SOLABS QM10: System Administration for the PROCESS Section

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Purpose of this Guide

This guide is intended for "Super-Users" who are assigned the SOLABS System Administrator Role and/or SOLABS Document Administrator Role and who will manage Process Role assignments, User Privileges and maintenance of Custom Lists for the **PROCESS** Section of **SOLABS QM10**.

The SETUP Section

The **SETUP** section is used to manage **System Access** and **System Parameters**. It is available to Users who have been assigned the System Roles of **SOLABS System Administrator** and **SOLABS Document Administrator**.

Selecting **SETUP** from the top menu, brings most users to their own **Setup > User > View** page. On this page, they can view their **User Account Details**, **User Account Settings**, **Company Structure Details** and **Assigned Roles**, as set by their System Administrator.

November 2021
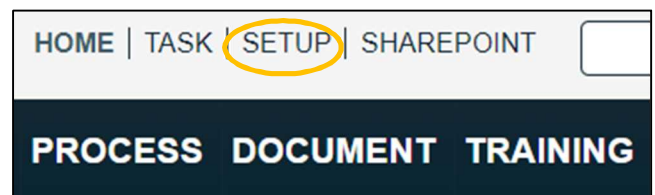
For System Administrators and Document Administrators, the left-hand **Administration** tab will be enabled.   This gives System Administrators access to menus for User Management, such as assignment of Process Roles. It gives Document Administrators access to manage Custom Lists that may be associated with Process APPs.
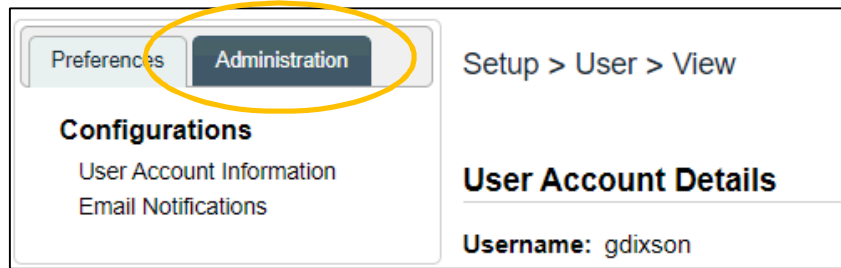
When System Administrators access the PROCESS Section, they also have the **Manage Privileges** menu option.
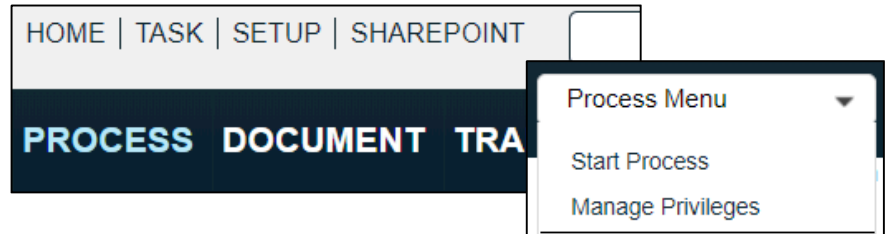
## Administrative Activities for the PROCESS Section

Assigning Process (PR_) Roles

For any of the SOLABS QM10 Process APPs, 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. There are Process Roles that need to be assigned to the Users in SOLABS QM10 who will make the related decisions. If these Process Roles are not assigned to any Users, the Process workflow will not move forward.

When SOLABS QM10 Users are assigned a Process Role, their names are then available on drop-down lists to be selected for their step in the process. The process will automatically notify them to Act On that Step in the Process. They will see the task in the Process Section of their SOLABS QM10 HOME Page and will also receive an email Notification.

Process Roles are available with the deployment of a Process APP and can be assigned to Users by the SOLABS System Administrator.   To view the Process Roles, go to the **Administration** tab in the SETUP Section and choose **System Administration > Roles > Active PR roles by name**.
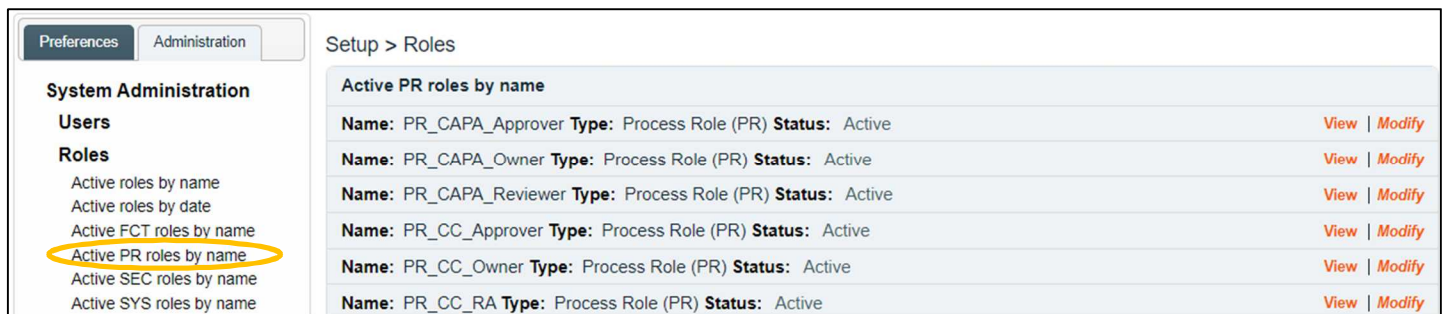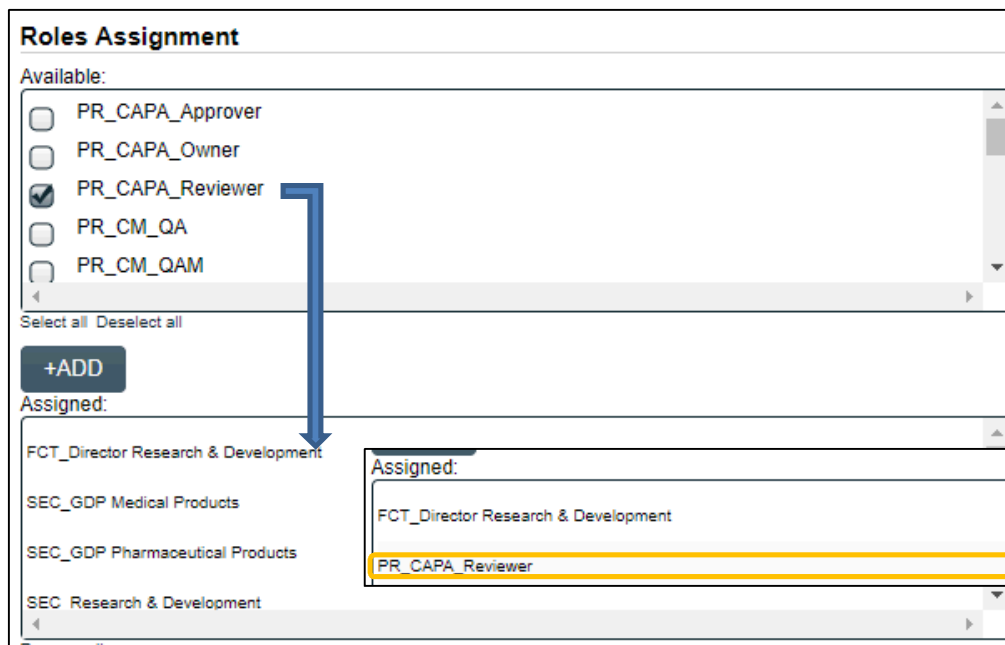
Assigning Process Roles to Users
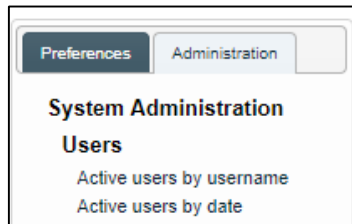
To assign one or more Process (PR) Roles to an Active User, go to **System Administration > Users** and choose one of the options to access Active Users.

Click the Modify option next to the listing for the User you would like to assign a Process Role to display the **Setup > User > Modify** screen.

The **Roles Assignment** section of the **Setup > User > Modify** screen includes the **Available** Process (PR) Roles for the deployed SOLABS QM10 Process APPs.

Select the Process Roles to be added for this User and then click the **+ADD** button. This will move them to the **Assigned** box.

There will be a **Remove** option beside the new listing in case it was added in error.

To save the change, click **Submit**.   At that point the **Assigned Roles** section of the screen will highlight the Role that was **Added**.   Click **Confirm**, enter a **Reason for Change** and then click **Confirm All**. The Process Role is now assigned to the User.
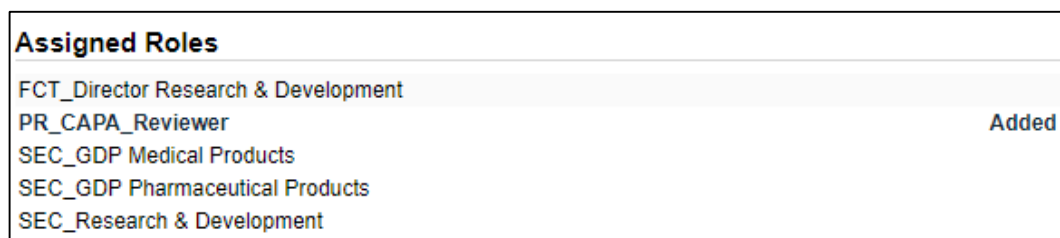
Adding/Removing Users from a Process Role

A Role can be modified to add or remove multiple users. Clicking on that option will bring up the **Add/Remove Users** screen. Choose the **View** option for the Process Role for which you would like to add or remove users.

Setup > Roles

Active PR roles by name

Name: PR_CAPA_Approver Type: Process Role (PR) Status: Active   View | Modify

Name: PR_CAPA_Owner Type: Process Role (PR) Status: Active   View | Modify

Name: PR_CAPA_Reviewer Type: Process Role (PR) Status: Active   View | Modify

From the right-hand **Role Actions** menu, choose **Add/Remove Users**.

The Filter by options allow searching for **Available** people from the entire **Active users** list or searching for them after filtering by **All Job Titles** (which is a list of active Function Roles).

Role Actions

View

Enable Editing

Add/Remove Users

Add/Remove Users

Filter by:
- ● Active users
- ○ All Job Titles ▼

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

OR

Available sub-filters:
- ☐ Administrative Coordinator
- ☐ Associate Director Quality Assurance
- ☑ Auditor - QA Compliance ➡
- ☐ Biostatistician

Available:
- ☐ csanders (Christina Sanders)
- ☐ dbarnes (Donald Barnes)

Select the User(s) and click **+ADD** to move them to the **Assigned** box. There is a **Remove** option beside each Username in the Assigned box.

Assigned:

eblake (Evan Blake)	Remove
epete (Elinor Pete)	Remove
fklein (Fred Klein)	Remove
jjohnson (Joanna Johnson)	Remove

Assigning Process Privileges

SOLABS System Administrators **Manage Privileges** for the PROCESS Section by choosing that option from the Quick Access **Process Menu**. This brings up the **Process > Manage Privileges > View by Role** screen.

PROCESS DOCUMENT TRAINING

Process Menu ▼

Start Process

Manage Privileges

By default, SOLABS System Administrators have Administer privileges in the PROCESS Section.   The SOLABS General User has the lowest level of permission, which is **Act On**. The SOLABS General User role is considered a "start up" role and is ideally replaced by appropriate Security or Function Roles for your organization so that you can more intentionally assign the **Act On** privilege level. Choose a **Process Type** and click on **Modify** to make changes.   The **Change Privileges** section will list all active Roles available in this instance of SOLABS QM10.

Process > Manage Privileges > View by Role

Status: Custom

Privileges

View

Modify

Available Processes

Process Type:

Document Control

Current Privileges

Role	Act On	Act On & Reassign	Modify	Administer
SOLABS System Administrator	☑	☑	☑	☑
SOLABS General User	☑	☐	☐	☐

Change Privileges

◉ All instances of the process and all its associated Related Items
◯ All instances of the process only

	Role	Act On	Act On & Reassign	Modify	Administer	
☐	SOLABS System Administrator	☑	☑	☑	☑	Remove
☐	SOLABS General User	☑	☐	☐	☐	Remove
☐	FCT_Administrative Coordinator					
☐	FCT_Associate Director Quality Assurance					
☐	FCT_Auditor - QA Compliance					
☐	FCT_Biostatistician					
☐	FCT_Change Control Coordinator					
☐	FCT_Clinical Operations					
☐	FCT_Complaint Coordinator					
☐	FCT_Director Clinical Operations					

Select all   Deselect all

Clear all except 'Administer'

		Act On	Act On & Reassign	Modify	Administer	
	Set Privileges:	☑	☐	☐	☐	Update

Submit   Cancel

To limit the privilege to Start a Process to only certain people in the organization, click the **Remove** option next to **SOLABS General User** and then add the **Act On** privilege to the Roles who will be able to Start a Process.

To allow certain Users the **Act On & Reassign** or **Modify** privileges, select the Role and then select the View and/or Modify box at the bottom before clicking the **Update** option.

Click **Submit** to verify the changes that have been made. The **Process Types**, Roles **Added** and Roles **Removed** will be displayed. All changes will be displayed for verification. Click **Confirm** to save the changes.
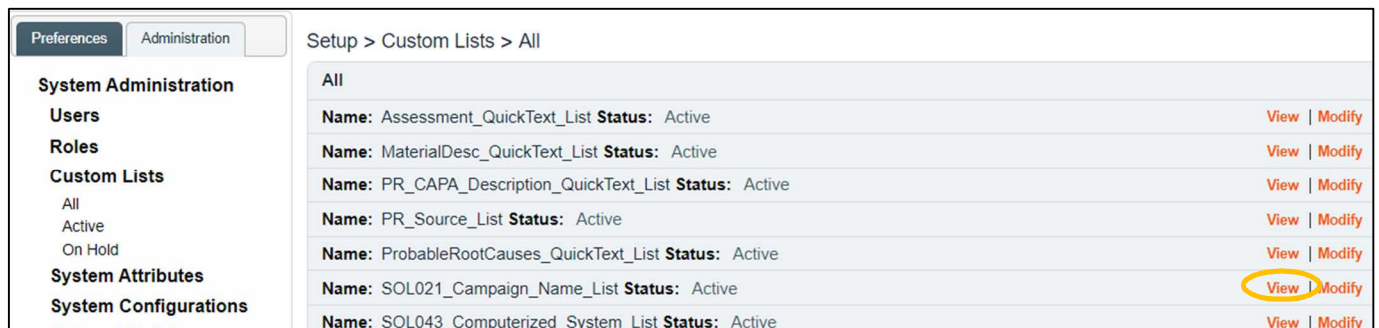
Custom List Management

From the **SETUP** Section, **Custom Lists** are available through the Administration tab of the left dashboard menu. Custom List Management actions require assignment of the System Role **SOLABS Document Administrator**.

Some Custom Lists are provided by default with any deployed SOLABS Process APPs. They support fields related to those process workflows. They may include default values but can be edited by the SOLABS System Administrator to reflect your company terminology.

These Custom Lists may have prefixes related to the Process, such as "CAPA_", "AUD_", "SOLDOC_", "'CMR_", etc. They may also include prefixes that start with "SOL_" and a number. Some may be shared across multiple processes.

Consult the User Guide (Knowledge Base) or the Process User, Functional & Design Specifications (PUFDS) document (eRoom) for your deployed Process APPs to confirm the names of the Custom Lists associated with each process step.

To view the list of all active Custom Lists, choose the <u>Active</u> option under Custom Lists from the left-hand SETUP Administration tab. View a specific list by using the **View** option to the right of the listing.
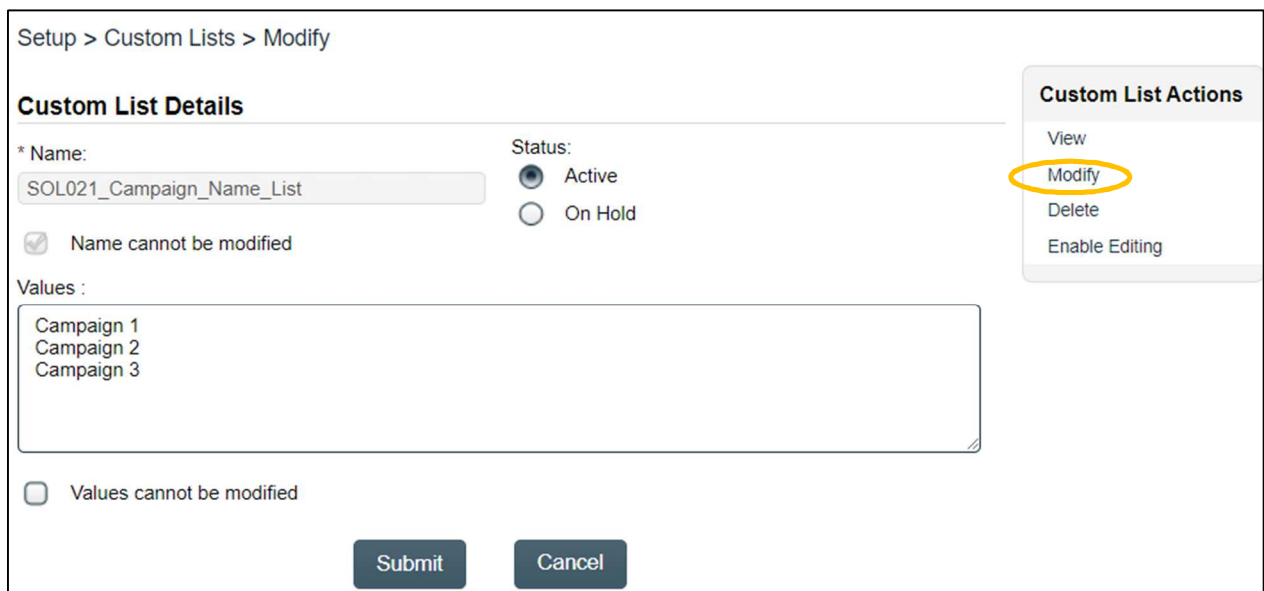

Modify a Custom List

To Modify a **Custom List**, either choose the **Modify** option to the right of the listing on the list of Active Custom Lists or choose the **View** option and then choose **Modify** from the right-hand **Custom List Actions** menu.

If **Name cannot be modified** or **Values cannot be modified** are checked, those fields can be enabled for editing by clicking on the **Enable Editing** option and then Confirming that choice. Use caution as the decision not to allow modification may be related to the use of that Custom List in an active process.

Modifying Task Types

Some Process APPs have specific Task Types defined. Those will be listed in the Administration tab under **System Configurations > Task Type Configuration**.

The Task Type Details will list all available Task Types. Consult the User Guide or the Process User Functional Design Specification document for each deployed Process APP to verify which ones apply to each Process.
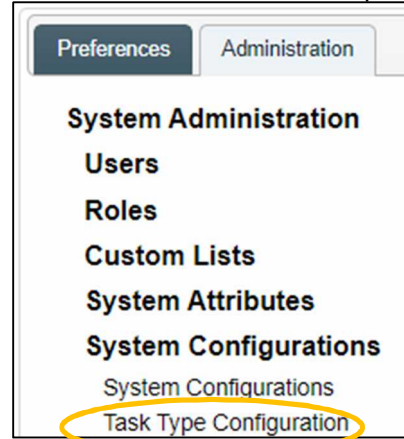
Click the Modify option to access Task Type Details that can be modified. For Process APP10.8
 Task Types, only the **Name** field can be modified.

Task Type Details

Name	Prefix
Task	Task
Pre-Implementation	PRE
Post-Implementation	POST
Open	OPEN
Miscellaneous	MISC
CAPA Task	CAPA

Task Type Actions

View

Modify

Task Type Details

* Name:

Task

* Prefix:

Task

Remove

* Name:

Pre-Implementation

* Prefix:

PRE

Remove

* Name:

Post-Implementation

* Prefix:

POST

Remove