

SOLABS QM10: PROCESS Section Privileges

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Introduction

The intent of this document is to address the setup and maintenance of privileges in the **PROCESS** section of **SOLABS QM10**. Assigning permissions/privileges allows the ability to have different levels of access for users within the system.

Privileges in the PROCESS Section

The four available permission levels in the **PROCESS** section are **Act On**, **Act On & Reassign**, **Modify** and **Administer**.

Note: The terms **privileges** and **permissions** are used interchangeable in this document. Privileges build cumulatively on one another, granting all lower-level privileges automatically upon assignment of a higher-level privilege.

Upon initial installation, some privileges are set by default but can be changed as needed:

- **SOLABS General User** is a generic role assigned to all users. It is set to allow just the minimum permission level of **Act On**. It is provided as a "start-up" role and should ideally be replaced with appropriate Security or Function Roles for your organization that will grant Act On permissions, and then removed.
- **SOLABS System Administrator** is a system role available to assign to those in your organization who will administer users, roles custom lists and system configurations. It is set to allow the maximum permission level of **Administer**.



PRIVILEGE LEVEL	ACTIONS POSSIBLE WITH THIS PRIVILEGE/PERMISSION LEVEL
ACT ON	View process, start process, act on process, get link, email link, link documents, link processes, modify descriptions, summary report, remove links
ACT ON & REASSIGN	ALL of the above, PLUS reassign tasks assigned to me, move out of waiting and view audit trail
MODIFY	ALL of the above, PLUS modify values, reassign any process task, manage the linking of documents, processes, and description of linked items on <i>closed</i> processes
ADMINISTER	ALL of the above, PLUS cancel processes, manage user privileges, and modify values in <i>closed</i> processes

PROCESS Section Privileges | Table

PROCESS Section Privileges | Graphic

		ACT ON	ACT ON & REASSIGN	MODIFY	ADMINISTER
	View	✓	\checkmark	✓	✓
	Start Process	✓	\checkmark	✓	✓
	Act On	✓	\checkmark	✓	✓
	Get Link	✓	\checkmark	\checkmark	✓
	Email Link	✓	\checkmark	\checkmark	✓
	Link Documents	✓	\checkmark	\checkmark	\checkmark
	Link Processes	✓	\checkmark	\checkmark	\checkmark
	Modify Description	✓	\checkmark	\checkmark	\checkmark
PRIVII FGF	Summary Report	✓	\checkmark	\checkmark	\checkmark
REQUIRED	Remove Links	\checkmark	\checkmark	\checkmark	\checkmark
TO	Reassign Tasks Assigned to me		\checkmark	\checkmark	\checkmark
10	Move Out of Waiting		\checkmark	\checkmark	\checkmark
	Audit Trail		\checkmark	\checkmark	\checkmark
	Modify Values			\checkmark	\checkmark
	Reassign a Process Task			\checkmark	\checkmark
	Manage Closed Process: Link Documents				
	Link Process			\checkmark	\checkmark
	Modify Descriptions of Linked Items				
	Cancel				✓
	Manage Privileges				✓
	Modify Value in Closed Process				\checkmark



Process Roles | Meaning & Examples

Process Roles are provided along with a Process APP when it is deployed. These Process Roles are assigned to users to allow them to be selected as to act on corresponding Process Workflow Steps. The names of these Process Roles are abbreviated in SOLABS QM10 Process Role list. The table below provides an example to help illustrate how the Process (PR_) Roles are identified:

SOLABS QM10	MEANING
ABBREVIATION	
PR_CC_Owner	Process (PR), Change Control (CC), Change Control Owner
PR_CC_RA	Process (PR), Change Control (CC), Regulatory Affairs (RA)
PR_DEV_QA_Approver	Process (PR), Deviation (DEV), Quality Assurance (QA), Approver
PR_DOC_COORD	Process (PR), Document Control (DOC), Document Coordinator (COORD)
PR_DOC_TRAIN_COORD	Process (PR), Document Control (DOC), Training Coordinator (TRAIN_COORD)

Assigning PROCESS Permissions & Privileges

Privileges can be handled three ways with regards to the PROCESS section; both are detailed below:

- 1. Through User Creation or Modification (Create User or User > Modify): This method assigns privileges to Users as you create/modify them, and is useful if you know the roles of the users in your workplace.
- 2. Through Active PR Roles > View > Add/Remove Users: This method allows the update of a Process Role to add or remove multiple users all at once.
- 3. Though **Process > Quick Access Menu > Manage Privileges:** This method assigns Process Roles to all users with the same Function and/or Security Roles, and is useful if want to assign the roles to all users with the same Job Function or in the same organizational area all at once.

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.

Roles Assignment	
Available:	Select the Process Roles
PR_CAPA_Approver	to be added for this User
PR_CAPA_Owner	and then click the +ADD
PR_CAPA_Reviewer	button. This will move
PR_CM_QA	them to the Assigned
PR_CM_QAM *	box.
Select all Deselect all	There will be a Remove option beside the new listing in case it was
Assigned: FCT_Director Research & Development	added in error.
Assigned:	
SEC_GDP Pharmaceutical Products FCT_Director Research & Development	
SEC Research & Development PR_CAPA_Reviewer	Remove

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.

Assigned Roles	
FCT_Director Research & Development	
PR_CAPA_Reviewer	Added
SEC_GDP Medical Products	
SEC_GDP Pharmaceutical Products	
SEC_Research & Development	

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**.

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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).



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.

ſ	Assigned:		
	eblake (Evan Blake)	Remove	*
	epete (Elinor Pete)	Remove	
	fklein (Fred Klein)	Remove	
	jjohnson (Joanna Johnson)	Remove	
L			

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.

By default, SOLABS System Administrators have full privileges in the PROCESS Section. The SOLABS General User has the lowest level of permission, which is **Act On**. 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 DOCUMENT	TRAINING	Process Menu	-
		Start Process Manage Privileges	



Proc	ess > Manage Privileges > View by	Role					
					5	status: Custo	Privileges
Avai	lable Processes						View
Proce	ss Type:						Modify
Doc	cument Control					•	
Curr	ent Privileges						_
Role			Act On A	ct On & leassign	Modify	Administer	
SOLA	BS System Administrator			Ø.	\bigcirc	\square	
SOLA	BS General User					\bigcirc	
Cha	nge Privileges						
۲	All instances of the process and all its as	sociated R	elated Items				
0	All instances of the process only						
	Role	Act On	Act On & Reassign	Modify	Administer	r	A
	SOLABS System Administrator			\odot		Remove	
\bigcirc	SOLABS General User		\Box	\Box		Remove	
\Box	FCT_Administrative Coordinator						
\bigcirc	FCT_Associate Director Quality Assurance						
\Box	FCT_Auditor - QA Compliance						
\bigcirc	FCT_Biostatistician						
	FCT_Change Control Coordinator						
\bigcirc	FCT_Clinical Operations						
\Box	FCT_Complaint Coordinator						
\bigcirc	FCT_Director Clinical Operations						-
Select	all Deselect all	Act On	Act On & Reassign	Modify	Administe	er	
Clear	all except 'Administer' Set Privileg	es: 🔗				Update	
	Subr	nit	Cancel				

All users have the SOLABS General User role by default, which allows the Act On privilege. It is recommended as a best practice to replace this role with appropriate Security or Function Roles for your organization to reflect those who will be able to Start a Process, then click the **Remove** option next to **SOLABS General User**.

Determine which users should have the **Act On & Reassign** or **Modify** privileges. Select the Security or Function roles associated with those users, then select the **Act On & Reassign** or **Modify** box at the bottom before clicking the **Update** option in the lower right corner of the screen.



Cha	nge Privileges						
۲	All instances of the process and all its asso	ciated Relate	ed Items				
\bigcirc	All instances of the process only						
	Role	Act On	Act On & Reassign	Modify	Administer		
	SOLABS System Administrator			\checkmark	\checkmark	Remove	
\bigcirc	SOLABS General User						
\bigcirc	FCT_Administrative Coordinator						
	FCT_Associate Director Quality Assurance						
	FCT_Auditor - QA Compliance						
\bigcirc	FCT_Biostatistician						
\Box	FCT_Change Control Coordinator						
\bigcirc	FCT_Clinical Operations						
\bigcirc	FCT_Complaint Coordinator						
\bigcirc	FCT_Director Clinical Operations						
Selec	t all Deselect all	Act On	Act On & Reassign	Modify	Administer		
Clear	all except 'Administer' Set Privileges:					Update	

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.

Available Processes				
Process Type: Document Control				
Change Privileges of: All instances of the process and all its associated Related Items				
Current Privileges				
Added				
Role	Act On	Act On & Reassign	Modify	Administer
FCT_Associate Director Quality Assurance				
FCT_Auditor - QA Compliance	Ø		\bigcirc	\Box
Removed				
Role	Act On	Act On & Reassign	Modify	Administer
SOLABS General User	S			
Modified				
<empty></empty>				
Not Logged in Audit Trail				
	te esta esta esta esta a			
		Canad		
Confirm Bac	k to Edit	Cancel		