place those names in the **Assigned** field.
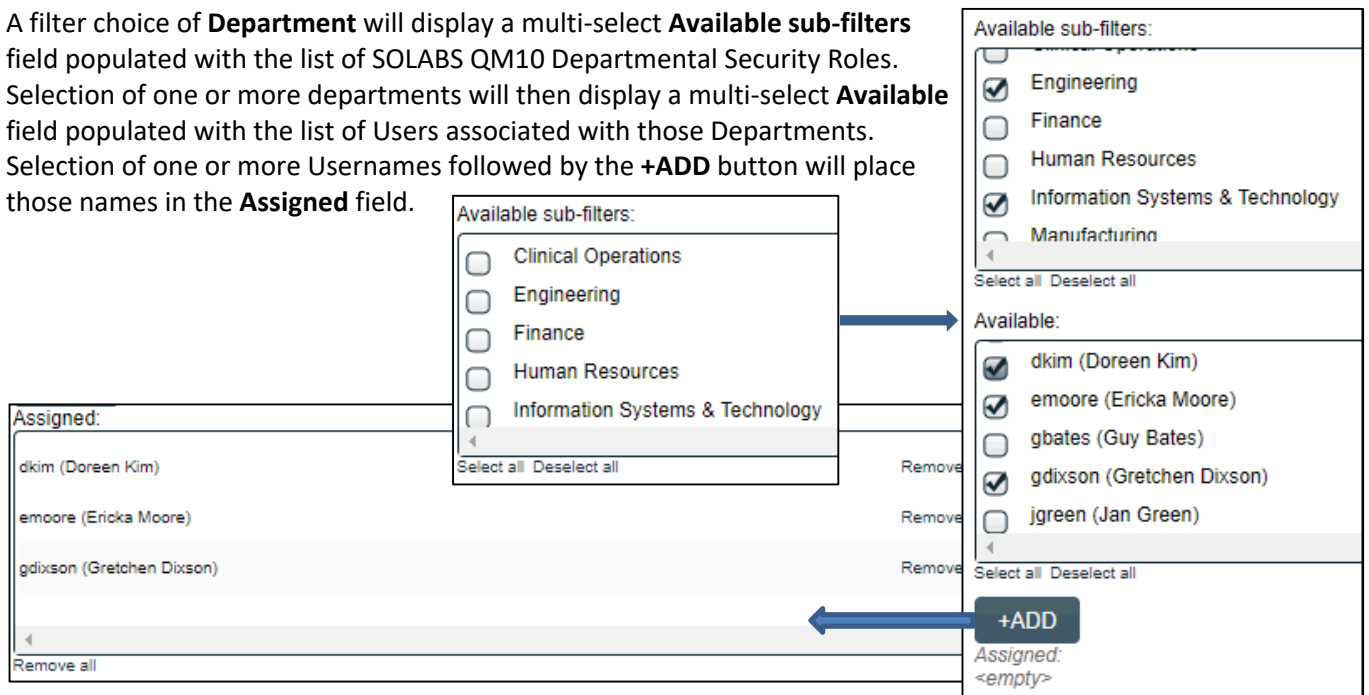
Reviewing Secondary Tasks and Related Processes

Before making the final **QA Decision**, the assigned User should also review the Related Items, by using the available **Expand all** and **View** options.

Related Items

Secondary Tasks

Name: Create User Guide Unique ID: Task-00000001 Due: 2018-02-09 Status: Not Started — View

Expand all

Related Processes

Unique ID: CAPA-000001 Date Initiated: 2018-02-07 Status: In Process — View
Current Process Task: Initiation and CAPA Definition

Unique ID: DOC-000001 Date Initiated: 2018-02-07 Status: In Process — View
Current Process Task: Change Request for Creation, Review or Withdrawal of Document

Expand all

Secondary Tasks

☑ Create User Guide
Due Date: 2018-02-09   Type: Task
Originator: solabssupport (Default Admin)

Modify Remove

+ADD

There are Modify or Remove options for the existing Secondary Tasks. Additional Secondary Tasks can be created using the **+ADD** option.

The User acting on Step 2 can also **Link Documents** or **Link Processes** using the right-hand Related Items menu. The options to initiate a new **Related Process** or initiate a new **Document Control Process** are also enabled at Step 2.

Submit and Confirm the Agreement of Change Decision

After reviewing all information from Step 1, completing all required fields in the **Process Task Form**, reviewing any **Secondary Tasks** and reviewing any **Related Processes** or **Doc Control Process**, the assigned User for Step 2 will make the **QA Decision**.   The **QA Decision** section allows for three options.

QA Decision:
○ Approve to proceed
◉ Return to initiator
○ Reject
* Comments to Initiator:

A QA Decision of **Return to initiator** brings up a mandatory free-text area **Comment** field allowing up to 4000 characters.

Submission of this QA Decision will return the Change Control Process back to **Step 1**.

QA Decision:
○ Approve to proceed
○ Return to initiator
◉ Reject
* Rationale for Rejection:

A QA Decision of **Reject** brings up a mandatory free-text area **Rationale for Rejection** field allowing up to 4000 characters.

Submission of this QA Decision will **Close** the Change Control Process.

QA Decision:
- ● Approve to proceed
- ○ Return to initiator
- ○ Reject

A QA Decision of **Approve to proceed** will progress the Change Control Process to **Step 3: Change Control Review**.

The **Process Flowchart** will highlight the next step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with.** In this case three people were selected for the Change Control Review Step so all three are listed. The tasks are identified with "_1", "_2" and "_3".

Process Details

Name: Change Control	**Date Initiated:** 22-Mar-2019 12:47:28
Unique ID: CC-000028	**Initiated by:** gdixson (Gretchen Dixson)
Day(s) opened: 75	**Date Closed :** *<empty>*
Secondary Tasks Completion (%): 0 (0/1)	**Dependent Processes Completion (%) :** 0 (0/1)

Current Process Tasks
Change Control Review_1
Change Control Review_2
Change Control Review_3

Currently with
dkim (Doreen Kim)
emoore (Ericka Moore)
gdixson (Gretchen Dixson)

Flowchart: Open

Process Values

Process Tasks

Name: Change Control Request **Last Confirmation Date:** 04-Jun-2019 1

Name: Quality Assessment and Selection of Reviewers **Last Confirmatio**

Name: Change Control Review_1

Name: Change Control Review_2

Name: Change Control Review_3

Expand all Print all

Change Control Review

RETURN TO INITIATOR — — — — ◇ — — — — APPROVE RA NOT NEEDED

APPROVE

Related Items

Secondary Tasks

Name: Identify list of int[...] **Unique ID:** PRE-00000034 **Due:** 05-Jul-2019 **Status:** Not Started   View

Expand all

Dependent Processes

Unique ID: AUD-000017 **Date Initiated:** 04-Jun-2019 **Status:** In Process   View
Current Process Task: Audit Planning

Expand all

Related Processes

Unique ID: DOC-000040 **Date Initiated:** 04-Jun-2019 **Status:** In Process   View
Current Process Task: Document Coordinator Processing

Collapse all

At this step in the Change Control Process, the person(s) selected as Reviewers in Step 2 will receive an email Notification and will see the **Step 3 – Change Control Review** task listed in the Process section of their SOLABS QM10 HOME Page. Each person selected will need to Act on that task. In this example there were three people assigned the task, so the numbers **_1**, **_2** and **_3** will appear after the task name to differentiate those tasks.

Doreen Kim

Home > Views

PROCESSES

Received this week / last week

Unique ID: CC-000028 **Date Initiated:** 22-Mar-2019 **Status:** In Process   View | Act on
Current Process Task: Change Control Review_1

As the **Change Control Process** progresses from Step to Step, the information from each step is added to the **Process Values** table so that it is available for those acting on later steps to review. If the process goes back to a previous step at any point, and then progresses again, all that detail will be captured as well. If **Secondary Tasks**, **Related Documents** or **Related Processes** are added along the way, they will be added to the **Related Items** section.

As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the Process Values table for additional details and to toggle back and forth between the Process and any **Related Items**.

Acting on the Change Control Review Task

When a **Change Control Review** assignee clicks on the **Act on** option to the right of the Process Task, they will go immediately to the **Act on** screen for **Step 3 – Change Control Review.**

As described previously, the person can use the **Expand all** option under the **Process Values** table to see all information entered at Steps 1 and 2 of the process. They can also review all **Related Items** by clicking on **View** in the right-hand Process Actions menu.

The options to **Link Documents**, **Link Processes**, Review/Modify/Remove/Add **Secondary Tasks** and initiate additional **Related Processes** or **Document Control** Processes are enabled at Step 3 as well.

The Reviewers will use the **Approval to Proceed Comments** section to provide any information they would like to add regarding the Change Control being proposed.

They then have two choices for the **Approval to Proceed Decision**.

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

- A choice of **Approve, by all the reviewers,** will progress the process to **Step 4 – Regulatory Assessment** if the CC is <u>not</u> an External Change with no impact (selected at Step 2) and a

Regulatory Assessment is required (selected at Step 2). It will be assigned to the Users selected at Step 2.

- A choice of **Approve, by all the reviewers,** will progress the process to Step 5 – QA Approval to Proceed if the CC is <u>not</u> an External Change with no impact (selected at Step 2) and <u>no</u> regulatory Assessment is required (selected at Step 2). It will be assigned to the Users selected at Step 2.

- A choice of Approve, by all the reviewers, will close the process if the CC is an External Change with no impact (selected at Step 2).

- A choice of **Return to initiator** will require **Comments to the Initiator**. When that decision is made by at least one Reviewer, the Change Control process will go back to **Step 1 – Change Control Request**, after all Reviewer's decisions are submitted, so that the Initiator can address the comments.

The **Process Flowchart** will highlight the next step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with.** In this case, since the Regulatory Assessment was selected as **Yes** at Step 2, the Change Control Process progresses to **Step 4 – Regulatory Assessment**. If the selection for Regulatory Assessment had been **No** at Step 2, the Change control Process would skip Step 4 and go to **Step 5 – QA Approval to Proceed**. (See Page 26)

Step 4 – Regulatory Assessment

At this step in the Change Control Process, the person selected at Step 2 for Regulatory Assessment, will receive an email Notification and will see the **Step 4 – Regulatory Assessment** task listed in the Process section of their SOLABS QM10 HOME Page.

Corrina Dunn

Home > Views

PROCESSES

Received this week / last week
Unique ID: CC-000028 Date Initiated: 22-Mar-2019 Status: In Process View	Act on Current Process Task: Regulatory Assessment

Again, as the **Change Control Process** progresses from Step to Step, each step is added to the **Process Values** table so that it is available for those acting on later steps to review.   If **Secondary Tasks**, **Related Documents** or **Related Processes** are added along the way, they will be added to the **Related Items** section**.**
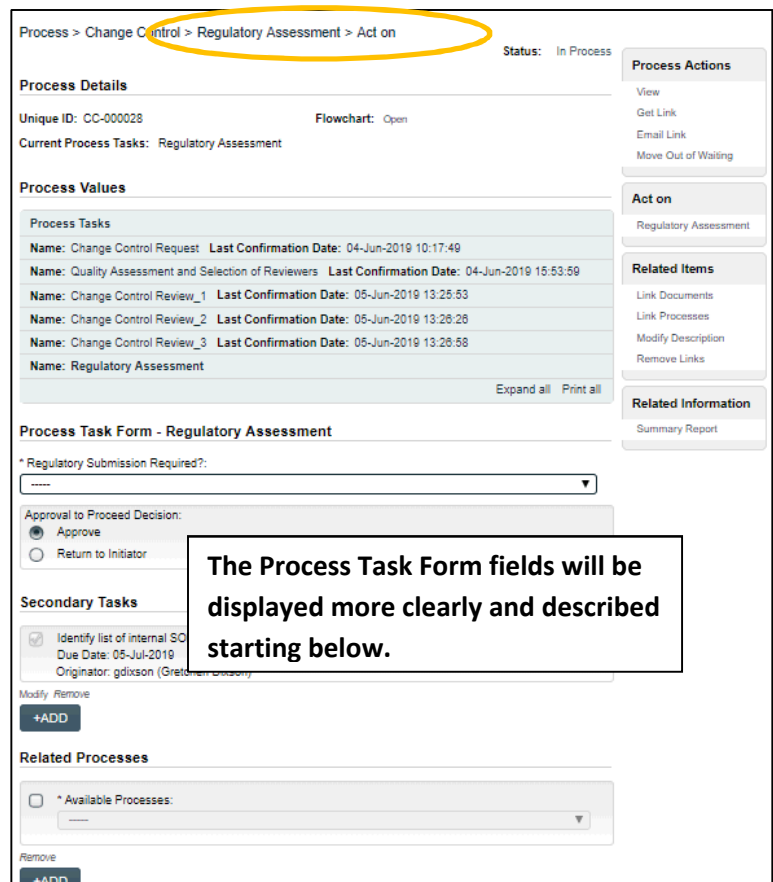
As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the Process Values table for additional details and to toggle back and forth between the Process and any **Related Items**.

Acting on the Regulatory Assessment Task

When a **Regulatory Assessment** assignee clicks on the **Act on** option to the right of the Process Task, they will go immediately to the **Act on** screen for **Step 4 – Regulatory Assessment**.

As described previously, the person can use the **Expand all** option under the **Process Values** table to see all information entered at Steps 1 - 3 of the process. They can also use **Process Actions/View** to review all **Related Items**.

The options to **Link Documents**, **Link Processes**, Review/Modify/Remove/Add **Secondary Tasks** and initiate additional **Related Processes** or **Document Control** Processes are enabled at Step 4 as well.

Process > Change Control > Regulatory Assessment > Act on

Status: In Process

Process Details

Unique ID: CC-000028   Flowchart: Open

Current Process Tasks: Regulatory Assessment

Process Values

Process Tasks
Name: Change Control Request   Last Confirmation Date: 04-Jun-2019 10:17:49
Name: Quality Assessment and Selection of Reviewers   Last Confirmation Date: 04-Jun-2019 15:53:59
Name: Change Control Review_1   Last Confirmation Date: 05-Jun-2019 13:25:53
Name: Change Control Review_2   Last Confirmation Date: 05-Jun-2019 13:26:26
Name: Change Control Review_3   Last Confirmation Date: 05-Jun-2019 13:26:58
Name: Regulatory Assessment

Expand all   Print all

Process Task Form - Regulatory Assessment

* Regulatory Submission Required?:

----- ▼

Approval to Proceed Decision:
- ● Approve
- ○ Return to Initiator

The Process Task Form fields will be displayed more clearly and described starting below.

Secondary Tasks

☐ Identify list of internal SO
   Due Date: 05-Jul-2019
   Originator: gdixson (Gretchen Dixson)

Modify Remove

+ADD

Related Processes

☐ * Available Processes:
   ----- ▼

Remove

Process Actions
View
Get Link
Email Link
Move Out of Waiting

Act on
Regulatory Assessment

Related Items
Link Documents
Link Processes
Modify Description
Remove Links

Related Information
Summary Report

Regulatory Submission Required? is a single-item selection with two choices: **Yes** or **No**. Depending on the choice selected, additional mandatory fields will be displayed.

* Regulatory Submission Required?:

No

* Rationale for Regulatory Submission not Required:

ry free-text area field for **Rationale for Regulatory Submission not** s.

A selection of **Yes** will bring up a mandatory multi-item selection field for **Regions**. The values are populated from an **editable Shared Custom List** maintained by your SOLABS System Administrator, with terminology unique to your organization.

For every **Region** selected, a set of mandatory data entry fields will be displayed.

* Regulatory Submission Required?:

Yes

* Regions:

Expand

☐ Region 1
☐ Region 2

Application Type and **Submission Type** are multi-select fields populated by values from **editable Custom Lists** maintained by your SOLABS System Administrator, with terminology unique to your organization.

Submission Requirements (Internal Assessment) is a free-text area that allows up to 4000 characters.

Partner Assessment Attached? is a single-item selection field with values of either **Yes** or **No**. Assessments can be attached using the right-hand **Link Documents** menu option.

* Regions:

Expand

☑ Region 1
☐ Region 2

Region 1

* Application Type:

Name: CC_Application_Type_List **Status:** Active

Values : List 1 ; List 2 ; List 3

Expand

☐ NDA
☐ ANDA

* Submission Type:

Name: CC_Submission_Type_List **Status:** Active

Values : List 1 ; List 2 ; List 3

Expand

☐ Annual Report
☐ CBE 0

* Submission Requirements (Internal Assessment):

* Partner Assessment Attached?:

Add additional secondary task for this region

Secondary Tasks Created for Submissions and Related Approval Letters

For every **Region** selected, the **Secondary Tasks** section is automatically updated with a set of two Secondary Tasks for **Submission** and for **Obtain Regulatory Approval Letter**. The **Add additional secondary tasks for this region** button can be used for additional Region-specific Secondary Tasks, as needed. These Secondary Tasks are used by the Regulatory Assessment assignee to assign those related activities.

The first of the two added Secondary Tasks will be titled **Region 1 Submission** but can be edited. The task **Type** must be changed to an allowable task type (Pre Implementation, Post Implementation, Other).

The **Description** field will be pre-populated with **Submission** but is editable up to 4000 characters.

A **Due Date** can be selected for the Submission using the calendar.

The **Originator** field defaults to the person assigned the Regulatory Assessment Step and is not editable.

The mandatory **Assignee (Role)** and **Assignee (User)** fields are single-item selection fields populated with Active FCT Roles and Active Users. Either can be populated first, and then the other will be populated with only those values applicable to that selection.

The second of the two added Secondary Tasks will be titled **Region 1 Obtain Regulatory Approval Letter** but can be edited. The task **Type** must be changed to an allowable task type (Pre

Implementation, Post
Implementation, Other).

The **Description** field will be pre-populated with **Approval Letter** but is editable up to 4000 characters.

A **Due Date** can be selected for the Submission using the calendar.

The **Originator** field defaults to the person assigned the Regulatory Assessment Step and is not editable.

The mandatory **Assignee (Role)** and **Assignee (User)** fields are single-item selection fields populated with Active FCT Roles and Active Users. Either can be populated first, and then the other will be populated with only those values applicable to that selection.

If more than one Region was selected, there will be another set of Secondary Tasks to populate for the related Submission and Approval Letter.

As mentioned on the previous page, the **Add additional secondary task for this region** button is available in the Regions section for additional Secondary Tasks associated with a particular Region. An **+ADD** button is available at the end of the entire Secondary Tasks section for any general Secondary Tasks for the Regulatory area.

At this point the **Regulatory Assessment** assignee will review all the information that has been entered so far, add any additional **Secondary Tasks**, **Related Documents**, **Related Processes** or **Document Control** Processes, and then make their **Approval to Proceed Decision**.

There are just two choices for that decision:

- A choice of **Return to Initiator** will require mandatory **Comments to Initiator**. After submission of this step, the process will then go back to **Step 1 – Change Control Request** so that the Change Control Initiator can address the comments.
- A choice of **Approve** will progress the process to **Step 5 – QA Approval to Proceed**. It will be assigned to any Users who have the Process Role **PR_CC_QA_Approver** assigned. (Note: if PR_CC_QA_Approver is not assigned to any users, the Step will be assigned to anyone who has the SOLABS Documentation Administrator role assignment).

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

Step 5 - QA Approval to Proceed

At this step in the Change Control Process, the person assigned as QA Approver in Step 1 will receive an email Notification and will see the **Step 5 – QA Approval to Proceed** task listed in the Process section of their SOLABS QM10 HOME Page.   As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the Process Values table for additional details and to toggle back and forth between the Process and any **Related Items**.

Acting on the QA Approval to Proceed 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 **Step 5 - QA Approval to Proceed** task.

As described previously, the person can use the **Expand all** option under the **Process Values** table to see all information entered at Steps 1 - 4 of the process. They can also choose the View option in the Process Actions menu to review all **Related Items**.

The options to **Link Documents**, **Link Processes**, add **Secondary Tasks** and initiate additional **Related Processes** or **Document Control**

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Processes are enabled
at Step 5 as well.

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

An optional 4000- character text area is available
for **QA Change Approval Comments**.

Was the client notified? is a mandatory **Yes** or **No**
single-item selection field that ONLY appears IF the
field **Client Notification or Approval Required** at
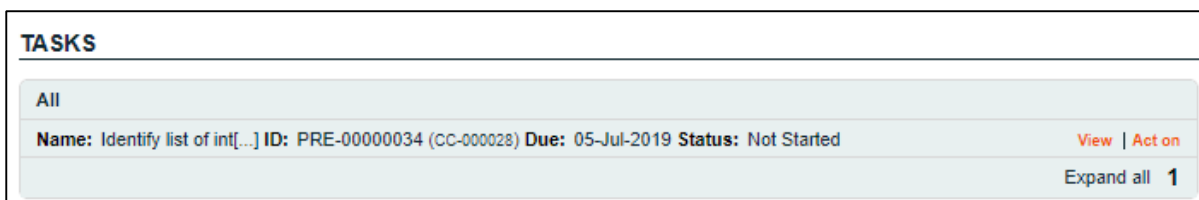Step 2 was set at **Notification Required**.

Was approval from client obtained? is a mandatory
Yes or **No** single-item selection field that ONLY
appears IF the field **Client Notification or Approval
Required** at Step 2 was set at **Approval Required**.

The **Proposed Implementation Date** defaults to
what was selected at Step 1 but is editable.

At this step in the Change Control process, the **QA Approver** will review all the information that has been
entered so far, add any additional **Secondary Tasks**, **Related Documents**, **Related Processes** or **Document
Control Processes**, and then make their **QA Approval to Proceed Decision**. There are two choices for that
decision:

- A choice of **Return to initiator** will require mandatory **Comments to initiator**. After this decision is
submitted, the process will then go back to **Step 1 – Change Control Request** so that the Change Control
Initiator can address the comments.

- A choice of **Approve** will progress the process to **Step 6 – Pre Implementation Task Completion**. When this
Step is Submitted, all **Secondary Tasks** with Task Type = Pre-Implementation and/or Task Type = Open will
be released for assignees to **Act on**. Any Post Implementation Secondary Tasks will not be released until
after Step 9.   Any **Document Control Processes** will progress out of the "Waiting for Parent Process" phase.

Assignees of **Secondary Tasks** will receive email Notifications and see those activities listed in the **TASKS** section
of their SOLABS QM10 HOME Page.

Process Details

Name: Change Control	**Date Initiated:** 22-Mar-2019 12:47:28
Unique ID: CC-000028	**Initiated by:** gdixson (Gretchen Dixson)
Day(s) opened: 77	**Date Closed :** *<empty>*
Secondary Tasks Completion (%): 0 (0/3)	**Dependent Processes Completion (%) :** 0 (0/1)

Current Process Tasks	**Currently with**
Pre Implementation Task Completion	mwagner (Margarita Wagner)

Flowchart: Open

Process Values

Process Tasks

Name: Change Control Request **Last Confirmation Date:** 04-Jun-2019 10:17:49

Name: Quality Assessment and Selection of Reviewers **Last Confirmation Date:** 04-Jun-2019 15:53:59

Name: Change Control Review_1 **Last Confirmation Date:** 05-Jun-2019 13:25:53

Name: Change Control Review_2 **Last Confirmation Date:** 05-Jun-2019 13:26:26

Name: Change Control Review_3 **Last Confirmation Date:** 05-Jun-2019 13:26:58

Name: Regulatory Assessment **Last Confirmation Date:** 06-Jun-2019 16:01:32

Name: QA Approval to Proceed **Last Confirmation Date:** 07-Jun-2019 14:10:42

Name: Pre Implementation Task Completion

Expand all Print all

Related Items

Secondary Tasks

Name: Identify list of int[...] **Unique ID:** PRE-00000034 **Due:** 05-Jul-2019 **Status:** Not Started View

Name: FDA Submission **Unique ID:** PRE-00000035 **Due:** 31-Aug-2019 **Status:** Not Started View

Name: FDA Approval Letter **Unique ID:** PRE-00000036 **Due:** 31-Dec-2019 **Status:** Not Started View

Expand all

Dependent Processes

Unique ID: AUD-000017 **Date Initiated:** 04-Jun-2019 **Status:** In Process View
Current Process Task: Audit Planning

Related Documents

Name: Client Notification Letter **No.:** *<empty>* **Due:** *<empty>*
Effective

Related Processes

Unique ID: DOC-000040 **Date Initiated:** 04-Jun-2019 **Status:**
Current Process Task: Document Coordinator Processing

Collapse all

The **Process Flowchart** will highlight the next step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with** – the **Change Control Owner** identified at Step 1.

The Change Control Process will stay at Step 6 until all **Dependent Processes** and **Secondary Tasks** with Task Types of Pre Implementation or Open are completed.

When the Change Control Owner chooses the **Act on** option for this step, the following message will be displayed: *You are assigned this task because some Pre-Implementation Secondary Tasks are not completed. Please wait until all Pre-Implementation Secondary Tasks are completed to submit this step.*

The Change Control owner can use an optional **Next Follow-Up Date** field if desired.

No new Secondary Tasks or Document Control Processes can be initiated at Step 6.
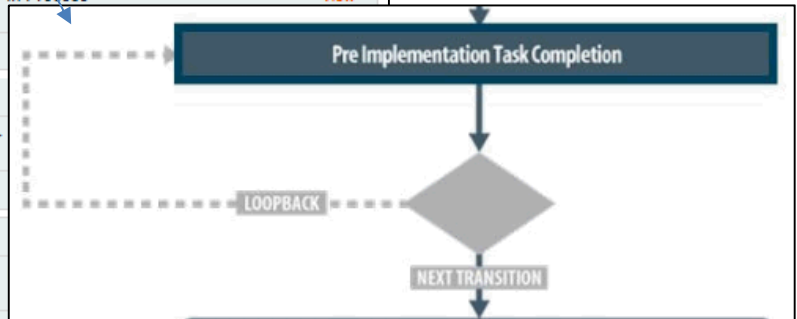
Step 6 – Pre Implementation Task Completion

Any **Secondary Tasks** are now released to **Act on** since the Change Control Process has been approved by QA.   Step 1 of any Related Processes initiated from within the Change Control were assigned to the selected User at the time of assignment and can be progressed concurrently.   Any that were set with Process Relation of Dependent, will need to be completed during this Waiting Phase.

Viewing a Secondary Task

When the Assignee for a **Secondary Task** chooses the **View** option from their HOME Page, they are brought to the **Task > View** screen for that Task.   They can now review what has been assigned to them and can also toggle to the **Change Control Process** that triggered the Task, since it is listed at the bottom of the screen as a **Related Item**.

TASKS

All

Name: Identify list of int[...] **ID:** PRE-00000034 (CC-000028) **Due:** 05-Jul-2019 **Status:** Not Started   View | Act on

Expand all 1

Task > View

Task Details

Name: Identify list of internal SOPs that will require update to reflect this change

Type: Pre-Implementation   **Unique ID:** PRE-00000034

Description: Identify list of internal SOPs that will require update to reflect this chang.

Reference Date:

Location: Root\CC-000028 Process Task Group\Change Control Request Task Group

Estimated Start Day Offset: N/A   **Estimated End Day Offset:** N/A

Estimated Start Date: 07-Jun-2019   **Estimated End Date:** 05-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: CC-000028 **Date Initiated:** 22-Mar-2019 **Status:** In Process   View
Current Process Task: Pre Implementation Task Completion

Collapse all

Task Actions

View

Act on

Modify

Return to Originator

Get Link

Email Link

Related Items

Link Documents

Link Processes

Modify Description

Remove Links

Related Information

Audit Trail

Acting on a Secondary Task

When the Assignee for a Secondary Task chooses the **Act on** option from their HOME Page, they are brought to the **Task > Act on** screen for that Task.

From this screen, the Assignee can also review the **Task Details**.

The fields they have available to them are to select a **Start Date**, enter an **End Date** when they are finished with the task and to change the **Status** as they progress it.

They can also enter free-text **Comments** at any point.

The task will default to a status of **Not Started**. If a status of **In Progress** is selected, the **Start Date** field will be populated with the current date. If a **Start Date** is entered, the Status will automatically move to **In Progress.** For longer term tasks, it is best practice to periodically log in and provide status updates in the **Comments** field.

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

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

The **Return to Originator** option is grayed out since it is currently not available.

If the Assignee would like to add evidence / documentation to support completion of the task, the **Link**

Task > Act on

Task Details

Name:
Identify list of internal SOPs that will require update to reflect this change

Type: Pre-Implementation

Unique ID: PRE-00000034

Description:
Identify list of internal SOPs that will require update to reflect this chang.

Reference Date:

Location: Change Control Request Task Group
Available Task Groups

Estimated Start Date Offset: 0

Estimated End Date offset: 0

Estimated Start Date: 07-Jun-2019

Estimated End Date: 05-Jul-2019

Start Date: Clear

End Date: Clear

Status:
- ( ) Not Started
- ( ) In Progress
- ( ) Pending
- ( ) Completed
- ( ) Return to Originator

Comments:

Task Ownership

Originator: gdixson (Gretchen Dixson)

Assignee (Role): FCT_Documentation Coordinator

Assignee (User): jclark (Jaqueline Clark)

Submit   Cancel

Related Items

Link Documents

Link Processes

Modify Description

Remove Links

Documents option is available on the
right-hand menu.

Acting on the Pre Implementation Task Completion Task

When all Secondary Tasks of Task Type Pre Implementation and Open are completed, and any Dependent Processes are at a status of Completed (or Cancelled), the Change Control Owner will be able to **Act on Step 6 by simply entering the current Date into the Next Follow-Up Date** field.

The Change Control Process will then move to **Step 7 – Owner Implementation Approval**. It will stay assigned to the Change Control owner but will be tracked as a separate step in the Change Control Process.

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

Step 7 – Owner Implementation Approval

At this step in the Change Control Process, the Change Control Owner will receive an email Notification and will see the **Step 7 – Owner Implementation Approval** task listed in the Process section of their SOLABS QM10 HOME Page.

As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the **Process Values** table for additional details and to toggle back and forth between the Process and any **Related Items**.

Acting on the Change Control Final Approval Task

When an 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 **Step 7 – Owner Implementation Approval** task.

They need to complete the **Pre-Implementation tasks completed as described?** and also have the option to choose other people for **Approval to Implement Assignment** to obtain concurrence that the Change Control is ready to implement. These fields are described on the next page.

At this point they have the option to initiate more **Secondary Tasks** (Post Implementation or Open) or **Document Control Processes** if needed. A new **Related Process** can still be initiated, and the **Link Documents** and **Link Processes** options on the Related Items menu are still possible.

The Process Task Form fields will be displayed more clearly and described starting below.

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The **Save Draft** option can be used if the required fields cannot all be completed at the same time or if the **Link Documents** and **Link Processes** options on the Related Items menu are used.

Submit   Save Draft   Cancel

* Pre-Implementation tasks completed as described?:

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

The **Pre-Implementation tasks completed as described?** field is a mandatory single-item selection field with choices of **Yes**, **No** or **N/A**. If No is selected another mandatory Text Area field will be displayed to **Specify** the status, allowing up to 4000 characters.

* Pre-Implementation tasks completed as described?:

No

* Specify:

The optional **Approval to Implement Assignment** section allows the Change Control Owner to seek formal input from others regarding whether the Change Control is ready to implement. Users can be selected using the following **Filter by** options:

- The **Active users** filter displays all active users in the **Available** box. One or more users can be selected.
- The **Department** filter displays all active Departmental Security Roles in the **Available sub-filters** box. One or more Departments can be selected. The associated users will then be displayed in the **Available** box. One or more users from those Departments can then be selected. Selection of one or more Usernames followed by the **+ADD** button will place those names in the **Assigned** field.

Approval to Implement Assignment:
Filter by:
- ● Active users
- ○ Department

Available sub-filters:

Select all Deselect all

Available:
- ☐ administrator (Default Admin)
- ☐ aingram (Abel Ingram)
- ☑ amoore (Alice Moore)
- ☑ ariver (Alan River)
- ☐ arivera (Amy Rivera)

Select all Deselect all

+ADD

Assigned:
<empty>

Assigned:
amoore (Alice Moore)
ariver (Alan River)

Approval to Implement Assignment:
Filter by:
- ○ Active users
- ● Department

Available sub-filters:
- ☐ Engineering
- ☐ Finance
- ☐ Human Resources
- ☑ Information Systems & Technology
- ☐ Manufacturing

Select all Deselect all

Available:
- ☐ gbates (Guy Bates)
- ☑ gdixson (Gretchen Dixson)
- ☐ mboire (Martine Boire)
- ☐ mgervasio (Mandy Gervasio)
- ☐ pgaudreau (Philippe Gaudreau)

Select all Deselect all

+ADD

Assigned:
<empty>

Assigned:
gdixson (Gretchen Dixson)

When Step 7 is Submitted and Confirmed, the Change Control Process will progress as follows:

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- If one or more <u>users were selected</u> in the **Approval to Implement Assignment** field, the process will move to **Step 8 – Implementation Approval**.

- If no <u>users were selected</u> in the **Approval to Implement Assignment** field, the process will move to **Step 9 – QA Implementation Final Approval**. (See Page 37)

The **Process Flowchart** will highlight the next step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with** – in this case any users who were selected at Step 7 in the Approval to Implement Assignment field. If more than one user was selected, the Process Tasks will be differentiated as **Implementation Approval_1**, **Implementation Approval_2**, etc. Each selected user will need to complete the **Implementation Approval** task.

Process Details

Name: Change Control | Date Initiated: 22-Mar-2019 12:47:28
Unique ID: CC-000028 | Initiated by: gdixson (Gretchen Dixson)
Day(s) opened: 82 | Date Closed : <empty>
Secondary Tasks Completion (%): 100 (3/3) | Dependent Processes Completion (%) : 100 (1/1)
Current Process Tasks | Currently with

Implementation Approval_1 | gbates (Guy Bates)
Implementation Approval_2 | gdixson (Gretchen Dixson)

Flowchart: Open

...uest **Last Confirmation Date:** 04-Jun-2019 10:17:49
...and Selection of Reviewers **Last Confirmation Date:** 04-Jun-2019 15:53:59
...iew_1 **Last Confirmation Date:** 05-Jun-2019 13:25:53
...iew_2 **Last Confirmation Date:** 05-Jun-2019 13:26:26
...iew_3 **Last Confirmation Date:** 05-Jun-2019 13:26:58
...ent **Last Confirmation Date:** 06-Jun-2019 16:01:32
Name: QA Approval to Proceed **Last Confirmation Date:** 07-Jun-2019 14:10:42
Name: Pre Implementation Task Completion **Last Confirmation Date:** 07-Jun-2019 15:02:09
Name: Owner Implementation Approval **Last Confirmation Date:** 12-Jun-2019 15:53:40
Name: Implementation Approval_1
Name: Implementation Approval_2

Expand all   Print all

Related Items

Secondary Tasks

Name: Identify list of int[...] **Unique ID:** PRE-00000034 **Due:** 05-Jul-2019 **Status:** Completed   View
Name: FDA Submission **Unique ID:** PRE-00000035 **Due:** 31-Aug-2019 **Status:** Completed   View
Name: FDA Approval Letter **Unique ID:** PRE-00000036 **Due:** 31-Dec-2019 **Status:** Completed   View

Expand all

Dependent Processes

Unique ID: AUD-000017 **Date Initiated:** 04-Jun-2019 **Status:** Completed   View
Current Process Task:

Expand all

Related Documents

Name: Client Notification Letter **No.:** <empty> **Due:** <empty> **Status:** Approved & Effective   ± Open | View

Step 8 – Implementation Approval

At this step in the Change Control Process, each person selected at Step 7 in the **Approval to Implement Assignment** field will receive an email Notification and will see the **Step 8 – Implementation Approval** step listed in the Process section of their SOLABS QM10 HOME Page. They must all act on the task.

As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the Process Values table for additional details and to toggle back and forth between the Process and any Related Items.

Acting on the Implementation Approval Task

When a 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 **Step 8 – Implementation Approval** task.

At this step more **Secondary Tasks** (Post Implementation or Open), **Document Control Processes** or **Related Process** can still be initiated, and the **Link Documents** and **Link Processes** options on the Related Items menu are still available.

The only fields at this stage are an optional field for **Comments** and the **Implementation Approval Decision** or either **Approve** or **Return to Change Control Owner**.

A decision of **Return to Change Control Owner** brings up a mandatory text area for **Comments to Change Control Owner**. Upon confirmation of that decision, the process moves back to **Step 7 – Owner Implementation Approval**.

A decision of **Approve** by all assignees of Step 8 will progress the Change Control process to **Step 9 - QA Implementation Final Approval**.

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

Step 9 – QA Implementation Final Approval

At this step in the Change Control Process, the person assigned as QA Approver at Step 1 will receive an email Notification and will see the **Step 9 – QA Implementation Final Approval** task listed in the Process section of their SOLABS QM10 HOME Page.

As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the **Process Values** table for additional details and to toggle back and forth between the Process and any **Related Items**.

Acting on the QA Implementation Final Approval 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 **Step 9 – QA Implementation Final Approval** task.

If there were regulatory submissions associated with the Change Control, the QA Approver needs to select **Yes** or **No** for **Should approval from each regions be monitored separately?** This will allow the Change Control to progress for one region if an approval is received ahead of another. This choice is set to **No**, and is not editable, if the Step 4 decision was No for **Regulatory Submission Required** or if the Step 2 decision was No for **Is a regulatory assessment required?**

At this point the options to initiate more **Secondary Tasks** (Post Implementation or Open)**, Document Control Processes** or **Related Process** are available.

The **Link Documents** and **Link Processes** options on the Related Items menu are still possible. The **Save Draft** option can be used if the required fields cannot all be completed at the same time or when the **Link Documents** or **Link Processes** options are utilized.

The QA Approver then needs to make the **QA Imp**[Submit] [Save Draft] [Cancel]**cision**.
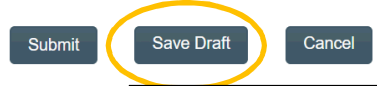
- A decision of **Return to change control owner** will require mandatory Comments and will return the process to **Step 7 – Owner Implementation Approval** upon confirmation.

QA Implementation Final Approval Decision:
○ Approve
● Return to change control owner
* Comments to Change Control Owner:

- A decision of **Approve** will progress the Change Control process to **Step 10 – Post Implementation Task Completion** if any of the following situations apply:
  o Secondary Tasks of Task Type = Post Implementation were initiated at Steps 1 - 9
  o Secondary Tasks of Task Type = Open or Task Type = Pre Implementation were initiated at Steps 7 - 9
  o Dependent Processes were initiated at Steps 7 - 9
  o Any Dependent Processes, Secondary Tasks of Task Type = Open or Secondary Tasks of Task Type = Pre Implementation initiated in Steps 1-5 are not yet complete.
  At this point all Post Implementation Secondary Tasks, other Secondary Tasks initiated at Steps 7-9 and Dependent Processes initiated at Steps 7-9 will be released to the Assignees.

- A decision of **Approve** will progress the Change Control process to **Step 11 – Close-Out** if all of the following conditions are met (see Page 41).
  o All Secondary Tasks have a status of Completed
  o All Dependent Processes have a status of Completed

Assignees of **Secondary Tasks** of Task Type = Post Implementation and of any Secondary Tasks initiated at Steps 7-9 will receive email Notifications and see those activities listed in the **TASKS** section of their SOLABS QM10 HOME Page.   Any dependent processes initiated at Steps 7-9 will move out of the "Waiting for Parent Process" phase.

TASKS

All

Name: Update all SOPs iden[...] ID: POST-00000002 (CC-000028) Due: 31-Dec-2019 Status: Not Started   View | Act on

The **Process Flowchart** will highlight the next step of the process. The **Process Details** screen will display the **Current Process Task** and who it is **Currently with** – the **Change Control Owner** identified at Step 1.

The Change Control Process will stay at Step 10 until all **Dependent Processes** and **Secondary Tasks** are completed.

When the Change Control Owner chooses the **Act on** option for this step, the following message will be displayed: *You are assigned this task because some Secondary Tasks and Dependent Processes are not completed. Please wait until all Secondary Tasks and Dependent Processes are completed to submit this step.*

The Change Control owner can use the optional **Next Follow-Up Date** field if desired.

No new Secondary Tasks or Document Control Processes can be initiated at Step 10.

Process Details

Name: Change Control   **Date Initiated:** 22-Mar-2019 12:47:28

Unique ID: CC-000028   **Initiated by:** gdixson (Gretchen Dixson)

Day(s) opened: 88   **Date Closed :** *<empty>*

Secondary Tasks Completion (%): 75 (3/4)   **Dependent Processes Completion (%) :** 100 (1/1)

Current Process Tasks   **Currently with**
Post Implementation Task Completion   mwagner (Margarita Wagner)

Flowchart: Open

Process Values

Process Tasks

Name: Change Control Request **Last Confirmation Date:** 04-Jun-2019

Name: Quality Assessment and Selection of Reviewers **Last Confirmation...**

Name: Change Control Review_1 **Last Confirmation Date:** 05-Jun-2019

Name: Change Control Review_2 **Last Confirmation Date:** 05-Jun-2019

Name: Change Control Review_3 **Last Confirmation Date:** 05-Jun-2019

Name: Regulatory Assessment **Last Confirmation Date:** 06-Jun-2019

Name: QA Approval to Proceed **Last Confirmation Date:** 07-Jun-2019 14:10:42

Name: Pre Implementation Task Completion **Last Confirmation Date:** 07-Jun-2019 15:02:09

Name: Owner Implementation Approval **Last Confirmation Date:** 12-Jun-2019 15:53:40

Name: Implementation Approval_1 **Last Confirmation Date:** 18-Jun-2019 11:37:43

Name: Implementation Approval_2 **Last Confirmation Date:** 18-Jun-2019 11:37:10

Name: QA Implementation Final Approval **Last Confirmation Date:** 18-Jun-2019 16:12:04

Name: Post Implementation Task Completion

Expand all   Print all

Related Items

Secondary Tasks

Name: Identify list of int[...] **Unique ID:** PRE-00000034 **Due:** 05-Jul-2019 **Status:** Completed   View

Name: FDA Submission **Unique ID:** PRE-00000035 **Due:** 31-Aug-2019 **Status:** Completed   View

Name: FDA Approval Letter **Unique ID:** PRE-00000036 **Due:** 31-Dec-2019 **Status:** Completed   View

Name: Update all SOPs iden[...] **Unique ID:** POST-00000002 **Due:** 31-Dec-2019 **Status:** Not Started   View

Expand all

Dependent Processes

Unique ID: AUD-000017 **Date Initiated:** 04-Jun-2019 **Status:** Completed   View
Current Process Task:

Expand all

Related Documents

Name: Client Notification Letter **No.:** *<empty>* **Due:** *<empty>* **Status:** Approved & Effective   ⬇ Open | View

Collapse all

Related Processes

Unique ID: DOC-000040 **Date Initiated:** 04-Jun-2019 **Status:** In Process   View
Current Process Task: Document Coordinator Processing

Collapse all

SECONDARY TASKS NOT COMPLETED

Post Implementation Task Completion

LOOPBACK

NEXT TRANSITION

Step 10 – Post Implementation Task Completion

Any new or Post Implementation **Secondary Tasks** are now released to **Act on**. Step 10 is a Waiting Phase for the Change Control Owner to monitor the activities and follow up with assignees as needed.

Acting on the Post Implementation Task Completion Task

When all Secondary Tasks and Dependent Processes are at a status of Completed (or Cancelled) for at least one Region (or if no Regulatory Submissions Required), the Change Control Owner will be able to **Act on Step 10 by simply entering the current Date into the Next Follow-Up Date** field.

Next Follow-Up Date:

If at Step 9 **Should approval from each regions be monitored separately** = **Yes**, the Change Control Process will then move to **Step 11 – Close-Out** and will be assigned to the QA Approver.

If at Step 9 **Should approval from each regions be monitored separately** = **No**, the Change Control Process will move back to Step 10 until all Secondary Tasks and Dependent Processes are at a status of completed.

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

Process Details

Name: Change Control   Date Initiated: 22-Mar-2019 12:47:28

Unique ID: CC-000028   Initiated by: gdixson (Gretchen Dixson)

Day(s) opened: 88   Date Closed : <empty>

Secondary Tasks Completion (%): 100 (4/4)   Dependent Processes Completion (%) : 100 (1/1)

Current Process Tasks   Currently with
Close-Out   mturner (Marilyn Turner)

Flowchart: Open

Process Values

Process Tasks

Name: Change Control Request

Name: Quality Assessment and Se

Name: Change Control Review_1

Name: Change Control Review_2

Name: Change Control Review_3   Last Confirmation Date: 05-Jun-2019 13:26:58

Name: Regulatory Assessment   Last Confirmation Date: 06-Jun-2019 16:01:32

Name: QA Approval to Proceed   Last Confirmation Date: 07-Jun-2019 14:10:42

Name: Pre Implementation Task Completion   Last Confirmation Date: 07-Jun-2019 15:02:09

Name: Owner Implementation Approval   Last Confirmation Date: 12-Jun-2019 15:53:40

Name: Implementation Approval_1   Last Confirmation Date: 18-Jun-2019 11:37:43

Name: Implementation Approval_2   Last Confirmation Date: 18-Jun-2019 11:37:10

Name: QA Implementation Final Approval   Last Confirmation Date: 18-Jun-2019 16:12:04

Name: Post Implementation Task Completion   Last Confirmation Date: 18-Jun-2019 16:39:51

Name: Close-Out

Expand all   Print all

Related Items

Secondary Tasks

Name: Identify list of int[...] Unique ID: PRE-00000034 Due: 05-Jul-2019 Status: Completed   View

Name: FDA Submission Unique ID: PRE-00000035 Due: 31-Aug-2019 Status: Completed   View

Name: FDA Approval Letter Unique ID: PRE-00000036 Due: 31-Dec-2019 Status: Completed   View

Name: Update all SOPs iden[...] Unique ID: POST-00000002 Due: 31-Dec-2019 Status: Completed   View

Expand all

Dependent Processes

Unique ID: AUD-000017 Date Initiated: 04-Jun-2019 Status: Completed   View
Current Process Task:

Expand all

Related Documents

Name: Client Notification Letter No.: <empty> Due: <empty> Status: Approved & Effective   ⬇ Open | View

Collapse all

Related Processes

Unique ID: DOC-000040 Date Initiated: 04-Jun-2019 Status: In Process   View
Current Process Task: Document Coordinator Processing

Collapse all

Step 11 – Close-Out

At this step in the Change Control Process, the person assigned as QA Approver at Step 1 will receive an email Notification and will see the **Step 11 – Close-Out** task listed in the Process section of their SOLABS QM10 HOME Page.

As mentioned previously, with each Primary Task assignment, Users can use the **View** option from their HOME Page to see the **Process Details** screen, to Expand the **Process Values** table for additional details and to toggle back and forth between the Process and any **Related Items**.
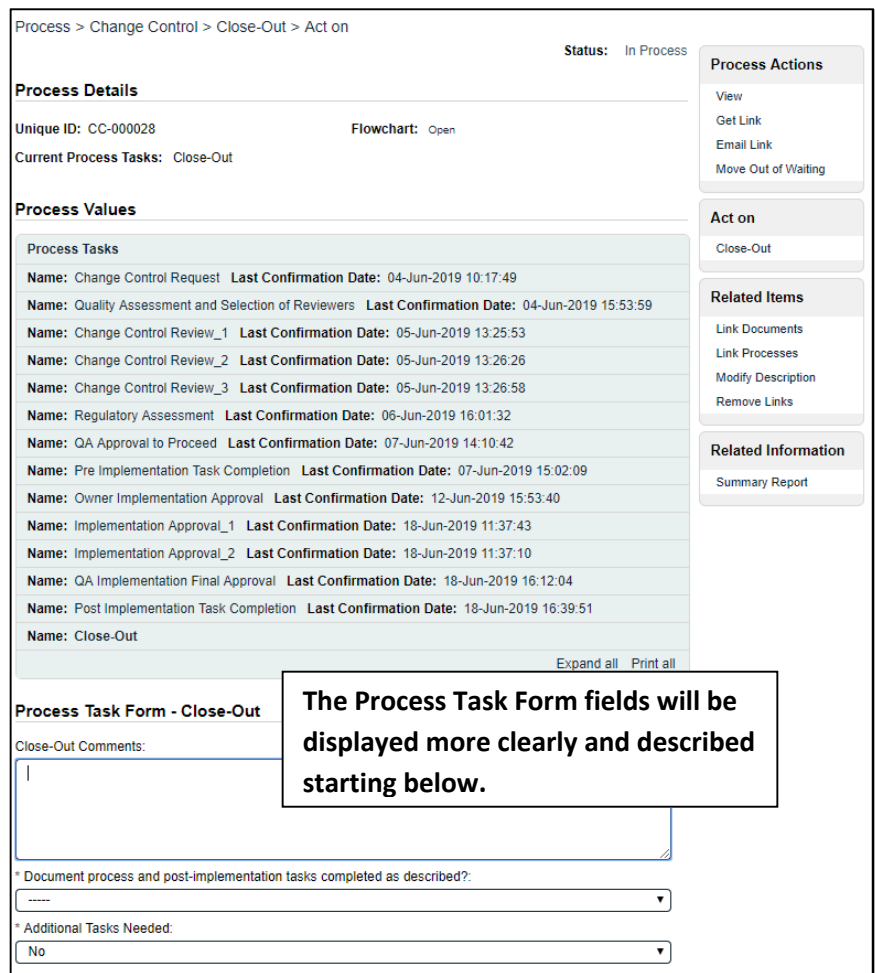
Acting on the Close-Out Task

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 **Step 11 – Close-Out** task.

There is an optional text area (4000 characters) field for any **Close-Out- Comments**.

The QA Approver will need to enter information regarding whether the **Document process and post-implementation tasks completed as described?** and whether there are **Additional Tasks Needed.** Information entered in these fields will impact where the process goes next.

Depending on choices made at previous steps, there are also additional fields displayed to enter information regarding regulatory **Region Title and Region Status**.

At this point no more **Secondary Tasks** or **Document Control Processes** can be initiated.

The **Link Documents** and **Link Processes** options on the Related Items menu are still possible, as is the ability to initiate a new **Related Process**. The **Save Draft** option can be used if the required fields cannot all be completed at the same time or when the **Link Documents** or **Link Processes** options are utilized.

> * Document process and post-implementation tasks completed as described?:
> `-----`   ▼   ncel

The mandatory **Document process and post-implementation tasks completed as described?** field is a single-item selection field with choices of **Yes**, **No** or **N/A**.

> * Document process and post-implementation tasks completed as described?:
> `No`
> Consider re-opening completed tasks or creating a new one
> * Specify:
> [   ]

If **No** is selected, the phrase **Consider re-opening completed tasks or creating a new one** is displayed and a mandatory text area (4000 characters) field **Specify** is opened.

If the decision at Step 9 for **Should approval from each regions be monitored separately?** was **Yes**, Step 11 will also include non-editable fields named **Region Title** and **Region Status** for each applicable regulatory region. When all related Secondary Tasks are completed, the corresponding **Region Status** field will be auto-populated with the value "Completed". For each regulatory region, a check box named **Assessed** is also displayed. It defaults to being unchecked but can be checked when applicable.

The mandatory **Additional Tasks Needed** field is a single-item selection field with either **Yes** or **No** as options. It defaults to **No**. A selection of **Yes** will result in the process going back to **Step 9 – QA Implementation Final Approval**, so the QA Approver can initiate the additional tasks.

> * Additional Tasks Needed:
> `No`   ▼

Confirmation of Step 11 – Close-Out

When Step 11 is Submitted and Confirmed, the Change Control Process will progress as follows, depending on the options selected:

- If **Additional Tasks Needed** = **Yes**, the process moves to **Step 9 – QA Implementation Final Approval** so the additional tasks can be added.

- If **Additional Tasks Needed** = **No**, but any of the following situations exist, the process moves to **Step 10 – Post Implementation Task Completion** to wait for completion of those activities to be complete.
  - There is at least one Secondary Task not complete
  - There is at least one Dependent Process not complete
  - There is at least one regulatory region at a status of "Completed" but its Assessed box is unchecked

- The Change Control Process moves to **Close (END)** if all the following conditions are met:
  - All Secondary Tasks are complete
  - All Dependent Processes are complete
  - **Additional Tasks Needed** = **No**
  and one of the following conditions are met:
  - The Assessed box is checked for each regulatory region

Status: Completed

     o   At Step 5, **Should approval from each regions be monitored separately?** = **No**

Viewing Details for a Completed Change Control Process

Users are able to search for and view processes at any stage, using the **Navigation** tab in the **PROCESS Section** of SOLABS QM10.   If the Process was recently worked on, it will also be available in the **Recent Items** section.

Using the Process Values Table

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

Status: Completed

Process Details

Name: Change Control	**Date Initiated:** 22-Mar-2019 12:47:28
Unique ID: CC-000028	**Initiated by:** gdixson (Gretchen Dixson)
Day(s) opened: 89	**Date Closed :** 19-Jun-2019 14:30:39
Secondary Tasks Completion (%): 100 (4/4)	**Dependent Processes Completion (%) :** 100 (1/1)
Current Process Tasks *N/A*	**Currently with** *N/A*

Flowchart: Open

Process Values

Process Tasks

Name: Change Control Request   **Last Confirmation Date:** 04-Jun-2019 10:17:49

Name: Quality Assessment and Selection of Reviewers   **Last Confirmation Date:** 04-Jun-2019 15:53:59

Name: Change Control Review_1   **Last Confirmation Date:** 05-Jun-2019 13:25:53

Name: Change Control Review_2   **Last Confirmation Date:** 05-Jun-2019 13:26:26

Name: Change Control Review_3   **Last Confirmation Date:** 05-Jun-2019 13:26:58

Name: Regulatory Assessment   **Last Confirmation Date:** 06-Jun-2019 16:01:32

Name: QA Approval to Proceed   **Last Confirmation Date:** 07-Jun-2019 14:10:42

Name: Pre Implementation Task Completion   **Last Confirmation Date:** 07-Jun-2019 15:02:09

Name: Owner Implementation Approval   **Last Confirmation Date:** 19-Jun-2019 10:48:10

Name: Implementation Approval_1   **Last Confirmation Date:** 19-Jun-2019 10:49:11

Name: Implementation Approval_2   **Last Confirmation Date:** 19-Jun-2019 10:48:41

Name: QA Implementation Final Approval   **Last Confirmation Date:** 19-Jun-2019 10:49:53

Name: Post Implementation Task Completion   **Last Confirmation Date:** 18-Jun-2019 16:39:51

Name: Close-Out   **Last Confirmation Date:** 19-Jun-2019 14:30:38

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.

Creating a Summary Report

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

Related Information
Audit Trail
Summary Report

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

Using the Audit Trail

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

Related Information

Audit Trail

Summary Report

There you will find all the details for every step of the Change Control 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 > CC-000028 > Audit Trail

Process Name: CC-000028

Action Details: Process Completed   Print
Process Task Name: N/A
Date: 19-Jun-2019 14:30:39
Role: FCT_Manager QA Compliance
Username (Full Name): mturner (Marilyn Turner)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Close-Out
Date: 19-Jun-2019 14:30:38
Role: FCT_Manager QA Compliance
Username (Full Name): mturner (Marilyn Turner)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: QA Implementation Final Approval
Date: 19-Jun-2019 10:49:53
Role: FCT_Manager QA Compliance
Username (Full Name): mturner (Marilyn Turner)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Implementation Approval_1
Date: 19-Jun-2019 10:49:11
Role: FCT_Director IS/IT
Username (Full Name): gbates (Guy Bates)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Implementation Approval_2
Date: 19-Jun-2019 10:48:41
Role: FCT_QMS System Administrator
Username (Full Name): gdixson (Gretchen Dixson)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Owner Implementation Approval
Date: 19-Jun-2019 10:48:10
Role: FCT_Change Control Coordinator
Username (Full Name): mwagner (Margarita Wagner)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: QA Implementation Final Approval
Date: 19-Jun-2019 10:45:33
Role: FCT_Manager QA Compliance
Username (Full Name): mturner (Marilyn Turner)
Reason for Change: N/A

Action Details: Task Performed   Print
Process Task Name: Close-Out
Date: 19-Jun-2019 10:42:41
Role: FCT_Manager QA Compliance
Username (Full Name): mturner (Marilyn Turner)
Reason for Change: N/A

Change Control Process Notifications

The Notifications available with the Off-the-Shelf Change Control Process APP P0036 are identified in the Process Roles section of this User Guide and at the related Process Steps. The content of these email Notifications is described below.

General information on SOLABS QM10 Notifications are available on the SOLABS Knowledge Base in a document titled **SOLABS QM10: Notifications Guide.**

- When Step 1 is confirmed**,** the following email notification is sent.

    TO: Change Control Owner selected at Step 1
    SUBJECT: Assignment of Change Control owner: Change Control Process CC-XXXXXX
    BODY: You received this notification because you have been assigned as the Change Control
          Owner for the following process:
          Process ID: [CC-XXXXXX]
          Title: [Step 1 Title]
          Implementation Date: [Step 1 Proposed Implementation Date]

- When one of the following conditions is met**,** the following email notification is sent.

    o Today >= Step 5 Proposed Implementation Date – X (where X = Step 2 Number of days to be
       notified prior to proposed implementation/close-out date) and some Pre-Implementation
       Secondary Tasks are not completed.
    o Today = Step 6 Next Follow-Up Date and some Pre-Implementation Secondary Tasks are not
       completed.

    TO: Change Control Owner selected at Step 1
    SUBJECT: SOLABS QM CC Process: some Pre-Implementation secondary tasks are not completed
    and the proposed implementation date is approaching (or is already reached)
    BODY: Please note that some Pre-Implementation secondary tasks are not completed and the
          proposed implementation date is approaching (or is already reached)
          CC#: [process number hyperlinked to process]
          Type of Change: [Step 1 Change Type]
          Title: [Step 1 Title]
          Proposed Implementation Date: [Step 5 Proposed Implementation Date]
          Next Follow-Up Date: [Step 6 Next Follow-Up Date]

- When all Pre-Implementation Secondary Tasks are completed**,** the following email notification is
  sent.

    TO: Change Control Owner selected at Step 1
    SUBJECT: SOLABS QM CC Process: all Pre-Implementation Secondary tasks are completed
    BODY: Please note that all Pre-Implementation secondary tasks are completed
          CC#: [process number hyperlinked to process]
          Type of Change: [Step 1 Change Type]
          Title: [Step 1 Title]

- When Today = Step 10 Next Follow-Up Date and some Secondary Tasks or Dependent Document Control Processes are not completed**,** the following email notification is sent.

  TO: Change Control Owner selected at Step 1
  SUBJECT: SOLABS QM CC Process: some secondary tasks or Dependent Document Control Processes are not completed
  BODY: Please note that some Secondary tasks OR Document Control Processes are not completed and the proposed implement date is approaching (or is already reached).
  CC#: [process number hyperlinked to process]
  Type of Change: [Step 1 Change Type]
  Title: [Step 1 Title]
  Next Follow-Up Date: [Step 10 Next Follow-Up Date]

- When all the following conditions are met**,** the following email notification is sent.

  o   All Open Secondary Tasks are completed
  o   All Post-Implementation Secondary Tasks are completed
  o   All Dependent Document Control Processes are completed

  TO: Change Control Owner selected at Step 1
  SUBJECT: SOLABS QM CC Process: all Post-Implementation and Open secondary tasks and all Dependent Document Control Process are completed
  BODY: Please note that all Post-Implementation and Open secondary tasks and all Dependent Document Control Process are completed
  CC#: [process number hyperlinked to process]
  Type of Change: [Step 1 Change Type]
  Title: [Step 1 Title]

- When all the secondary tasks related to one region are completed and if Yes is selected at Step 9 for Should approval from each regions be monitored separately?**,** the following email notification is sent.
  TO: Change Control Owner selected at Step 1
  SUBJECT: SOLABS QM CC Process: all the secondary tasks for [Region] are completed.
  BODY: Please note that all the tasks required for [Region] are completed.
  CC#: [process number hyperlinked to process]
  Type of Change: [Step 1 Change Type]
  Title: [Step 1 Title]