

SOLABS QM10: Guide for System Administrators – Maintaining Users, Roles and System Configurations

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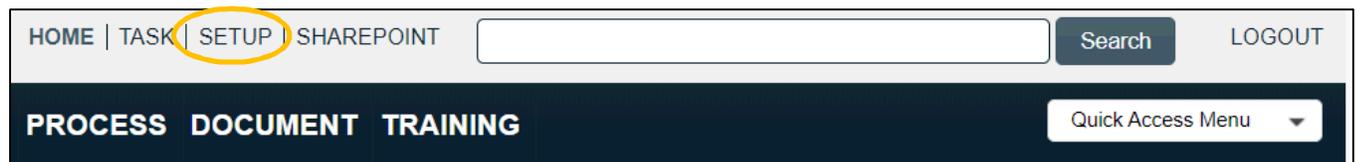
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Purpose of this Guide

This guide is intended for “Super-Users” who are assigned the SOLABS System Administrator Role and who perform setup, maintenance and administration of Users, Roles, Role Assignments, Custom Lists, System Attributes and System Configurations in **SOLABS QM 10**. Refer to separate User Guides for Administration of the Process Section, Document Section and Training Section.

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 Role of **SOLABS System Administrator**. Some System Administration tasks (Custom Lists, System Configurations) in the **SETUP** also support document management so are available to Users who have been assigned the System Role of **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.

Setup > User > View

Status: Active

User Actions

- Modify
- Change Password

User Account Settings

Account Type: Standard
Login Type: Database
Sharepoint Access: N/A

Signature Graphic :



User Account Details

Username: gdixson	Language: English
Full Name: Gretchen Dixon	Alias: GD
Email Address: gdixson@solabs.com	Employee ID:
Time Zone: US/Eastern (UTC-04:00)	SOLABS Unique ID: 61118ouy6

Company Structure Details

Department Head:	Manager: gbates (Guy Bates)
Job Title: Employee Orientation Training; QMS System Administrator	
Organization: GDP Medical Products	Division: GDP Medical Device Products; GDP Pharmaceutical Products
Department: Information Systems & Technology	Sub-Department:

Assigned Roles

- FCT_Employee Orientation Training
- FCT_QMS System Administrator
- PR_CCR_CCC
- PR_DEV_Lead_Investigator
- PR_DEV_QA_Approver
- PR_DOC_Business_Owner
- PR_DOC_COORD
- PR_DOC_TRAIN_COORD
- SEC_GDP Medical Device Products
- SEC_GDP Medical Products
- SEC_GDP Pharmaceutical Products
- SEC_Information Systems & Technology
- SOLABS Document Administrator

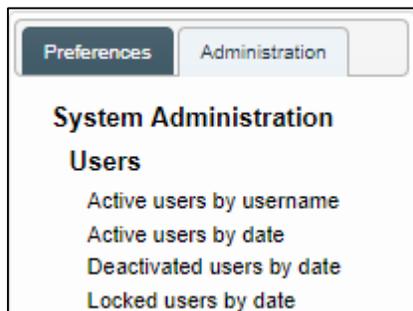
Most users only have the option to change languages (where available) and to modify their passwords. Super Users, however, have the option to do a lot of ‘behind the scenes’ User Management maintenance activities.

The User Management section of this guide will cover those maintenance activities that are available to System Administrators/Super Users.

Left- and Right-hand SETUP Menus

Sorting and Filtering Menus

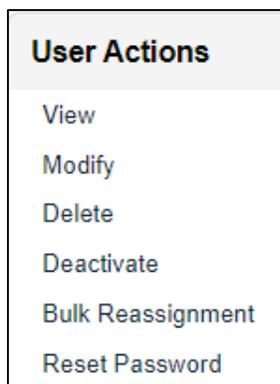
To the left, as consistent throughout the **SOLABS** interface, you have **Sorting and Filtering Menus**, in this case called **Preferences** and **Administration**.



Example: The left-hand menu options for **Users** allow sorting subsets of **Active Users** differently, as well as **Deactivated** and **Locked Users**.

Actions Menus

To the right, also consistent throughout the **SOLABS** interface, you have contextual **Actions Menus**.



Example: The right-hand menu options for User Management are the actions you can perform on Users — due to your **Administrator** role; not actions done by **Users** themselves.

In the **User Actions** menu, you can find **View User**, **Modify User**, **Delete User**, **Deactivate User** and **Bulk Reassignment**. These functions are covered in the User Management section.

If a User is locked, there will also be an **Unlock** option when accessing that user as an Administrator.

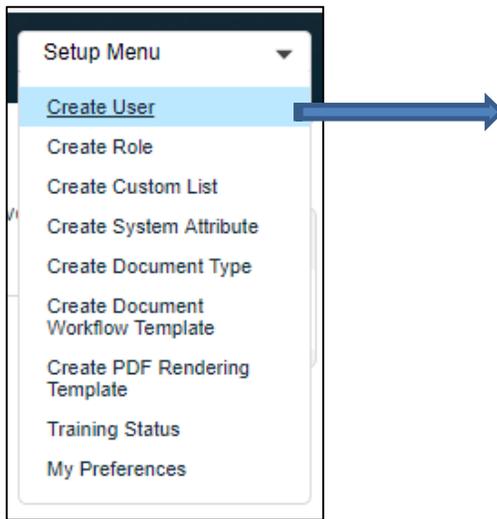
Starting with SOLABS QM 10.8, there is also a **Reset Password** option available for Database instances such as Validation Environments.

User Management

The following User Management actions require assignment of the System Role **SOLABS System Administrator**.

Create User

From the Quick Access menu, click **Create User**. The **Create User** page is then loaded. Required fields are identified by an asterisks (*).



For some companies, some of the **User Account Details** may be populated automatically by a validated interface with the company HR system.

When completing this section manually, an **Auto-populate fields from** option is available. When opened, a list of active users is displayed. Selecting one of these users will auto-populate the fields with that same information; fields which may be different – Username, Full Name, Email Address, etc. - then need to be edited.

The fields on this screen will be displayed more clearly and described starting on the next page.

Setup > User > Create User

User Account Settings

* Account Type:

* Login Type: Clear
180 x 80 px, 100KB (JPEG/PNG/GIF)

* Sharepoint Access:

User Account Details

* Username: * Language:

* Full Name: * Alias:

Email Address: Employee ID:

* Time Zone:

Company Structure Details

Department Head: * Manager:

Job Title:

Administrative Coordinator Expand

Associate Director Quality Assurance

Organization: Expand Division: Expand

GDP Medical Products

GDP Medical Device Products

Quality Control Document Processing

GDP Pharmaceutical Products

Department: Expand Sub-Department: Expand

Clinical Operations

QA Compliance

Customer Support

Quality Assurance

Roles Assignment

Available:

PR_CAPA_Approver

PR_CAPA_Owner

PR_CAPA_Reviewer

PR_CC_Approver

PR_CC_Owner

PR_CC_RA

PR_OCR_CCC

PR_OCR_QAM

PR_CM_QA

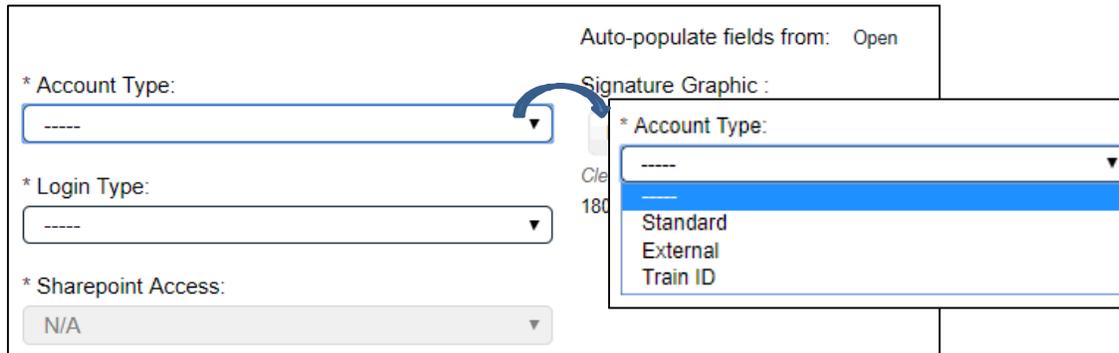
PR_CM_QAM

PR_CM_RA

Select all Deselect all

Assigned: <empty>

User Account Settings

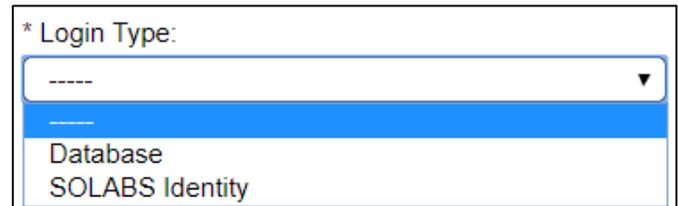


The screenshot shows the 'User Account Settings' form. The 'Account Type' dropdown menu is open, showing three options: 'Standard', 'External', and 'Train ID'. The 'Standard' option is currently selected. Other fields visible include 'Login Type' and 'Sharepoint Access'.

Account Type is a Single-item Selection field that has three choices.

- **Standard** must be chosen for users who will take any actions in SOLABS QM (create or modify a document, review or approval a document, act on a process task, administer training activities, etc.).
- **External** can be used to grant limited permissions (such as to review/approve a document or process step) to outside contractors, auditors, consultants, etc.
- **Train ID** is used for those users who will only view content for the purposes of completing assigned training activities. It can also be used for external users who should be limited to only viewing documents.

Login Type is a Single-item Selection field. A Login Type of **Database** is typically used for Test, Sandbox or Validation instances of SOLABS QM. A Login Type of **SOLABS Identity** should be selected for Production instances of SOLABS QM 10. If you are using one of the Single Sign-On features such as AzureAD or OneLogin, you will see a related Login Type in place of SOLABS Identity.

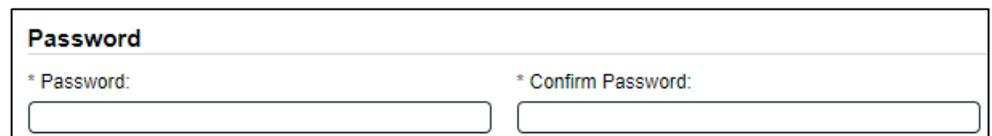


The screenshot shows the 'Login Type' dropdown menu with 'Database' and 'SOLABS Identity' as options. 'SOLABS Identity' is currently selected.



The screenshot shows the 'Login Type' dropdown menu with 'Azure AD' as an option. 'Azure AD' is currently selected.

When **Login Type** is **Database**, additional fields will be displayed to enter and confirm a Password for the user being created.



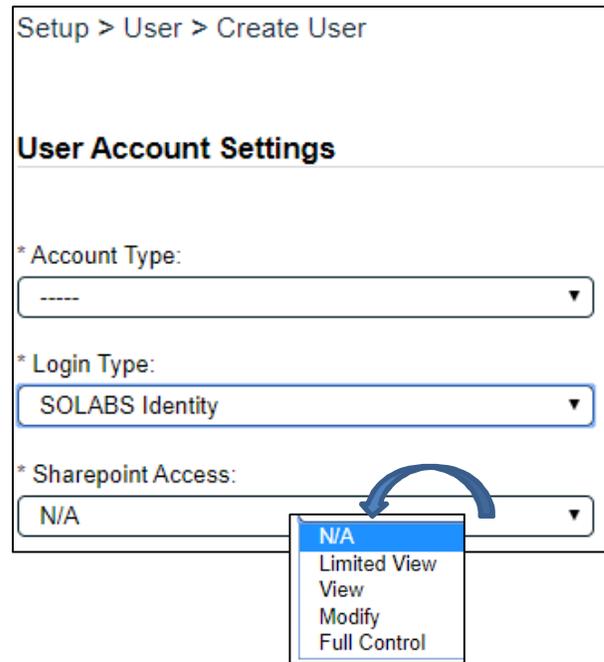
The screenshot shows the 'Password' section of the form, with two input fields: '* Password:' and '* Confirm Password:'.

If the **Login Type** is **SOLABS Identity**, or a Login Type related to a Single Sign-On feature such **AzureAD** or **OneLogin**, the Email Address field in the User Account Details section will become mandatory. The System Administrator will not select a Password in this case because new users will be sent an email with instructions to set up their own Password.

Starting with SOLABS QM10 Version 10.8, System Administrators can grant access to the SharePoint Portal for users with a Login Type of SOLABS Identity, AzureAD or OneLogin.

There are four levels of **SharePoint Access** that can be granted:

- **Limited View** access allows users to view and execute reports in the Production Library.
- **View** access allows users to view and execute reports in the Validation Library and the Production Library.
- **Modify** access allows users to view, add, update and delete list items and documents in the Validation Library and the Production Library.
- **Full Control** access allows users full control access for administration of reports in the Validation Library and the Production Library.



Setup > User > Create User

User Account Settings

* Account Type: -----

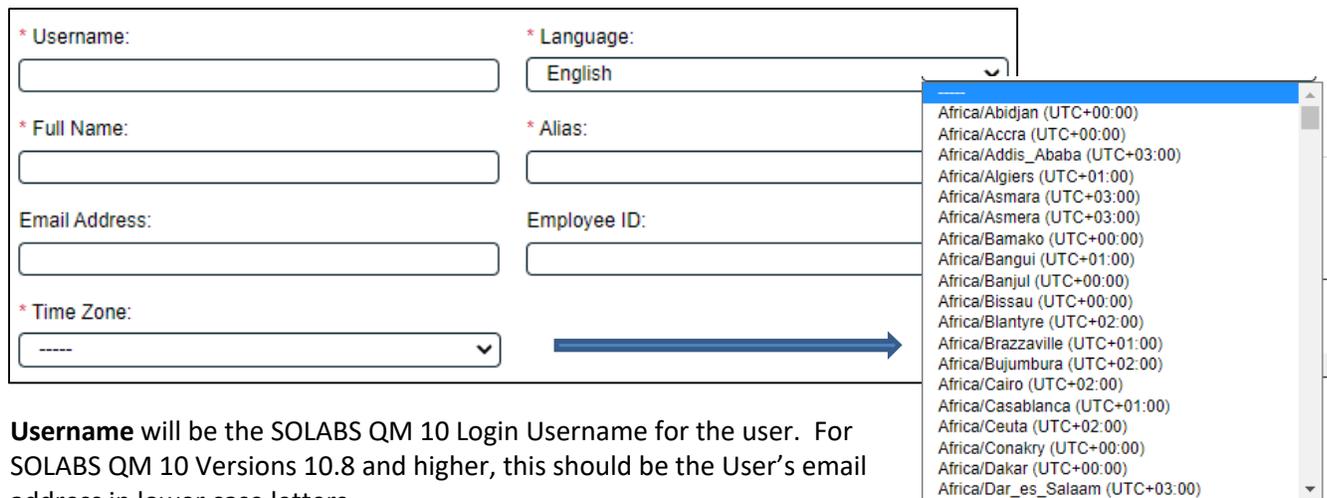
* Login Type: SOLABS Identity

* Sharepoint Access: N/A

N/A
Limited View
View
Modify
Full Control

For Database instances, such as Sandboxes or Validation Environments, this is grayed out if those environments are not set up to provide access to Reports.

User Account Details



* Username: _____

* Language: English

* Full Name: _____

* Alias: _____

Email Address: _____

Employee ID: _____

* Time Zone: -----

Africa/Abidjan (UTC+00:00)
Africa/Accra (UTC+00:00)
Africa/Addis_Ababa (UTC+03:00)
Africa/Algiers (UTC+01:00)
Africa/Asmara (UTC+03:00)
Africa/Asmera (UTC+03:00)
Africa/Bamako (UTC+00:00)
Africa/Bangui (UTC+01:00)
Africa/Banjul (UTC+00:00)
Africa/Bissau (UTC+00:00)
Africa/Blantyre (UTC+02:00)
Africa/Brazzaville (UTC+01:00)
Africa/Bujumbura (UTC+02:00)
Africa/Cairo (UTC+02:00)
Africa/Casablanca (UTC+01:00)
Africa/Ceuta (UTC+02:00)
Africa/Conakry (UTC+00:00)
Africa/Dakar (UTC+00:00)
Africa/Dar_es_Salaam (UTC+03:00)

Username will be the SOLABS QM 10 Login Username for the user. For SOLABS QM 10 Versions 10.8 and higher, this should be the User's email address in lower case letters.

Language will default to English. There will be other options only if supported for the client.

Full Name is the First Name and Last Name for the user, with a space in between (John Smith).

Alias will be auto-populated with the initials of the First/Last Name, but can be edited if needed. This field will need to be edited if there is already a user with the same initials. In that case a middle initial could be added or a number could be added as a suffix. This need will not be apparent until the Submit step, at which point an error will identify the need to update that field because a user with the same Alias already exists.

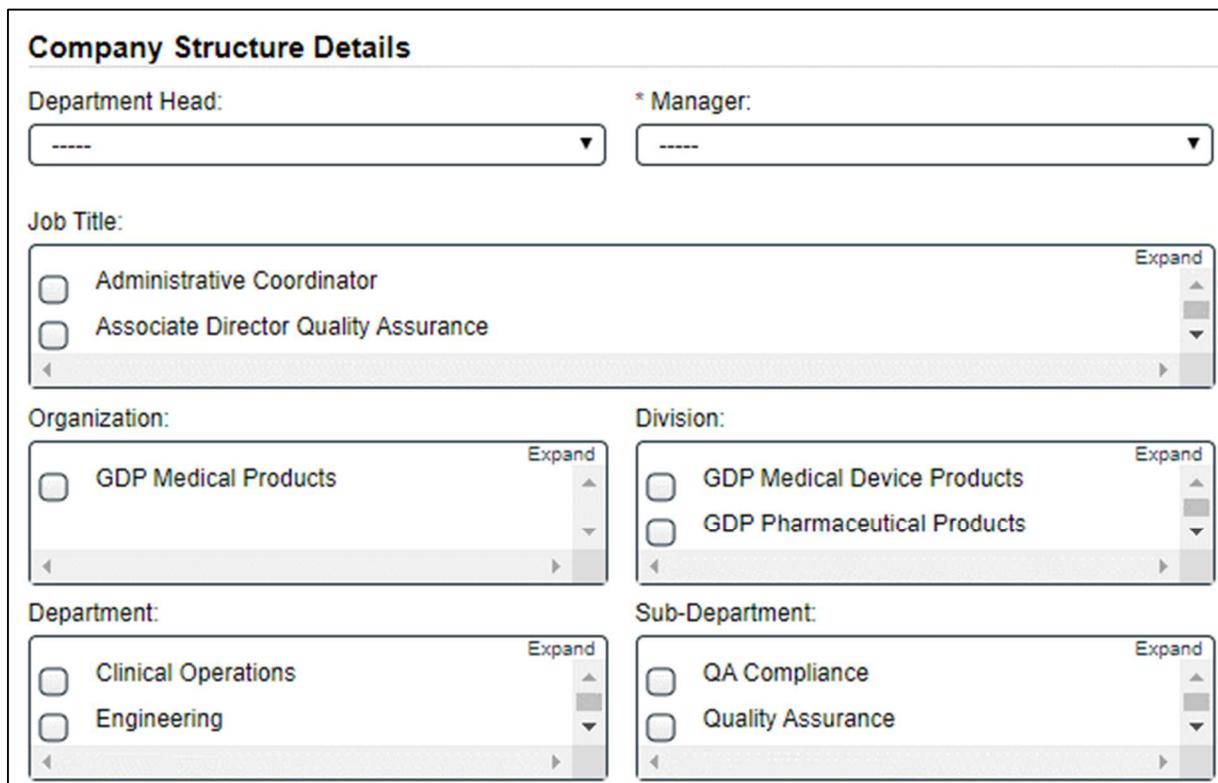
Email Address is necessary if the user will need to get any SOLABS QM Notifications for training assignments, document review/approval tasks, process tasks, etc. This field is not mandatory for Sandbox and Validation instances but is mandatory for Production instances.

Employee ID is optional but can be filled in or populated from an HR interface.

Time Zone is a mandatory field. It is a single-item selection list of worldwide time zones. If you start typing part of the name, you will get to that part of the list.

Company Structure Details

IMPORTANT NOTE: In order for information in this section to be available for selection, it must already have been created by the SOLABS System Administrator in SOLABS QM. If it is created afterwards, you will need to come back later and Modify User in order to add that information. See Page 10 for Role Management.



Company Structure Details

Department Head: * Manager:

Job Title:

- Administrative Coordinator
- Associate Director Quality Assurance

Organization:

- GDP Medical Products

Division:

- GDP Medical Device Products
- GDP Pharmaceutical Products

Department:

- Clinical Operations
- Engineering

Sub-Department:

- QA Compliance
- Quality Assurance

Department Head is a single-item selection field that includes all active SOLABS QM Users. Selecting the Department Head for a SOLABS QM User can be helpful when running queries and reports.

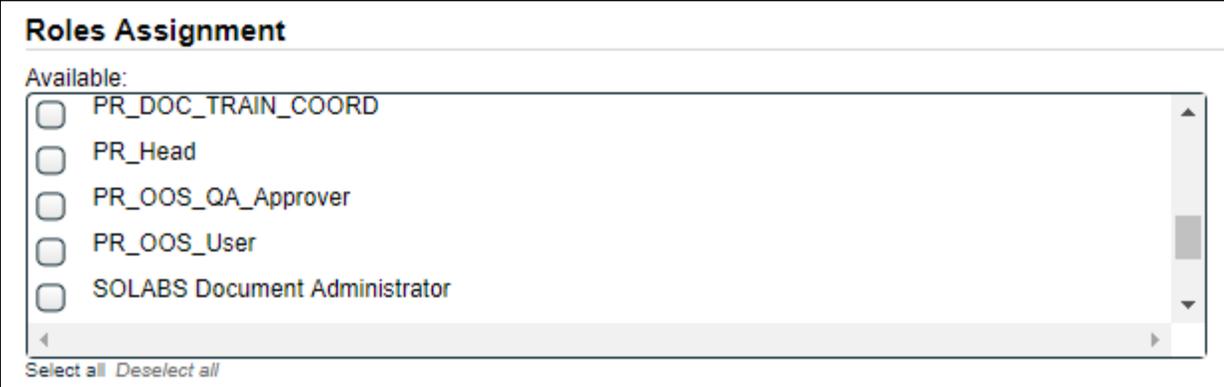
Manager is also a single-item selection field that includes all active SOLABS QM Users. Selecting a manager for a SOLABS QM User is mandatory in order to support various Notifications, Queries/Reports and Training Second Confirmations. An option of “myself” is available if for some reason there is no manager.

Job Title is a multi-item selection field that includes **all active Function (FCT_) Roles**. Selecting one or more Function Roles for a SOLABS QM User is important if you plan to assign training by Job Profile, if the user will be involved in the Review/Approval of documentation or if the user will be required to act on a process task.

Function Roles can also be used to set document privileges. As Job Title selections are made, those Function Roles will appear in the **Assigned** section at the bottom of the screen.

Organization, Division, Department and **Sub-Department** are multi-item selection fields that include all active Security (SEC_) Roles. Selecting one or more Security Roles for a SOLABS QM User can be helpful for setting document privileges and also for queries and reports. As these selections are made, those Security Roles will also appear in the **Assigned** section at the bottom of the screen.

Roles Assignment



The screenshot shows a window titled "Roles Assignment". Inside, there is a section labeled "Available:" followed by a list of roles, each with an unchecked radio button. The roles listed are: PR_DOC_TRAIN_COORD, PR_Head, PR_OOS_QA_Approver, PR_OOS_User, and SOLABS Document Administrator. At the bottom of the list, there are two links: "Select all" and "Deselect all".

The **Available** Roles is a multi-item selection field that includes the Process (PR_) Roles that come with any deployed Process APPs and the four System (SYS_) Roles that come with the Core Software – SOLABS Document Administrator, SOLABS Help Desk, SOLABS System Administrator and SOLABS Training Administrator. These Roles are not created by the SOLABS System Administrator; they are available with the software and can be assigned to Users as applicable.

- The Process Roles must be assigned to users who will need to Act On the related Process Tasks (such as QA Approver for an CAPA).
- The System Roles must be assigned to users who will be performing SOLABS QM system administration activities for User Management, Configuration, Document Management or Training Management.

After the appropriate selections are made for a user, the **+ADD** button must be clicked in order to manually add these to the **Assigned** section at the bottom of the screen.

Submit and Confirm

When all information is complete on the Create User screen, click **Submit** and then check your work. Click **Confirm** to Save your settings.

Once the User is created, the **User Account View** page is loaded and will display all the entered information. This information will be visible to the User when they click on **SETUP** from the Top Menu, as described on Page 3 of this document.

Modify a User

To modify a User, click **User Actions > Modify** to the right, to access the **Setup > User > Modify** screen. User account information can be modified at any time by the SOLABS System Administrator.

Modify the setting as required, **Submit** and then **Confirm** after checking your work.

Deleting or Deactivating a User

You can **Delete** a user, only if there has never been any activity on the account, including a user Login. If you try to delete an account that has had any activity, you will get the following message:

Unauthorized action: User cannot be deleted.

User Actions

- [View](#)
- [Modify](#)
- [Delete](#)
- [Deactivate](#)
- [Bulk Reassignment](#)
- [Reset Password](#)

User Preferences

- [View Notifications](#)
- [Enable/Disable Notifications](#)

Related Information

- [Audit Trail](#)

You can **Deactivate** a user, either permanently if they have left the company or temporarily if they are on leave. When this action is taken, you will be prompted to enter **Reassignment Actions** for open **Process Tasks**, active **Tasks and Secondary Tasks**, **Document Workflow Tasks**, **Trainer Assignments** and **General System Configurations** (Department Head, Manager, Standard Attribute Default Value, System Attribute Default Value, Delegate). For each of these, you will need to enter another User and/or Role as prompted, even if there are actually no outstanding tasks. Grayed out checkmarks mean that selecting a value in the related field is mandatory.

Process Tasks

- Unassign from open process tasks (where not specifically assigned)
- Reassign process tasks (where last user in the role)
 - * Assignee (Role):

 - * Assignee (User):

- Reassign process tasks (where specifically assigned)
 - * Assignee (User):

You will also see a section to take **Action on Ongoing Training Activities**. This allows you to remove any training assignments that are no longer applicable. These are selected by default but usually it is best to remove the checkmarks.

Action on Ongoing Training Activities

- Keep Training Record in Untrained User Section
- Remove assignments for unconfirmed activities

Finally, you will get a warning if the person you are attempting to Deactivate is the only person in a particular Function Role. This is just an alert so that you can assign that role to another user if needed.

Unique user assigned to role(s): FCT_Medical Monitor. It is recommended that you assign another user to this role before deactivating this user.

Bulk Reassignment of Open Tasks for a User

If you need to make the above **Reassignment Actions** for an active user – for example if they change jobs – you would use the **Bulk Reassignment** option. It will bring up the same reassignment fields as described above for the deactivation of a user.

Other User Management Actions

The **Reset Password** option is new with version 10.8 in Database instances only. Passwords for Production instances are managed through the Password Management Portal. Users can be unlocked by a System Administrator if they locked their account with too many login attempts.

The **User Preferences** options of **View Notifications** and **Enable/Disable Notifications** are available to SOLABS System Administrators as well as individual users.

The **Related Information** section includes an **Audit Trail** option for the SOLABS System Administrator to view all historical actions on a user account.

Role Management

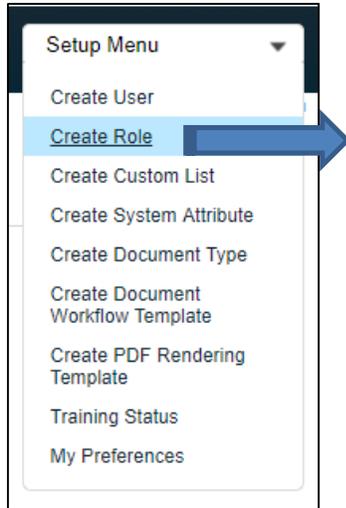
There are four types of **Roles** available in **SOLABS QM**. Users can be assigned one or more as required. Role Management actions require assignment of the System Role **SOLABS System Administrator**.

Role Type	Description
Security Role	<p>Assigned to defines what part(s) of the organization a user belongs to:</p> <ul style="list-style-type: none"> • Department, • Sub-Department • Division • Organization <p>Security Roles can be used to set Document privileges and are helpful in running Reports, such as Departmental Training Compliance.</p> <p>The Organization Security Roles will be displayed as values in the Concerned Company Structure field at Step 1 of a Document Control Process. This allows you to have different Document Coordinators for different parts of the organization, and ensure the process goes to the correct one.</p> <div style="float: right;"> <p>* Concerned Company Structure:</p> <div style="border: 1px solid black; padding: 2px;"> <p>-----</p> <p>-----</p> <p>All</p> <p>GDP Medical Device Products</p> <p>GDP Medical Products</p> <p>GDP Pharmaceutical Products</p> </div> </div>
Function Role	<p>Assigned to define the User’s Job Title and/or other functions they perform.</p> <p>Function Roles are necessary as part of the electronic signature for Document Reviews/Approvals and Process Tasks.</p> <p>They can also be created for linking Training Activities that may not be unique to a particular Job Title – such as employee orientation training, departmental training or training related to a particular task that may be conducted by users in multiple Job Titles.</p>

Process Role	Associated with SOLABS QM Process APPs , and assigned to define a User’s responsibility in a given Process workflow.
System Role	Reserved for specific individuals involved in SOLABS System Administration activities, and assigned to provide related permissions.

Create a Role

From the Quick Access menu, click **Create Role**. The **Create Role** page is then loaded. Required fields are identified by an asterisks (*).



Setup > Roles > Create Role Status: Active

Role Details

* Type:

Role cannot be modified

* Name:

Description:

* Type:

Function Role (FCT)

Process Role (PR)

Security Role (SEC)

Company Structure Details

* Job Title: * Job Title Abbreviation:

* Company Structure:

* Name: * Abbreviation:

Role Members

The mandatory **Type** field is a single-select drop-down list to choose the type of Role being created. Depending on the choice made, related fields in the Company Structure Details section will become enabled.

- For Function Roles, the mandatory **Name**, **Job Title** and **Job Title Abbreviation** fields will be enabled. The **Job Title** field will be auto-populated with the information entered in the **Name** field. The Prefix FCT_ will also be auto-populated in the Name field after moving to the next entry.
- For Security Roles, the mandatory **Name**, **Company Structure**, **Name** and **Abbreviation** fields will be enabled. The lower **Name** field will be auto-populated with the information entered in the upper **Name** field under Role Details. The prefix SEC_ will also be auto-populated in the upper **Name** field after moving to the next entry.

Selecting **Submit** will save the Role and make it available to assign to Users (see above section on **User Management**). As the Role is assigned to Users, they will be listed under **Role Members**.

Modify a Role

A role can be modified through the **Modify** action in the right-hand menu of the **Roles** page.

Setup > Roles > Modify

Status: Active

Role Details

Type:
Function Role (FCT) ▼

Role cannot be modified

* Name:
FCT_QA Specialist

Role Actions

View

Modify

Add/Remove Users

Related Information

Audit Trail

NOTE: Use caution in modifying the Role Name for any roles that may be associated with active document or process workflows. All roles identified with the prefix **PR** refer to **Process related roles** and should never be modified, in order to avoid an impact in the workflow of the related Processes. The **Role cannot be modified** box should be checked for all Process (PR) Roles in order to prevent inadvertent modification.

Starting with version 10.8, a Role can be modified to add or remove multiple users. Clicking on that option will bring up the Add/Remove Users screen.

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).

Add/Remove Users

Filter by:

Active users

All Job Titles

Available:

- aingram (Abel Ingram)
- amooore (Alice Moore)
- ariver (Alan River)
- arivera (Amy Rivera)

Available:

- csanders (Christina Sanders)
- dbarnes (Donald Barnes)

Available sub-filters:

- Administrative Coordinator
- Associate Director Quality Assurance
- Auditor - QA Compliance
- Biostatistician

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

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 to support fields in the Core Software DOCUMENT management and TRAINING management sections. They are prefixed by “System_List_” and include the following:

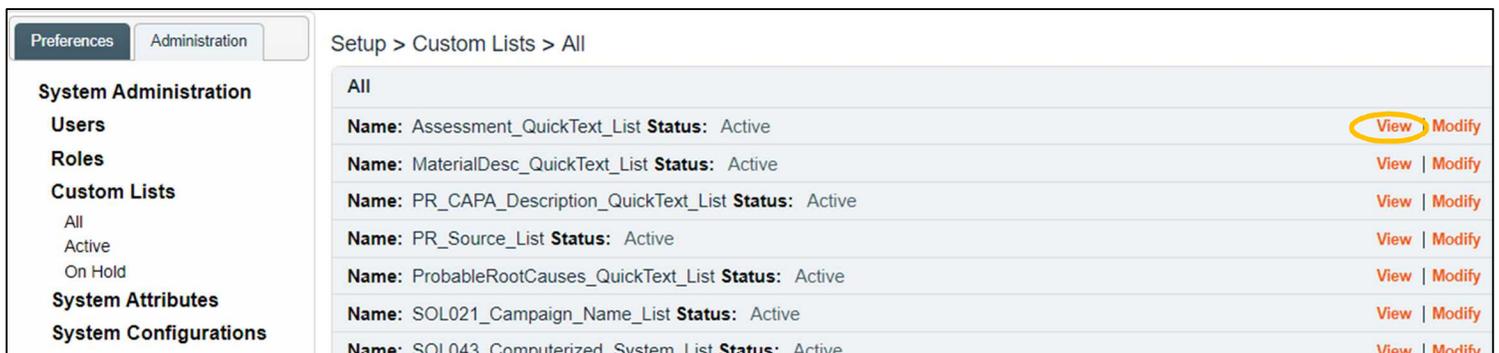
- System_List_Document_Publishing_Location
- System_List_PDF_Header_Quick_Text
- System_List_PDF_Watermark_Quick_Text
- System_List_Reason_for_Change
- System_List_Search_Queries
- System_List_Sign-off_Meaning
- System_List_Training_Activity_Categories
- System_List_Training_Activity_Description
- System_List_Training_Activity_MethodOfEvaluation
- System_List_Training_Activity_MethodOfInstruction
- System_List_Training_Activity_Purpose

Some of the System Lists include default values but can be edited by the SOLABS System Administrator to reflect your company values and terminology. Others include no values, allowing values to be added by the SOLABS System Administrator.

Additional 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 Process User, Functional & Design Specifications (PUFDS) document for your deployed Process Apps to confirm the names of the Custom Lists associated with each process step.

More Custom Lists can be created as needed by the SOLABS System Administrator, to support System Attribute fields for Document Types.

To view the list of all active Custom Lists, choose the Active 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.



Setup > Custom Lists > All

All	
Name: Assessment_QuickText_List Status: Active	View Modify
Name: MaterialDesc_QuickText_List Status: Active	View Modify
Name: PR_CAPA_Description_QuickText_List Status: Active	View Modify
Name: PR_Source_List Status: Active	View Modify
Name: ProbableRootCauses_QuickText_List Status: Active	View Modify
Name: SOL021_Campaign_Name_List Status: Active	View Modify
Name: SOL043_Computerized_System_List Status: Active	View Modify

Create Custom List

From the **SETUP** Section, access the Quick Access **Setup Menu** at the top right of the screen and choose the **Create Custom List** option. The **Setup > Custom Lists > Create** screen will be displayed.

Setup > Custom Lists > Create

Custom List Details

* Name:

Status: Active On Hold

Name cannot be modified

Values :

Values cannot be modified

Setup Menu

- Create User
- Create Role
- Create Custom List**
- Create System Attribute
- Create Document Type
- Create Document Workflow Template
- Create PDF Rendering Template
- Training Status
- My Preferences

Enter a meaningful, intuitive **Name** for the custom list. Then enter the list of **Values**; separating multiple values with either semi-colons or by using the Enter key to list them underneath each other.

For example: Manufacturing, Packaging, Laboratory, R&D, then **Submit & Confirm** to save the Custom List.

Setup > Custom Lists > Create

Custom List Details

* Name:

Status: Active On Hold

Name cannot be modified

Values :

Values cannot be modified

Setup > Custom Lists > Create

Custom List Details

* Name:

Status: Active On Hold

Name cannot be modified

Values :

Values cannot be modified

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.

Setup > Custom Lists > Modify

Custom List Details

* Name:

Name cannot be modified

Values :

Supplier A
 Supplier B
 Supplier C
 Supplier D
 Supplier E

Values cannot be modified

Custom List Actions

- View
- Modify
- Delete
- Enable Editing

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.

Delete a Custom List

User-created **Custom Lists** can be deleted by clicking the **Delete** option from the right-hand **Custom List Actions** menu. This action will require Confirmation.

Setup > Custom Lists > Clinical_Safety_Email > Delete

Not Logged in Audit Trail

Name: Clinical_Safety_Email **Status:** Active

Custom List Actions

- View
- Modify
- Delete
- Enable Editing

NOTE: system Lists cannot be deleted.

Setup > Custom Lists > System_List_Search_Queries > Delete

Unauthorized action: A System List cannot be deleted.

Not Logged in Audit Trail

Name: System_List_Search_Queries **Status:** Active

Custom List Actions

- View
- Modify
- Delete
- Enable Editing

Managing System Attributes

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

Some System Attributes are provided by default to support fields in the DOCUMENT, TRAINING or PROCESS Sections of the software. These System Attributes can be modified only to change the Optional Settings related to whether the field is **Mandatory** and/or has a **Default Value**.

Optional Settings:

Mandatory

Default Value

Additional System Attributes can be created as needed for creating different Document Types.

To view the list of all active System Attributes, choose the Active option under System Attributes from the left-hand SETUP Administration tab. View a specific list by using the **View** option to the right of the listing.

All system attributes		
Name: Active Pharmaceutical Ingredient	Status: Active	View Modify
Name: Additional Information	Status: Active	View Modify
Name: Applicable Div	Status: Active	View Modify
Name: Approved Supplier	Status: Active	View Modify
Name: Approved Supplier List	Status: Active	View Modify
Name: Assembly Line	Status: Active	View Modify

Create a System Attribute

From the **SETUP** Section, access the Quick Access **Setup Menu** at the top right of the screen and choose the **Create System Attribute** option. The **Setup > System Attributes > Create** screen will be displayed.

- Setup Menu
- Create User
- Create Role
- Create Custom List
- Create System Attribute**
- Create Document Type
- Create Document Workflow Template
- Create PDF Rendering Template
- Training Status
- My Preferences

Setup > System Attributes > Create

System Attribute Details

* Name:

Status: Active On Hold

* Alias:

Type:

Text field

Text field with quick text

Text area

Text area with quick text

Date

Numeric

Single item selection

Multiple items selection

Optional Settings:

Mandatory

Default Value

Enter a meaningful, intuitive **Name** for the System Attribute. The **Alias** will be auto-populated with the same information, if it is within the allowable number of characters (12). Otherwise, you will need to enter a shortened version of the Name into the Alias field.

You then need to select the Attribute **Type** from the available options. Depending on the **Type** you select, different options are then presented to you to further define the field. The options for each choice are displayed on the next page.

System Attribute Types

Type:

- Text field
- Text field with quick text
- Text area
- Text area with quick text
- Date
- Numeric
- Single item selection
- Multiple items selection

Optional Settings:

- Mandatory
- Default Value

Optional Settings:

- Mandatory
- Default Value

An Attribute Type of **Text field** can be defined as **Mandatory** (asterisks * will identify the field as mandatory to the user entering information in it) or not. It can also be set to have a **Default Value**. Selecting Default Value will bring up a field to enter that Value.

Type:

- Text field
- Text field with quick text
- Text area
- Text area with quick text
- Date
- Numeric
- Single item selection
- Multiple items selection

Optional Settings:

- Mandatory
- * Quick Text Options:
 -
 - AUD_Audit_Purpose_QuickText_List
 - AUD_Audit_Scope_QuickText_List
 - AUD_Audit_Type
 - AUD_Comp_Activities
 - AUD_PerformedBy_List
 - Active Pharmaceutical Ingredient (API)
 - Audit Reason
 - CMR_AdditionalInformation_QuickText
- Default Value

* Quick Text Options:

-
- Audit Reason
- Default Value
-
- Routine Periodic
- For Cause - See Additional Information
- New Supplier

An Attribute Type of **Text field with quick text** can be defined as Mandatory or not. The mandatory **Quick Text Options** field is a single-select drop-down list that will bring up the **Active Custom Lists**. If another list is needed, simply create a new Custom List (see previous section), which will then be available to choose. Selecting **Default Value** will bring up a single-select drop-down list with the Values related to the chosen Custom List.

Type:

- Text field
- Text field with quick text
- Text area
- Text area with quick text
- Date
- Numeric
- Single item selection
- Multiple items selection

Optional Settings:

- Mandatory
- Default Value

Optional Settings:

- Mandatory
- Default Value

An Attribute Type of **Text area** is the same as a Text field (see above), except that there is room for more free-text characters, both for the user and for setting any Default Value.

An Attribute Type of **Text area with quick text** is the same as a Text field with quick text, except it would be used for Values that had more characters.

<p>Type:</p> <ul style="list-style-type: none"> <input type="radio"/> Text field <input type="radio"/> Text field with quick text <input type="radio"/> Text area <input checked="" type="radio"/> Text area with quick text <input type="radio"/> Date <input type="radio"/> Numeric <input type="radio"/> Single item selection <input type="radio"/> Multiple items selection 	<p>Optional Settings:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Mandatory * Quick Text Options: <input type="text" value="-----"/> <input type="checkbox"/> Default Value
--	--

<p>Type:</p> <ul style="list-style-type: none"> <input type="radio"/> Text field <input type="radio"/> Text field with quick text <input type="radio"/> Text area <input type="radio"/> Text area with quick text <input checked="" type="radio"/> Date <input type="radio"/> Numeric <input type="radio"/> Single item selection <input type="radio"/> Multiple items selection 	<p>Optional Settings:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Mandatory <p>Date Validation:</p> <ul style="list-style-type: none"> <input checked="" type="radio"/> Can't be set in the past <input type="radio"/> Allow to set in the past
--	--

An Attribute Type of **Date** can be set as Mandatory or not and requires a choice of **Date Validation** of either **Can't be set in the past** or **Allow to set in the past**.

<p>Type:</p> <ul style="list-style-type: none"> <input type="radio"/> Text field <input type="radio"/> Text field with quick text <input type="radio"/> Text area <input type="radio"/> Text area with quick text <input type="radio"/> Date <input checked="" type="radio"/> Numeric <input type="radio"/> Single item selection <input type="radio"/> Multiple items selection 	<p>Optional Settings:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Mandatory
--	--

An Attribute Type of **Numeric** will accept numbers only and can simply be set as Mandatory or not.

<p>Type:</p> <ul style="list-style-type: none"> <input type="radio"/> Text field <input type="radio"/> Text field with quick text <input type="radio"/> Text area <input type="radio"/> Text area with quick text <input type="radio"/> Date <input type="radio"/> Numeric <input checked="" type="radio"/> Single item selection <input type="radio"/> Multiple items selection 	<p>Optional Settings:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Mandatory <input checked="" type="radio"/> User List <input type="radio"/> Custom List <input type="radio"/> Company Structure <input type="radio"/> Role List <input type="checkbox"/> Default Value
--	---

An Attribute type of **Single item selection** is used to define the System Attribute field as a single-select drop-down list. It can be set as Mandatory or not. The selections can be **User List** (all active Users), **Custom List** (all active Custom Lists), **Company Structure** (all active lists for Organization, Division, Department, Sub-Department) or **Role List** (all active FCT and SEC Roles). Choosing to set a **Default Value** will bring up the list of Values for the selected list.

Type: <input type="radio"/> Text field <input type="radio"/> Text field with quick text <input type="radio"/> Text area <input type="radio"/> Text area with quick text <input type="radio"/> Date <input type="radio"/> Numeric <input type="radio"/> Single item selection <input checked="" type="radio"/> Multiple items selection	Optional Settings: <input type="checkbox"/> Mandatory <input checked="" type="radio"/> User List <input type="radio"/> Custom List <input type="radio"/> Company Structure List <input type="radio"/> Role List <input type="checkbox"/> Default Value
---	---

An Attribute type of **Multiple items selection** is used to define the System Attribute field as a multi-select list. The settings are the same as for the Single item selection field, but the user will be able to pick more than one value.

After making your System Attribute Type selections, click **Submit** and **Confirm** to save it to the Active System Attributes list. It will then be available to choose when creating a new Document Type or when modifying an existing Document Type.

Modify a System Attribute

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

Only certain parameters of a **System Attribute** can be modified, once the attribute is used in the system. In the example below, only the Name, a change to Mandatory or a selection of a Default Value can be modified; everything else is viewable but grayed out so cannot be changed.

Setup > System Attributes > Modify

System Attribute Details

* Name:

* Alias:

Type: <input type="radio"/> Text field <input type="radio"/> Text field with quick text <input type="radio"/> Text area <input type="radio"/> Text area with quick text <input type="radio"/> Date <input type="radio"/> Numeric <input checked="" type="radio"/> Single item selection <input type="radio"/> Multiple items selection	Optional Settings: <input checked="" type="checkbox"/> Mandatory <input type="radio"/> User List <input checked="" type="radio"/> Custom List <input type="radio"/> Company Structure <input type="radio"/> Role List * Select Custom List: <input type="text" value="Device Assembly Line"/> <input type="checkbox"/> Default Value
---	---

Actions

Status:
 Active
 On Hold

Delete a System Attribute

User-created **System Attributes** can be deleted by clicking the **Delete** option from the right-hand **Actions** menu. This action will require Confirmation. System Attributes already in use **cannot** be deleted. If the System Attribute is linked to a Document Type, deletion will not be able to be Confirmed – an **Unauthorized action** message will be displayed.

HOME | TASK | **SETUP** Search LOGOUT

PROCESS DOCUMENT TRAINING Setup Menu Default Admin

Setup > All system attributes > Delete

Not Logged in Audit Trail

Unauthorized action. System attribute is linked to a document type.

Status: Active

System Attribute Details

Name: Additional Information
Alias: Add_Info
Type: Text area

Confirm Cancel

Actions

- View
- Modify
- Delete

Managing System Configurations

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

There are two administrative activities in this section: System Configurations and Task Type Configuration.

Preferences Administration

System Administration

- Users
- Roles
- Custom Lists
- System Attributes
- System Configurations
 - System Configurations
 - Task Type Configuration

The **System Configurations** option is where company information and preferences are set up. Some of these settings may be set up during installation of the software but can be edited when needed.

The **Task Type Configuration** option is where you can configure the Task Types that will be available to users who may create Tasks or Task Groups in the TASK section of SOLABS QM.

System Configurations

The System Configurations screen includes a **Company Identity** section and an **Instance Configuration and Settings** section. All of the information on this screen is optional but feeds other settings within the software. The information can be entered/edited by clicking on the Modify option under System Configurations Actions on the right-hand side of the screen. Example screen:

Setup > Administration > System Configuration

Company Identity

Company Name: GDP Medical Products

Address (line 1): 1 GDP Boulevard

Address (line 2): Burlington, VT

Address (line 3): 05401

Address (line 4): USA

Address (line 5): 1-802-123-4567

Address (line 6): 1-800-123-4567

Company Website: www.gdmp.com

User Interface Logo:

Print Logo:

System Configuration Actions

View

Modify

Instance Configuration and Settings

Instance Watermark: None

Date Format: dd-MMM-yyyy 12-Oct-2017 **Time Format:** HH:mm:ss 09:52:22

Enable SOLABS QM Sharepoint Site

Address to Sharepoint: <https://online.solabs.com/sharepoint/>

When setting up document PDF Rendering Templates there are choices to display The **Company Name, Address, Company Website** and a **Print Logo** on Document Cover Pages. If that is desired, then the information needs to be entered in the System Configurations section.

Document Cover Pages:

- Display SOLABS Cover Pages
- Display company address on cover pages
- Display company website on cover pages
- Display company logo on cover pages

Logos can be uploaded from outside SOLABS QM. Information on file size for the logo is displayed in Modify mode. There is an option to Preview the results prior to Submitting and Confirming. The **User Interface Logo** appears on the very upper left-hand corner of your SOLABS QM screens. The **Print Logo** appears on documents.

User Interface Logo:

Update Clear

No file selected

200 x 30 px, 100KB (PNG/JPG/GIF)

Print Logo:

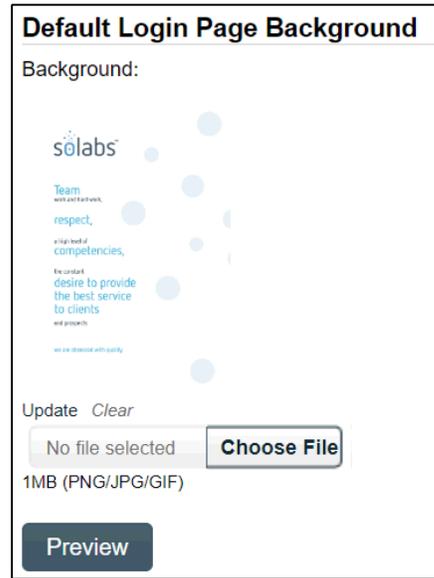
Update Clear

No file selected

360 x 100 px, 500KB (PNG/GIF)



An image can be uploaded as a company-specific **Default Login Page Background**, to replace the SOLABS Default Login Page Background. The file type and size requirements are displayed when the “Update” option is chosen.



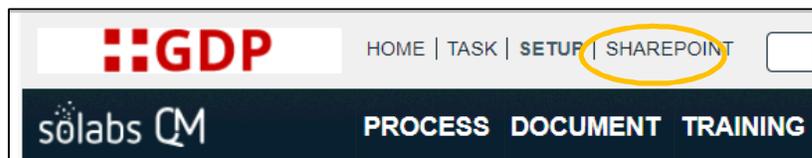
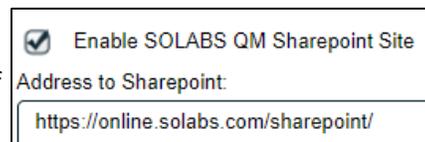
The **Instance Watermark** is helpful if you have more than one active instance of SOLABS QM, such as a Validation instance or a Test instance. For each active instance, this setting allows you to display watermarks on the screen to differentiate between the instances.



The selected **Date Format** and default **Time Format** settings apply across the entire SOLABS QM instance.



When the **Enable SOLABS QM SharePoint Site** box is checked, entering the applicable URL into the **Address to SharePoint** field will place the **SHAREPOINT** link at the top of the SOLABS QM screen and allow access to the SharePoint Portal for SOLABS QM Reports.



Task Type Configuration

When creating Tasks in SOLABS QM, initiators will choose a **Task Type**. Choose the **Modify** option in the Task Type Actions menu to **+ADD** additional Task Types or to edit existing Task **Name** and **Prefix** settings.

Setup > Administration > System Configuration > Task Type

Task Type Details		Task Type Actions
Name	Prefix	View
Task	Task	Modify
Pre-Implementation	PRE	
Post-Implementation	POST	
Open	OPEN	
Miscellaneous	MISC	

Managing External Training Provider Configurations

This is a Feature available starting with SOLABS QM 10 version 10.6.1 and part of the Training Section for all clients starting with version 10.9. When enabled, a **Questionmark OnDemand** instance is created for the client and then linked within their **SOLABS QM** instance. Assessments can then be authored within **Questionmark OnDemand** and are available to link to a **Training Activity** in **SOLABS QM 10**.

From the **SETUP** Section, **External Training Provider Configurations** settings are available through the Administration tab of the left dashboard menu.



Administration

- System Administration
- Users
- Roles
- Custom Lists
- System Attributes
- System Configurations
- External Training Provider Configurations
- QuestionMark**

Starting with SOLABS QM 10.6.1, the **SETUP/ System Administration** menu includes the option for **External Training Provider Configurations**.

For clients who have requested that this feature be enabled, **QuestionMark** will be listed in that section.

Clicking on the **QuestionMark** option in that section will bring up the **QuestionMark Details** screen, where the Questionmark OnDemand URL and administrative credentials will be displayed.

QuestionMark Details

External QuestionMark Assessment Enabled

QuestionMark Endpoint: <https://ondemand.questionmark.com/qmwise/404861/qmwise.aspx>

QuestionMark Username: 404861

QuestionMark Password: *****

QuestionMark Timezone: GMT

- The **QuestionMark Endpoint** field displays the URL to the Questionmark OnDemand instance created for your organization. This should **not** be modified or access to existing Assessments will be lost.
 - A separate but similar URL will be provided to Training Administrators for the authoring of Assessments.
 - The one for the example below would be <https://ondemand.questionmark/404861/home>

- The **QuestionMark Username** field displays the Username for your organization's Questionmark OnDemand instance. This is editable, to accommodate any future Questionmark Username change.
- The **QuestionMark Password** field includes the unique Questionmark OnDemand Password for the above QuestionMark Username. It will be provided to you by Solabs upon enabling this feature and is editable, to accommodate any future Questionmark Password change.

See the separate document **SOLABS QM 10 Questionmark OnDemand Interface** for more information on the actual use of this feature from within the TRAINING Section.