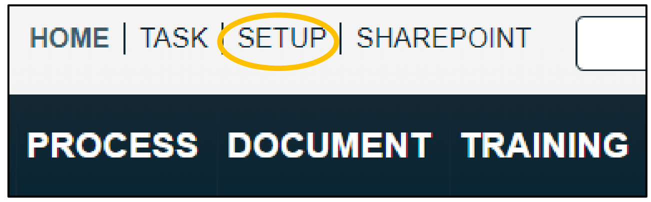
SOLABS QM10: Guide for SOLABS Document Administrators

Table of Contents

Purpose of this Guide

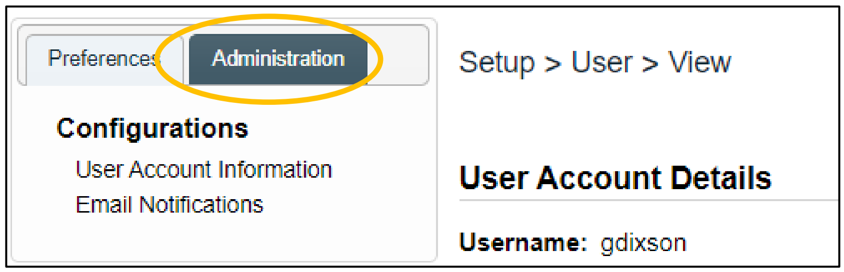
This guide is intended for “Super-Users” who are assigned the SOLABS Document Administrator Role and who will manage Documentation activities in **SOLABS QM10**.

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** or **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 own **User Account Details**, **User Account Settings**, **Company Structure Details** and **Assigned Roles**, as set by their System Administrator.



For System Administrators and Document Administrators, the left-hand **Administration** tab will be enabled after clicking on SETUP. This gives them access to menus for managing Custom Lists, System Attributes, Document Types, Document Workflow Templates and PDF Rendering Templates.

Document Administration Tasks in the Administration Menu

Managing Custom Lists

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_Timezone

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

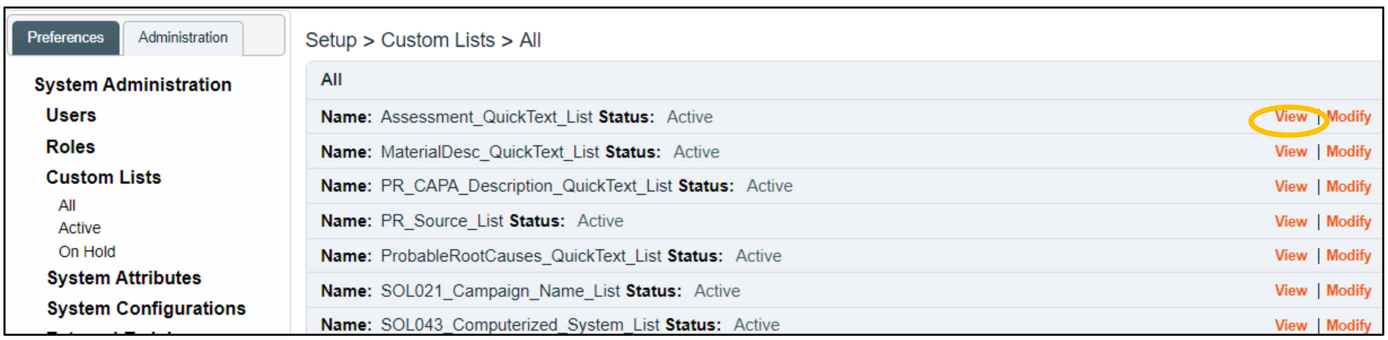
Some of the System Lists include default values but can be edited by the SOLABS System Administrator to reflect your company values and terminology. Others include no values, allowing values to be added by the SOLABS Document Administrator.

Additional Custom Lists are provided by default with any deployed SOLABS Process APPs, including the Document Control Process. They support fields related to those process workflows. They may include default values but can be edited by the SOLABS Document Administrator to reflect your company terminology. The Custom Lists for the Document Control Process have a prefix of SOLDOC_.

More Custom Lists can be created as needed by the SOLABS Document Administrator, to create the values for Single-item Selection and Multi-item Selection System Attribute fields for Document Types.

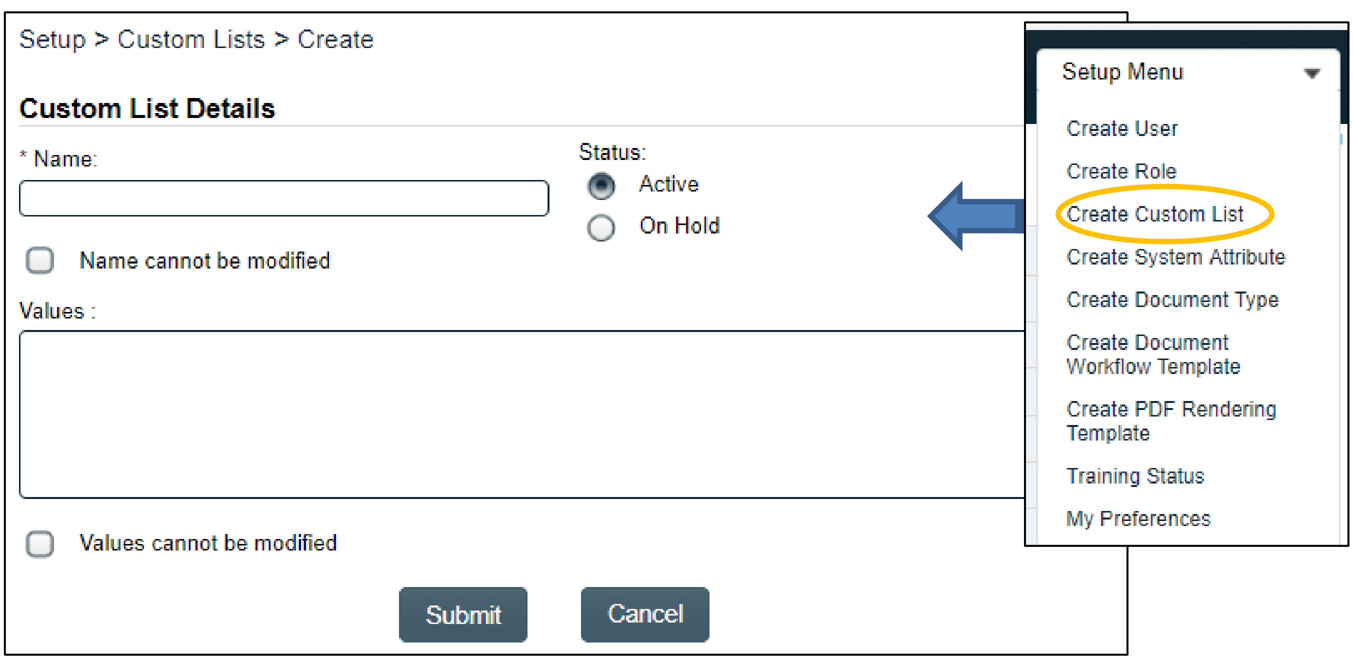
QuickText Lists are Custom Lists of values that are associated with certain Text Fields or Text Areas so that standard terminology can be associated with those fields if desired.

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.



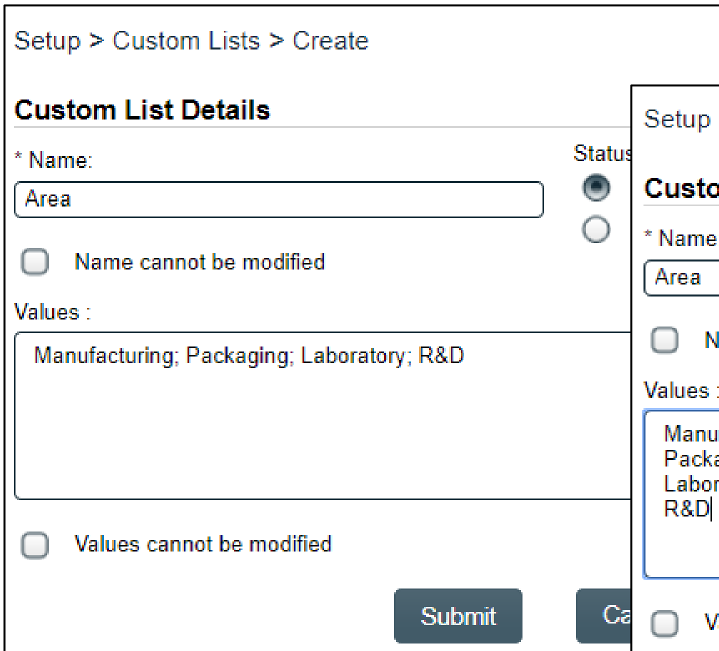
Create Custom List

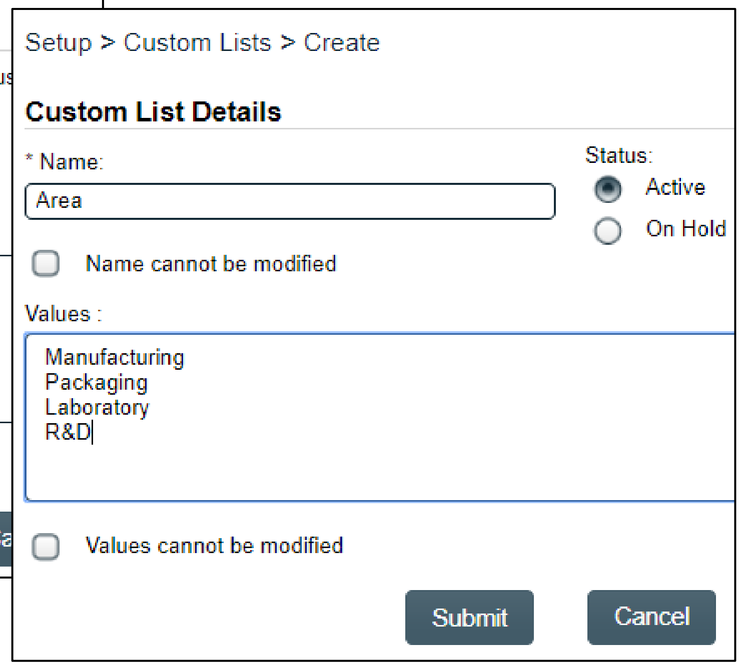
From the **SETUP** Section, access the Quick Access **Setup Menu** at the top right of the screen and choose the **Create Custom List** option. The **Setup > Custom Lists > Create** screen will be displayed.



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.

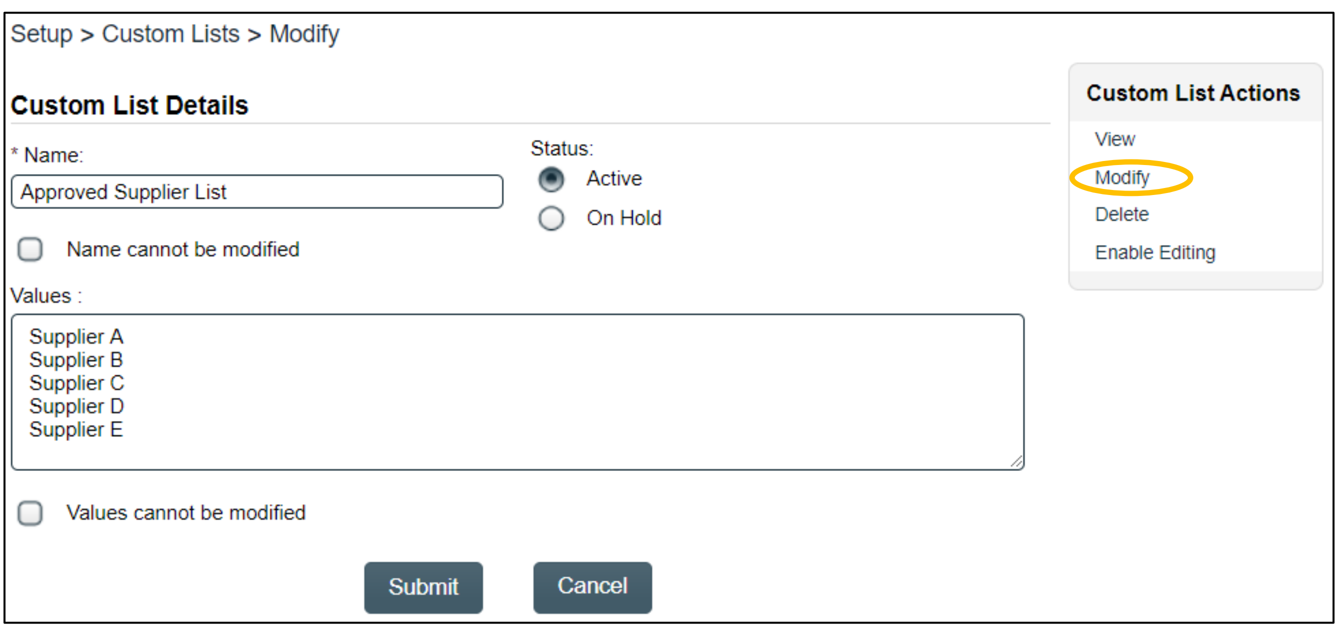
For example: Manufacturing, Packaging, Laboratory, R&D, then **Submit** & **Confirm** to save the Custom List.





Modify a Custom List

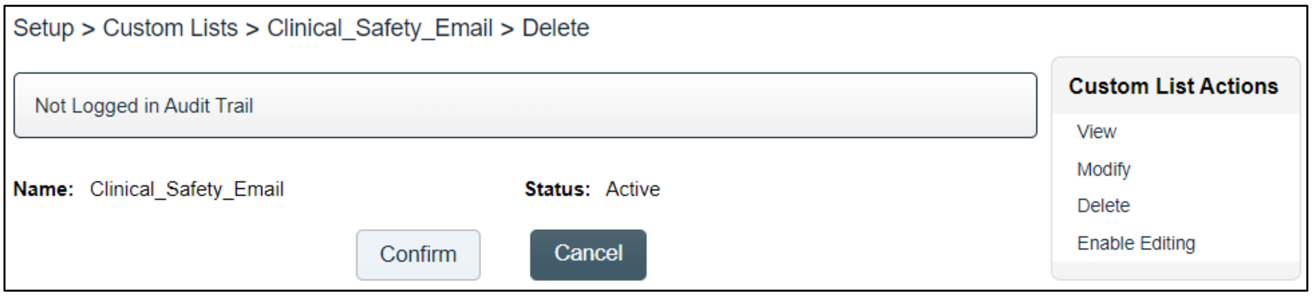
To Modify a **Custom List**, either choose the **Modify** option to the right of the listing on the list of Active Custom Lists, or choose the **View** option and then choose **Modify** from the right-hand **Custom List Actions** menu.



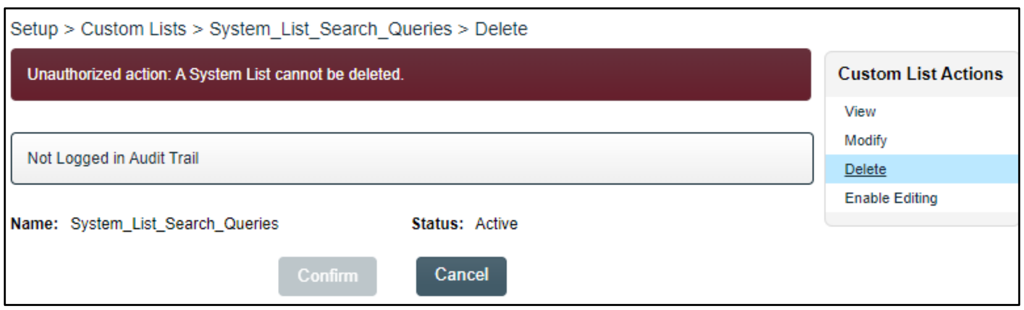
If **Name cannot be modified** or **Values cannot be modified** are checked, those fields can be enabled for editing by clicking on the **Enable Editing** option and then Confirming that choice. Use caution as the decision not to allow modification may be related to the use of that Custom List in an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

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.



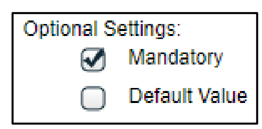
NOTE: System Lists **cannot** be deleted.



Managing System Attributes

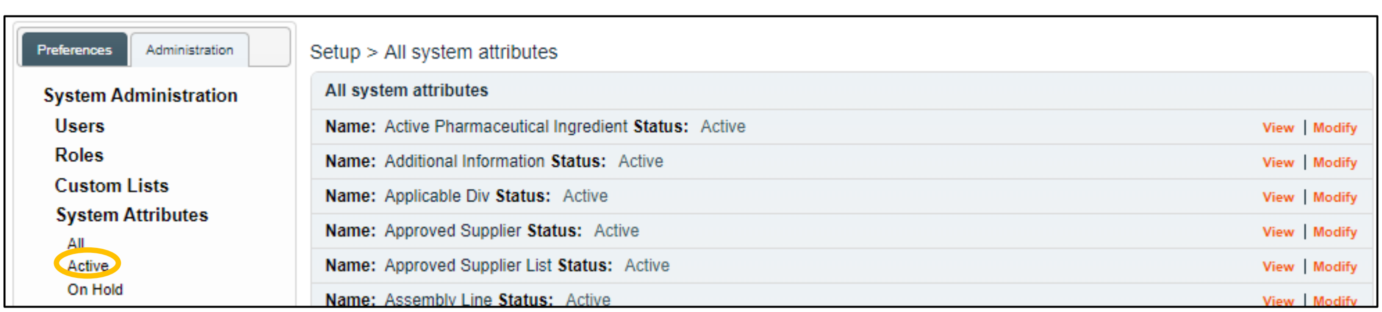
From the **SETUP** Section, **System Attributes** are available through the Administration tab of the left dashboard menu. System Attribute Management actions require assignment of the System Role **SOLABS Document Administrator**.

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**.



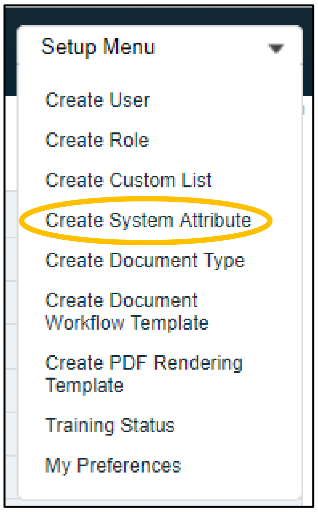
Additional System Attributes can be created as needed for different Document Types.

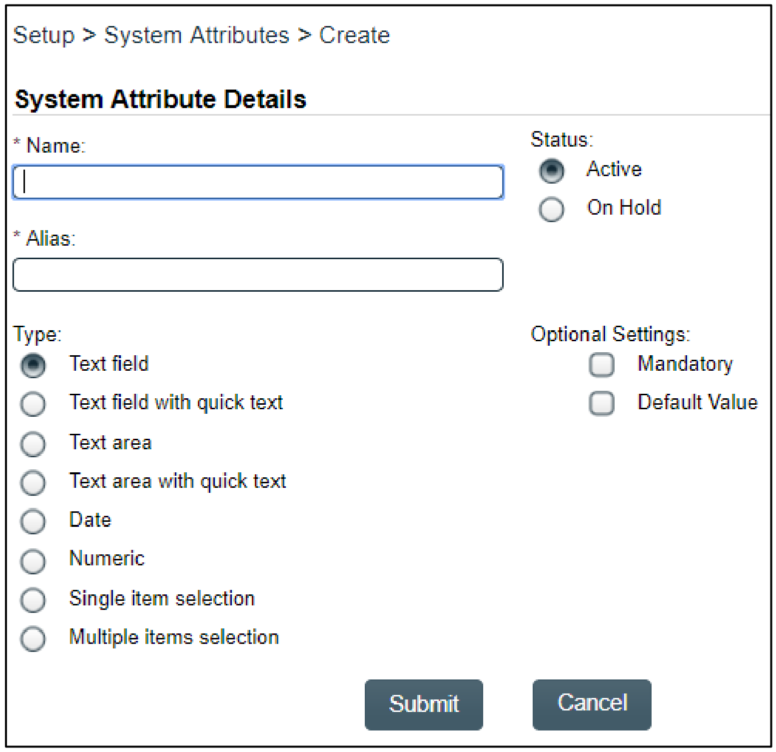
To view the list of all active System Attributes, choose the Active option under System Attributes from the left-hand SETUP Administration tab. View a specific list by using the **View** option to the right of the listing.



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.

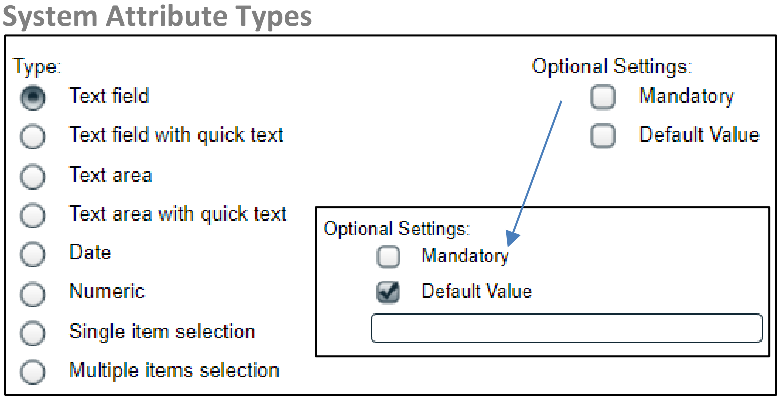




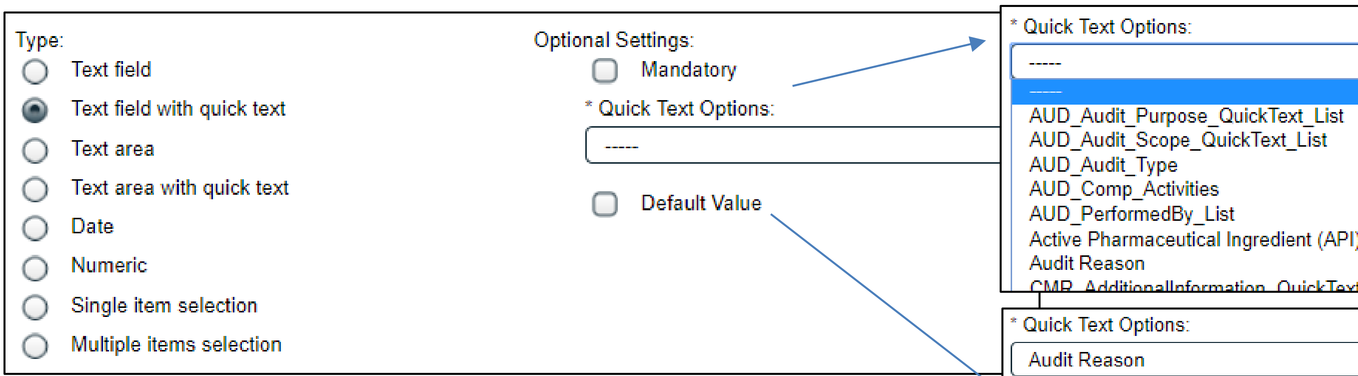
Enter a meaningful, intuitive **Name** for the System Attribute. The **Alias** will be auto-populated with the same information, if it is within the allowable number of characters (12). Otherwise, you will need to enter a shortened version of the Name into the Alias field.

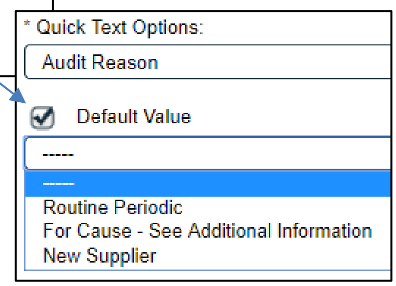
You then need to select the Attribute **Type** from the available options. Depending on the **Type** you select, different options are then presented to you to further define the field. The options for each choice are displayed on the next page.

System Attribute Types

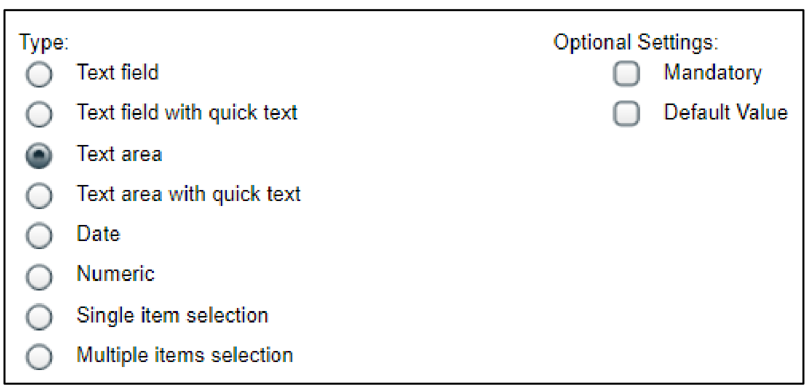


An Attribute Type of **Text field** can be defined as **Mandatory** (asterisks* will identify the field as mandatory to the user when entering information) or not. It can also be set to have a **Default Value**. Selecting Default Value will bring up a field to enter that Value.

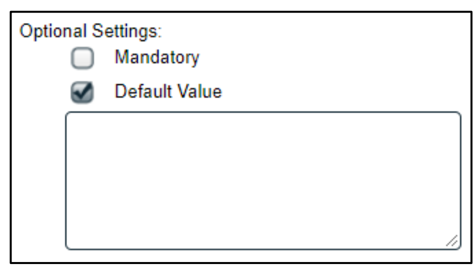




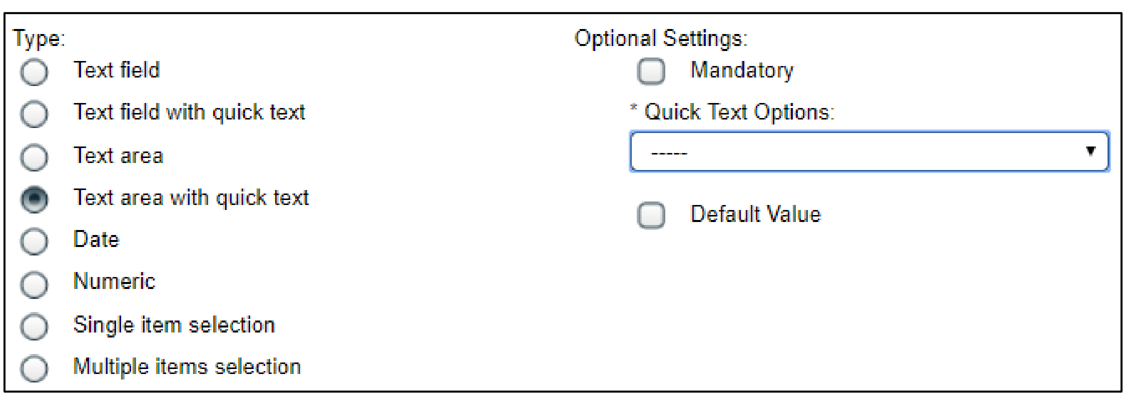
An Attribute Type of **Text field with quick text** can be defined as Mandatory or not. The mandatory **Quick Text Options** field is a single-select drop-down list that will bring up the **Active Custom Lists**. If another list is needed, simply create a new Custom List (see previous section), which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

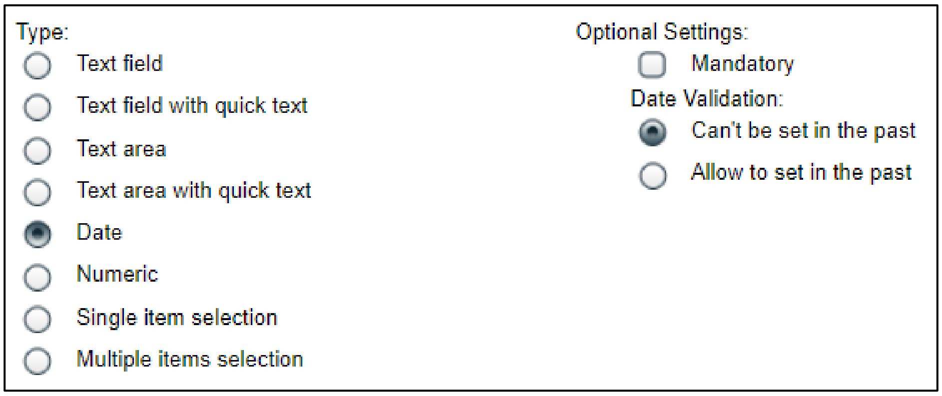


An Attribute Type of **Text area** is the same as a Text field (see above), except that there is room for more free-text characters, both for the user and for setting any Default Value.

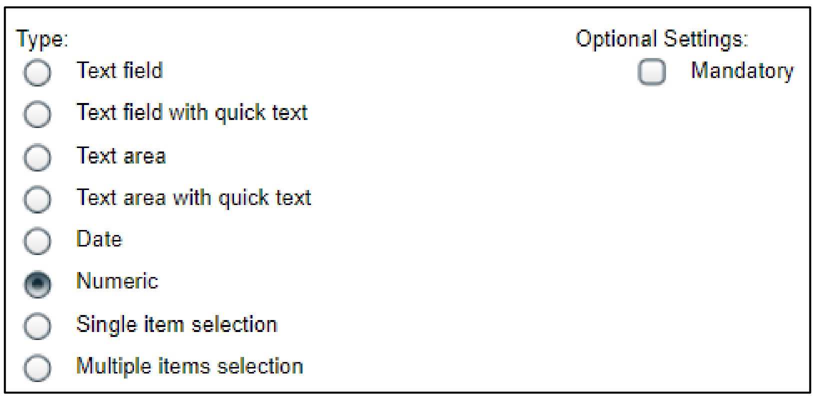


An Attribute Type of **Text area with quick text** is the same as a Text field with quick text, except it would be used for Values that had more characters.

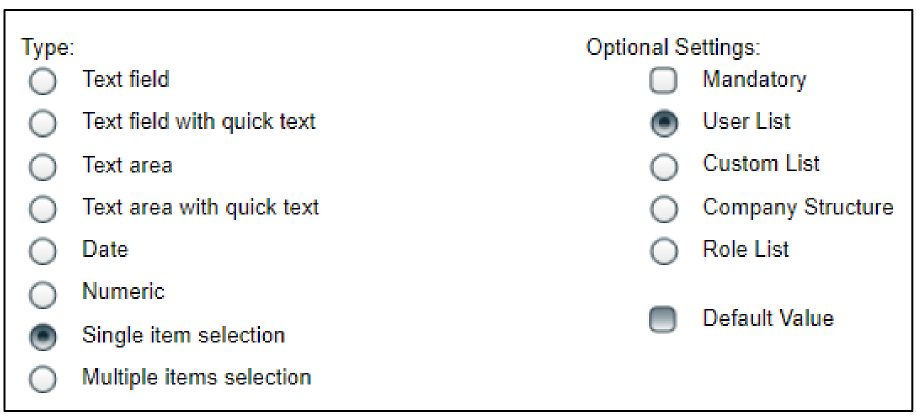




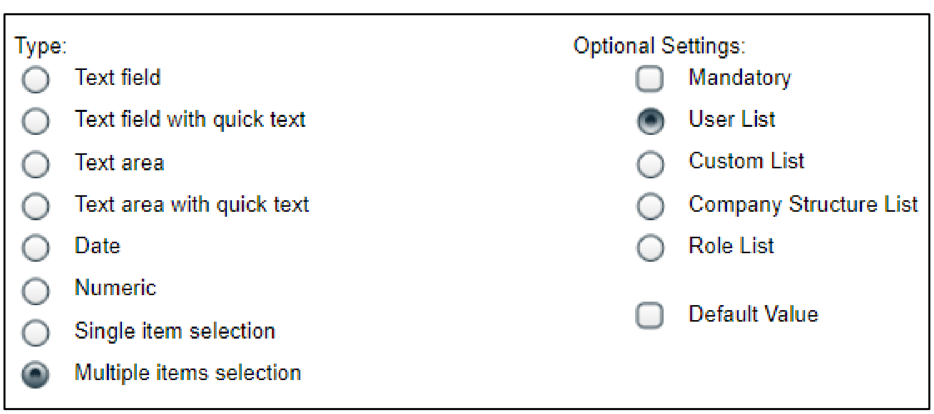
An Attribute Type of **Date** can be set as Mandatory or not and requires a choice of **Date Validation** of either **Can't be set in the past** or **Allow to set in the past**.



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



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 SEC Roles by Organization, Division, Department or Sub-Department) or **Role List** (all active FCT or SEC Roles). Choosing to set a **Default Value** will bring up the list of Values for the selected list.



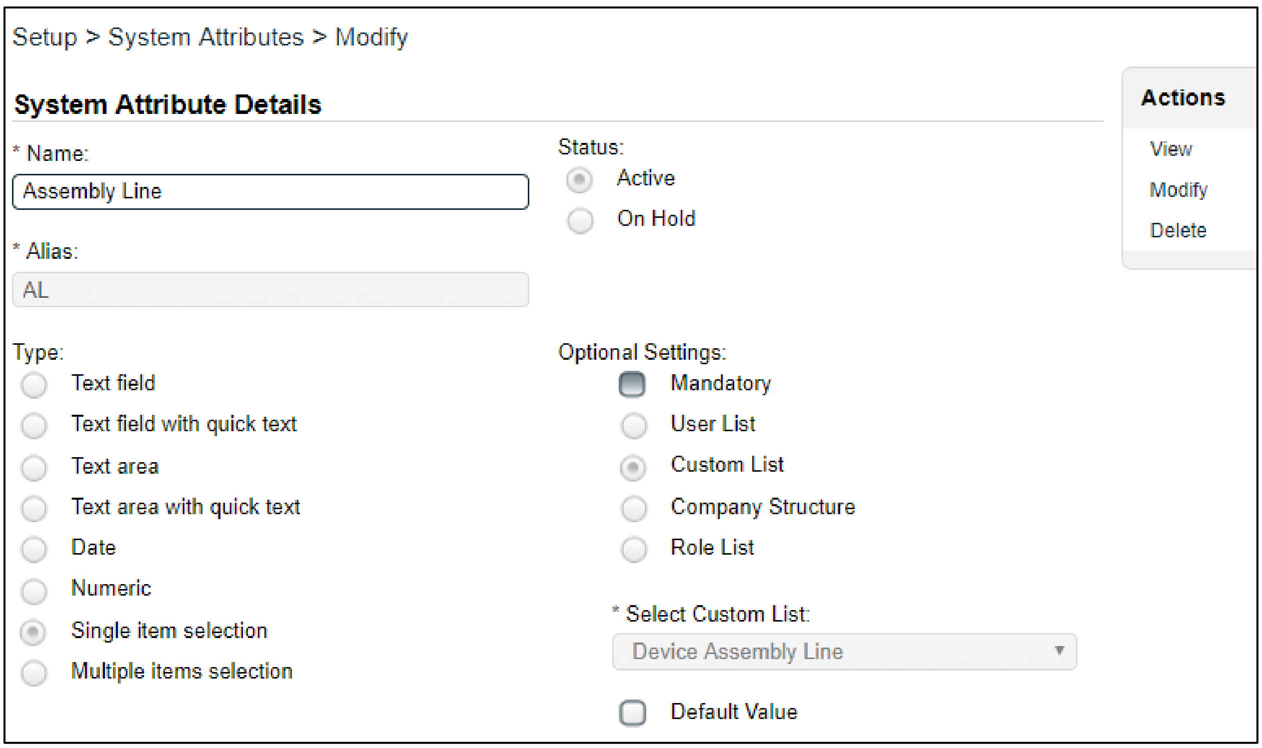
An Attribute type of **Multiple items selection** is used to define the System Attribute field as a multi-select list. The settings are the same as for the Single item selection field, but the user will be able to pick more than one value.

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

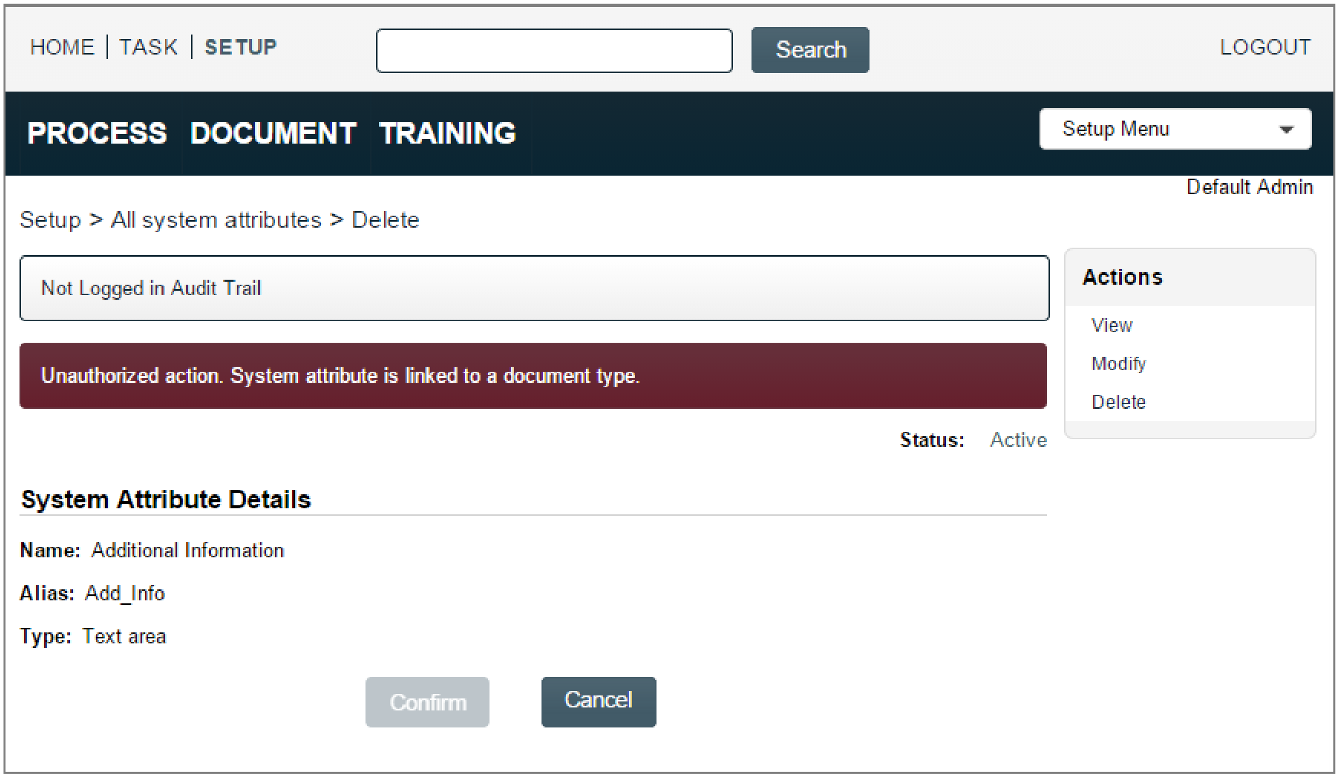
To Modify a **System Attribute**, either choose the **Modify** option to the right of the listing on the list of Active System Attributes, or choose the **View** option and then choose **Modify** from the right-hand **Actions** menu.

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 to prevent changes.



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 - deletion will not be able to be Confirmed – an **Unauthorized action** message will be displayed.

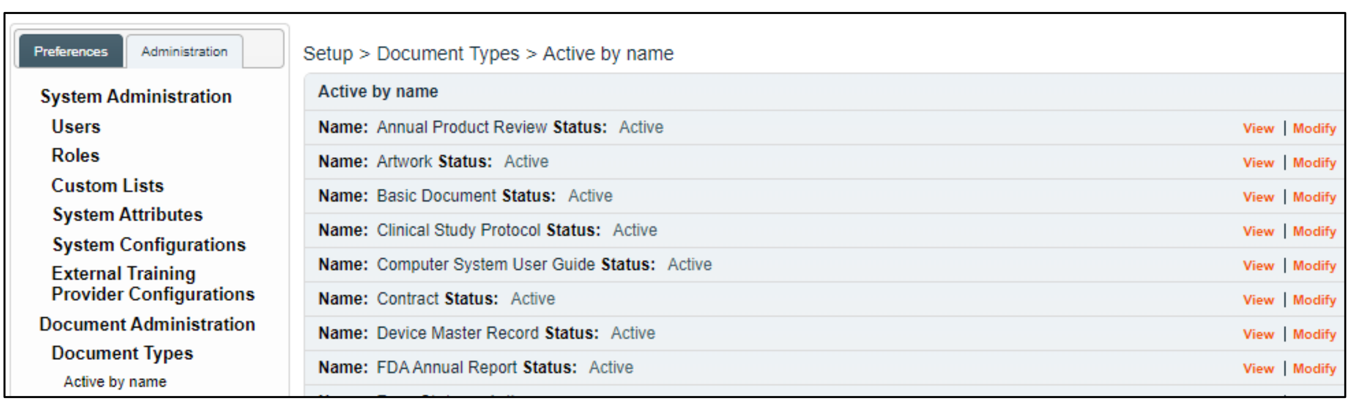


Document Administration Menus

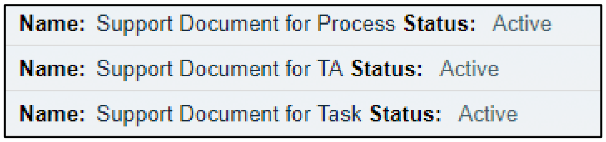
Document Types

Establishing **Document Types** allows differentiation between documents with respect to default settings for **Document Details**, **Standard Attributes**, **System Attributes** and **Document Ownership**. This allows storage of all different types of documents within the same **SOLABS QM10** Document Treeview and defines the metadata that authors will be required to enter for a given Document Type. Most default settings for Document Types can be overridden as needed for individual documents.

From the **SETUP** Section, **Document Types** are available through the Administration tab of the left dashboard menu. Choose **Document Administration** > **Document Type**s > **Active by name** to view all active Document Types.



Some Document Types are provided by default with the Core Software to support functionality related to the PROCESS, TRAINING and TASK sections. They are prefixed by "Support Document for" and cannot be modified.



Another Document type that is provided by default with the Core Software is the **Basic Document**. This Document Type is available to be used for documents that don't require any more unique settings. As mentioned above, in order to differentiate between documents, additional Document Types can be created.

Create a Document Type

From the **SETUP** Section, access the Quick Access **Setup Menu** at the top right of the screen and choose the **Create Document Type** option. The **Setup > Document Types > Create** screen will be displayed. It includes the sections to define the following for the new Document Type:

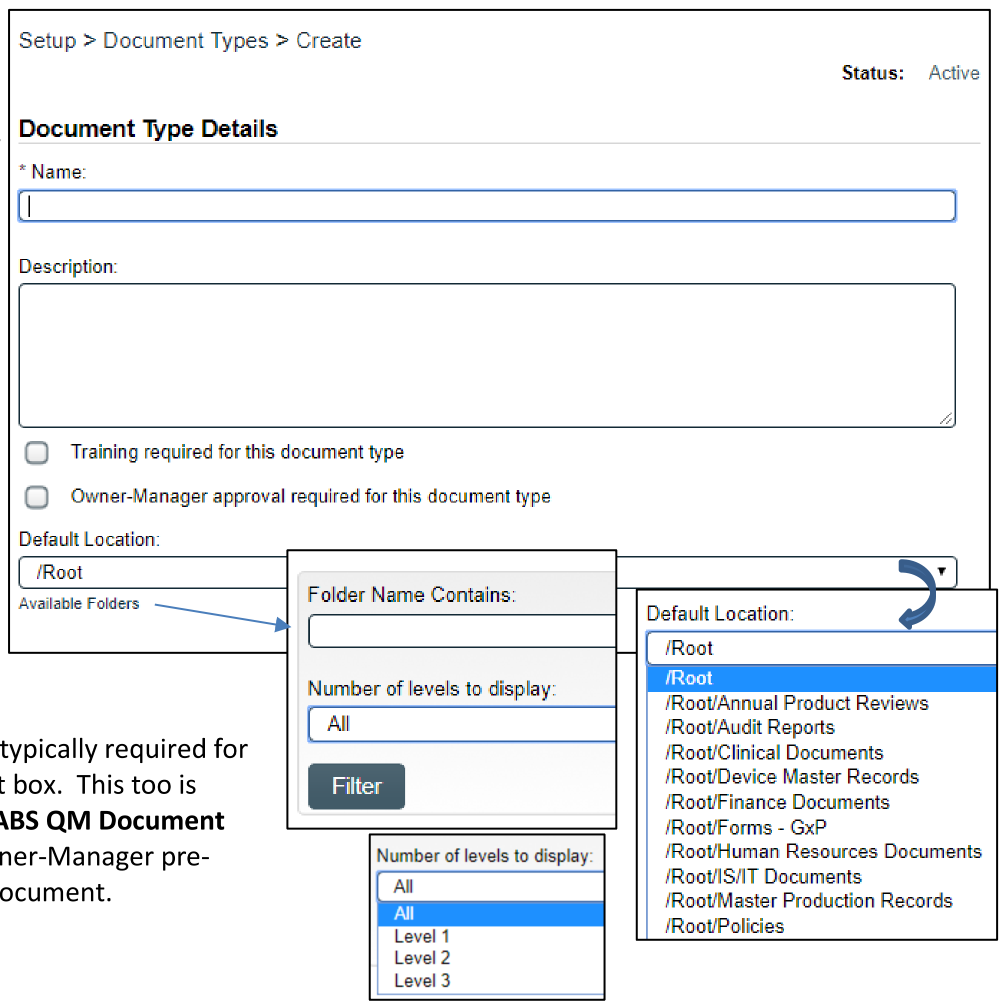
- Document Type Details
- Standard Attributes
- System Attributes
- Document Ownership

The first section on the **Setup > Document Types > Create** screen is for **Document Type Details**.

Enter a meaningful, intuitive **Name** for the Document Type. The **Description** field is optional but may be helpful for document authors to get more information on what types of documents this **Document Type** is intended to be used for.

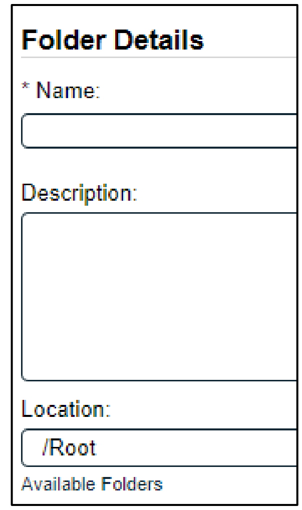
If **Training** is typically required for this Document Type, check that box. This is important when using the **SOLABS QM10 Document Control Process** since it includes a workflow step for the Training Administrator to manage requirements related to Training Activities.

If **Owner-Manager approval** is typically required for this Document Type, check that box. This too is important when using the **SOLABS QM Document Control Process** to support Owner-Manager pre-approval for the new/revised document.



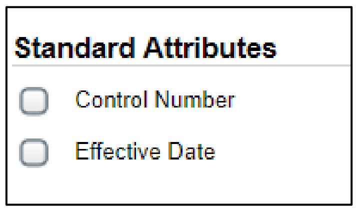
Choose the **Default Location** in the Document Treeview for this new Document Type.

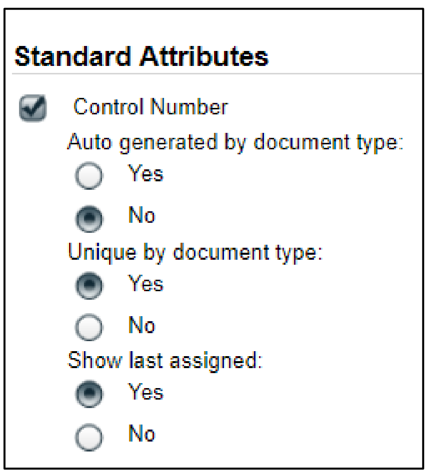
- Click on "**Available Folders**" to bring up search criteria for locating the Treeview folder to be used.
- Enter the search criteria and then click on the **Filter** button.
- At that point, clicking on the /Root drop-down list will bring up all the available folders that meet the search criteria.



If a new folder needs to be created, click on the **DOCUMENT** Section from the Main Menu, access the Quick Access **Document Menu** at the top right of the screen and choose the **Create Folder** option. After creating the new folder, it will show up on the list.

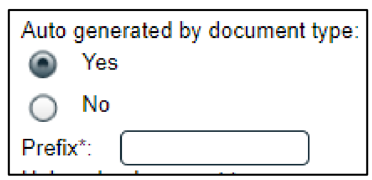
The next section on the **Setup > Document Types > Create** screen is for **Standard Attributes.** Checking the boxes next to **Control Number** and/or **Effective Date**, will bring up additional options.





The selected Radio Buttons on the **Control Number** selections to the left are the **defaults** that will come up when checking off Control Number. These can be edited for the new Document Type.

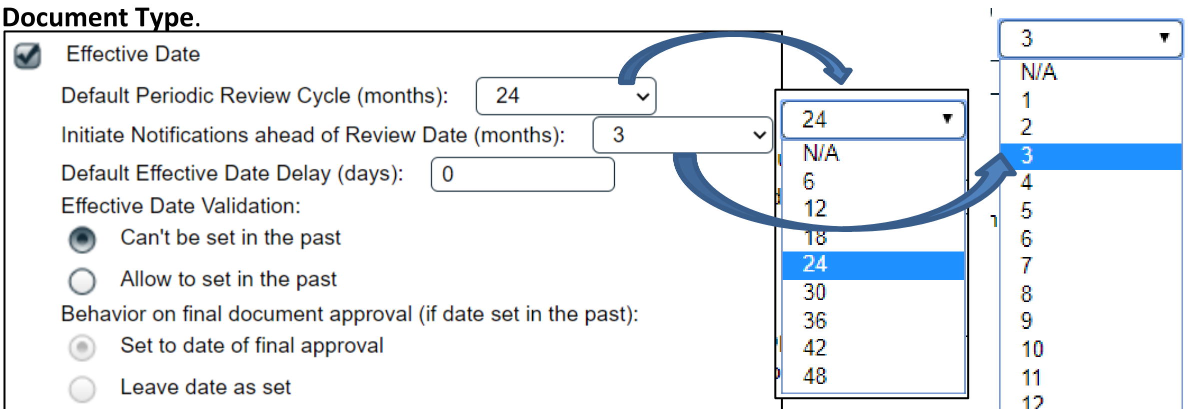
If **Auto generated by document type** is changed to **Yes**, a Prefix for the number will be required:



When **Unique by document type** is Yes, the Control Number field will be enabled for entry of the number when the new document is created.

There is also an option to choose whether to **Show last assigned** control number when the new document is created. When **Show last assigned** is **Yes**, a document author will see the last document number assigned, to help them assign the control number for the new document.

Below are the selections that will come up when checking off **Effective Date**. These can be edited for the new **Document Type**.

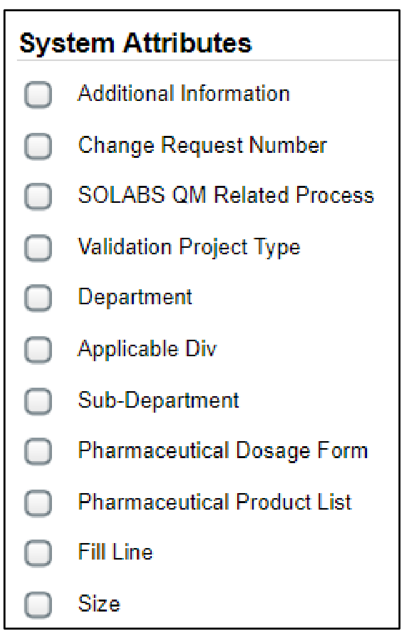


If the **Document Type** is one that requires a **Periodic Review Cycle**, there are single-item selection fields to choose the **Default Periodic Review Cycle (months)** and the default **Initiate Notifications ahead of Review Date (months)**. If N/A is selected for the Default Periodic Review Cycle, the Planned Review task duration will automatically default to N/A.

Starting with Release 10.9, this setting will trigger *Document Periodic Review Due* email Notifications to the Document Owner, Author and/or Document Coordinator (where defined for the Document Type) that many months ahead of the Periodic Review due date so that the review activities can be initiated. The Notifications are sent every two weeks on Mondays. If the document is not revised by the Review Date, *Document Periodic Review Late* email Notifications will be sent weekly on Mondays.

The numeric field for **Default Effective Date Delay (days)** is used to select a default period of time during which the document will be in an **Approved, not Effective status**, possibly for a document training period or to allow time to send documents to external partners. When using this setting (which can be overridden at the individual document level), the document will automatically become Effective the chosen number of days after it is Approved.

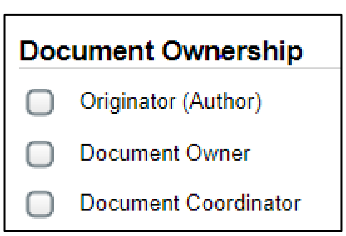
The **Effective Date Validation** defaults to **Can't be set in the past**. If need be, it can be changed to **Allow to set in the past**. This can be helpful when importing legacy documents during initial migration to SOLABS QM10 or when using SOLABS QM10 to import and store documents generated from another system, contractor, etc. The setting for **Behavior on final document approval (if date set in the past)**, defaults as appropriate based on the above selection, and is not editable.



The next section on the **Setup > Document Types > Create** screen is for **System Attributes.**

The **System Attributes** section includes a list of all active System Attributes. As System Attributes are created, they will appear on this list for the next Document Type created or when modifying existing Document Types. If a System Attribute field will be required for the new Document Type, but is not on the current list, it can be created afterwards and then added to the Document Type through the Modify option.

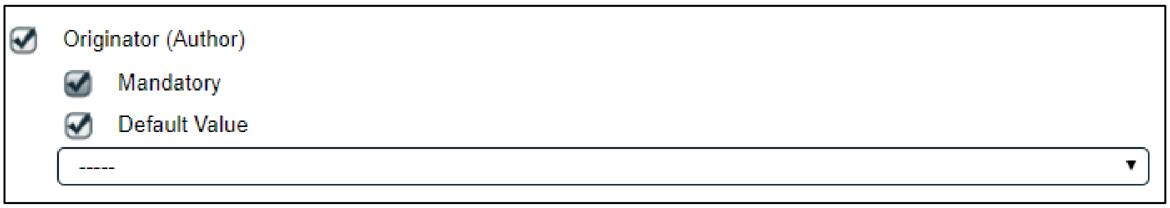
By making selections from this list, you are choosing the metadata fields that an author will be presented with when creating or revising a document associated with this Document Type – an electronic template for your Document Type.



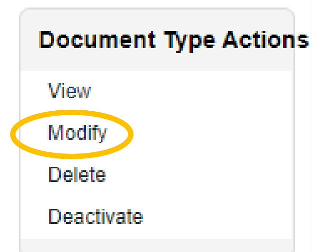
The last section on the **Setup > Document Types > Create** screen is for **Document Ownership.**

Making a selection for **Originator (Author)**, **Document Owner** and/or **Document Coordinator** enables those fields within the document, allowing ownership information to be entered during authoring. This also provides information for the Periodic Review task notifications mentioned above.

When Document Ownership selections are made, they can be set as **Mandatory** and can be set to have a **Default Value**. Selecting Mandatory results in the Author being required to enter data into that field when creating or revising a document. Selecting Default Value brings up a single-select drop-down list. For the Originator, it will be a list of all active SOLABS QM10 Users. For Document Owner and Document Coordinator, it will be a list of all active Functional (FCT_) Roles. These settings should be selected and set as Mandatory if you want to take full advantage of the email Notifications for Periodic Reviews.



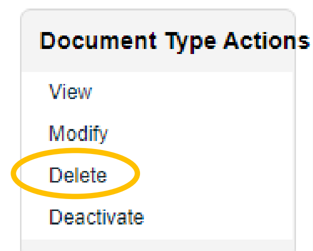
Modify a Document Type



To modify an existing **Document Type,** go to the **View** screen for that active Document Type. From the top right-hand **Document Type Actions** menu, choose the **Modify** option.

NOTE: Changes to Document Type settings will apply to the next new document of that Document Type or the next revision of an existing document.

Delete or Deactivate a Document Type



To delete an existing **Document Type,** go to the **View** screen for that active Document Type. From the top right-hand **Document Type Actions** menu, choose the **Delete** option.

You *cannot delete* a Document Type *that has already been assigned* to a SOLABS QM10 Document.

If you will no longer require this Document Type, and cannot delete it because there are existing documents with that Document Type, choose the **Deactivate** option instead.

Document Workflow Templates

Document Workflow Templates allow setup of default lists of Reviewers and/or Approvers for different Document Types or organizational needs. The active Document Workflow Templates can then be selected by a document author, pulling in those names for the Review Cycle, Approval Cycle and/or Retire Cycle for their document. These are default lists that are easily edited at the document level to either remove a person or add an additional person.

From the **SETUP** Section, **Document Workflow Templates** are available through the Administration tab of the left dashboard menu. Choose **Document Administration** > **Document Workflow Template**s > **All** to view all active Document Workflow Templates.

Create a Document Workflow Template

From the **SETUP** Section, access the Quick Access **Setup Menu** at the top right of the screen and choose the **Create Document Workflow Template** option. The **Setup > Document Workflows > Create** screen will be displayed. It includes sections to define the following for the new Document Workflow Template:

- Document Workflow Template Details
- Default Template for the Following Document Types
- Parameters

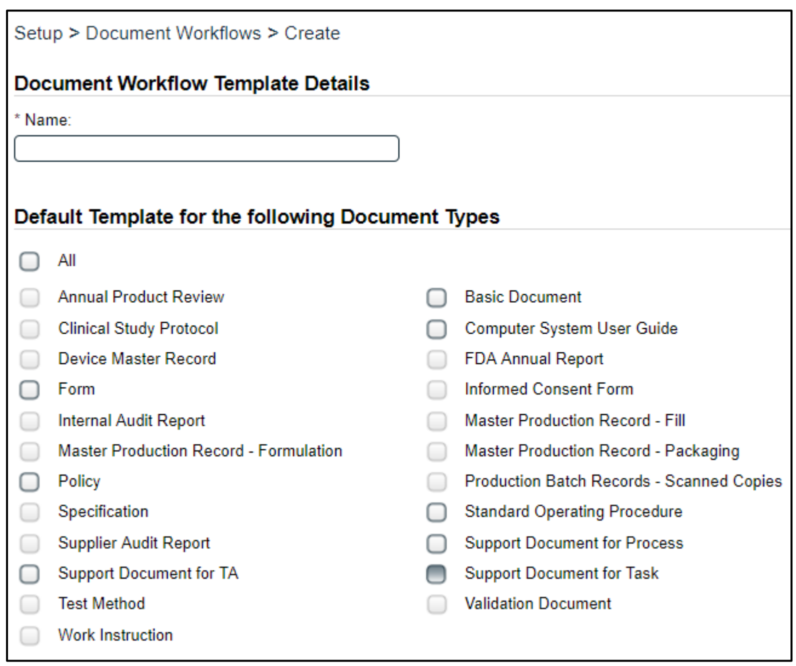
The first two sections on the **Setup > Document Workflows > Create** screen are for **Document Workflow Template Details** and **Default Template for the following Document Types**.

Enter a meaningful, intuitive **Name** for the Document Workflow Template; one that easily describes either the Document Type(s) that it will be used for or the Reviewer/Approver scenarios it will be used for.

The **Default Template for the following Document Types** section includes a list of all active Document Types.

Associating a Default Document Workflow Template for a particular Document Type is optional. They can also be created for typical Reviewer/Approver scenarios that cross many Document Types. When an author is ready to route a document for Review and/or Approval, they will see any available Default Document Workflow Template but can choose from all active Document Workflow Templates.

Document Types that are grayed out are already have a Default Document Workflow Template.



To associate the new Document Workflow Template with one or more existing Document Types, check the box(es) next to them.

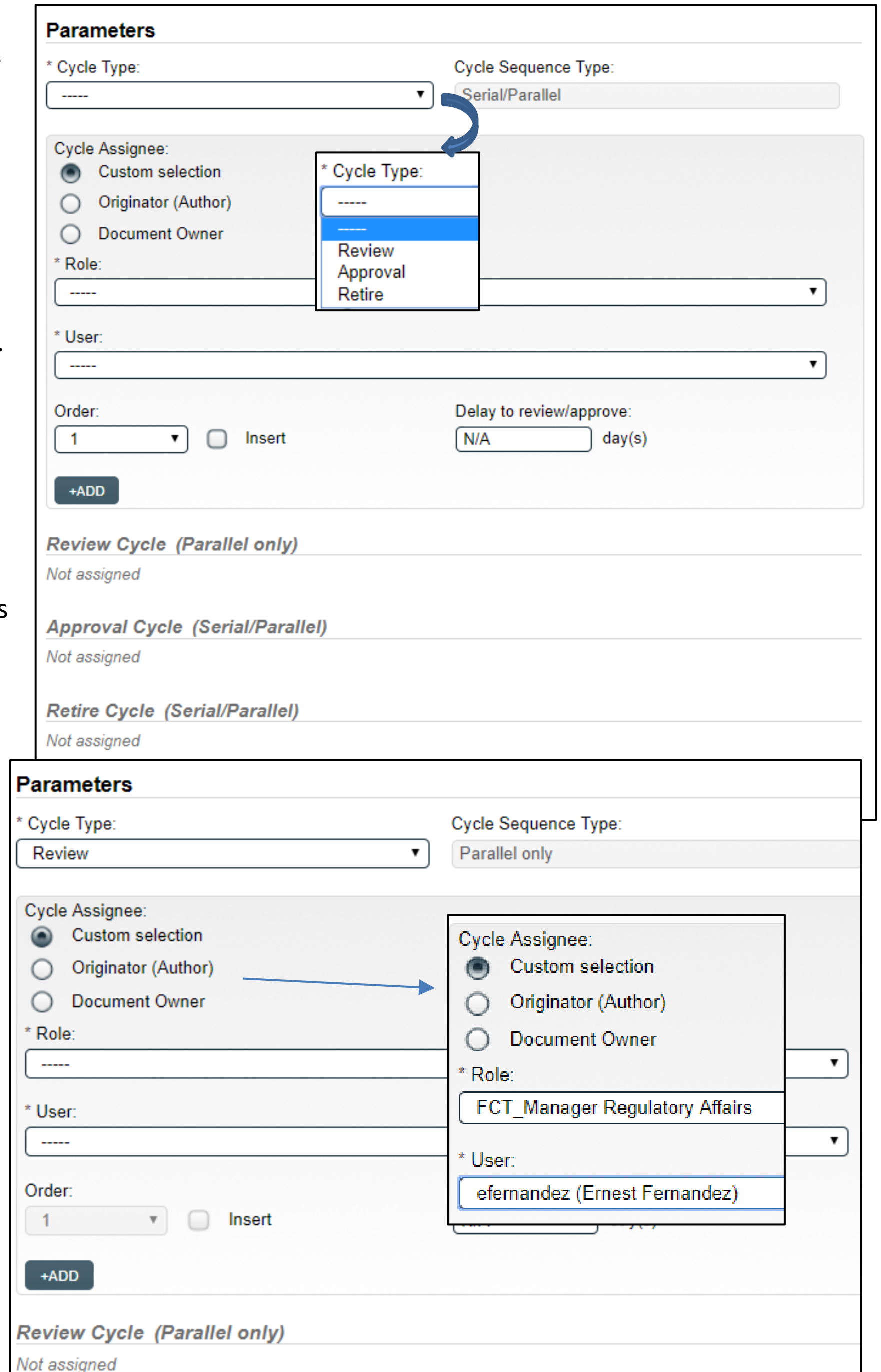
The next section on the **Setup > Document Workflows > Create** screen is for **Parameters**. This is where you will create the default lists of people for the Review Cycle, Approval Cycle and/or Retire Cycle. These will be default lists in that they can be chosen and then edited for a particular document. As people are added, they will be listed in the sections at the bottom of the screen.

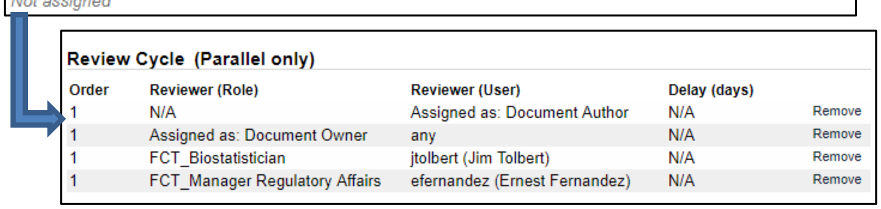
The mandatory **Cycle Type** field is a single-select drop-down list where you will choose the type of cycle you would like to define. The **Cycle Sequence Type** will then display the type of cycle allowed – either Parallel only (Review Cycles) or Serial/Parallel (Approval Cycles and Retire Cycles).

The **Cycle Assignees** will be added one at a time for each Cycle Type. After choosing an Assignee, click the **+ADD** button.

Choosing either **Originator (Author)** or **Document Owner** will simply add that category to the list, defaulting to the applicable person for the Document being created/revised. Choosing **Custom section** allows you to choose Assignees – by **Role** or by **User**. Both fields need to be filled in. If you choose a Role, the User drop-down list will display all Users in that Role or the option to choose **any**. If you choose a User, the Role drop-down list will display the FCT Role(s) associated with that User.

As **Review Cycle Assignees** are added, they will appear in the Review Cycle section at the bottom of the screen.





Review Cycle (Parallel only)

Order	Reviewer (Role)	Reviewer (User)	Delay (days)	
1	N/A	Assigned as: Document Author	N/A	Remove
1	Assigned as: Document Owner	any	N/A	Remove
1	FCT_Biostatistician	jtolbert (Jim Tolbert)	N/A	Remove
1	FCT_Manager Regulatory Affairs	efernandez (Ernest Fernandez)	N/A	Remove

The Review Cycle is Parallel only, so all Assignees will have an **Order** of “1”. As each Assignee is added, a **Delay to review/approve** can be defined in days. This is optional and simply communicates a length of time in which you would like the Assignees to complete the review or approval task. This should be used if you plan to set Due Dates for your Review Cycles. All Reviewers receive their email Notifications for the Review Task at the same time, and can act on it in any order.

The **Approval Cycle Assignees** and the **Retire Cycle Assignees** are added exactly as described above, but with an additional option to establish an **Order**, since Approval Cycles can be defined in Parallel or Series. When a Cycle Type of Approval is chosen, the Order option is enabled.

As assignees are added, the available choices on the Order drop-down list will increment by 1. The checkbox for Insert can be used if you would like to insert another assignee at an earlier order.

Approval Cycle (Serial/Parallel)

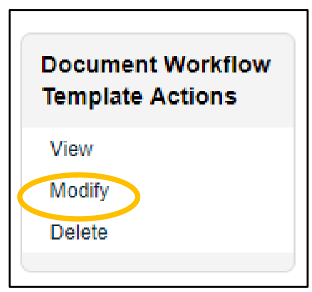
Order	Approver (Role)	Approver (User)	Delay (days)	
1	FCT_Director Clinical Operations	jbecket (Jennifer Becket)	N/A	Remove
1	FCT_Director Clinical Quality Assurance	lneil (Leo Neil)	N/A	Remove
2	FCT_VP Development & Clinical Operations	dthomas (Daniel Thomas)	N/A	Remove
3	FCT_VP Drug Safety	amoore (Alice Moore)	N/A	Remove

Note the **Remove** option next to each Assignee in any Cycle. This can be used if corrections are needed. It is also available at the Document level to make edits to a default workflow template.

When an Order is set for serial review, each user is alerted of the document when it is ready for their approval. The user/role next in line is not alerted until the previous user has approved the document.

If, for any reason, a document is rejected, any user or role further downstream in the chain of approval is not alerted that the document was sent for approval, and the approval cycle is stopped.

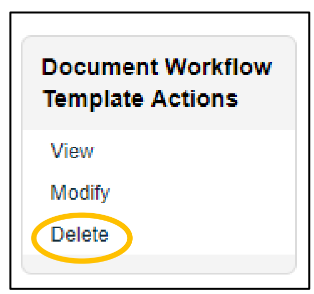
Modify a Document Workflow Template



To modify an existing **Document Workflow Template,** go to the **View** screen for that active Document Workflow Template. From the top right-hand **Document Workflow Template Actions** menu, choose the **Modify** option.

Modifications only affect documents created *after* this time. Any document currently assigned that workflow **will not** have its workflow updated.

Delete a Document Workflow Template



To delete an existing **Document Workflow Template,** go to the **View** screen for that active Document Workflow Template. From the top right-hand **Document Workflow Template Actions** menu, choose the **Delete** option.

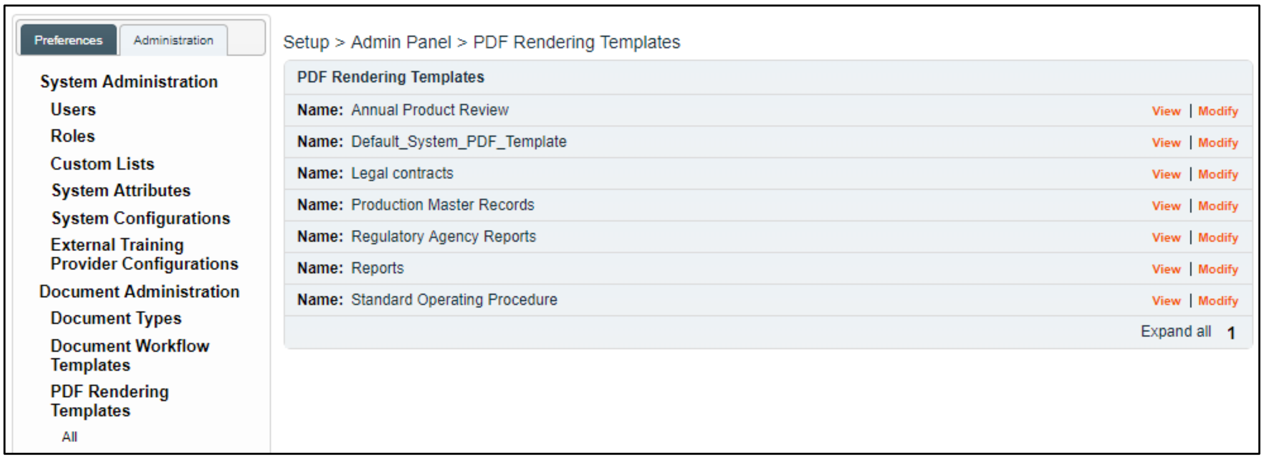
You cannot delete a Document Workflow Template that is associated with a Document Type or that is currently in use.

If you will no longer require this Document Workflow Template, first choose the **Modify** option to uncheck the Document Types it is associated with and then go back and try the **Delete** option. If the Delete action is still not allowed, the workflow may be actively in use for a new/revised document.

PDF Rendering Templates

PDF Rendering Templates allow setup of document Cover Pages, Status Watermarks and Headers for different Document Types or organizational needs. The active PDF Rendering Templates are then applied to the document when it is converted to PDF format at the For Approval stage of the document life cycle.

From the **SETUP** Section, **PDF Rendering Templates** are available through the Administration tab of the left dashboard menu. Choose **Document Administration** > **PDF Rendering Template**s > **All** to view all active PDF Rendering Templates.



One PDF Rendering Template that is provided by default with the Core Software is the **Default_System_PDF_Template.** It will be used for any PDF renderings of documents that don't have a more specific rendering template defined, and can be edited but not deleted.

Create a PDF Rendering Template

From the **SETUP** Section, access the Quick Access **Setup Menu** at the top right of the screen and choose the **Create PDF Rendering Template** option. The **Setup > Administration > Document Rendering Settings > CreateModify** screen will be displayed. It includes sections to define the following for the new PDF Rendering Template:

- PDF Rendering Template Details
- Default settings for the following document types
- Display Settings

The first two sections on the **CreateModify** screen for PDF Rendering Templates are for **PDF Rendering Template Details** and **Default settings for the following document types**.

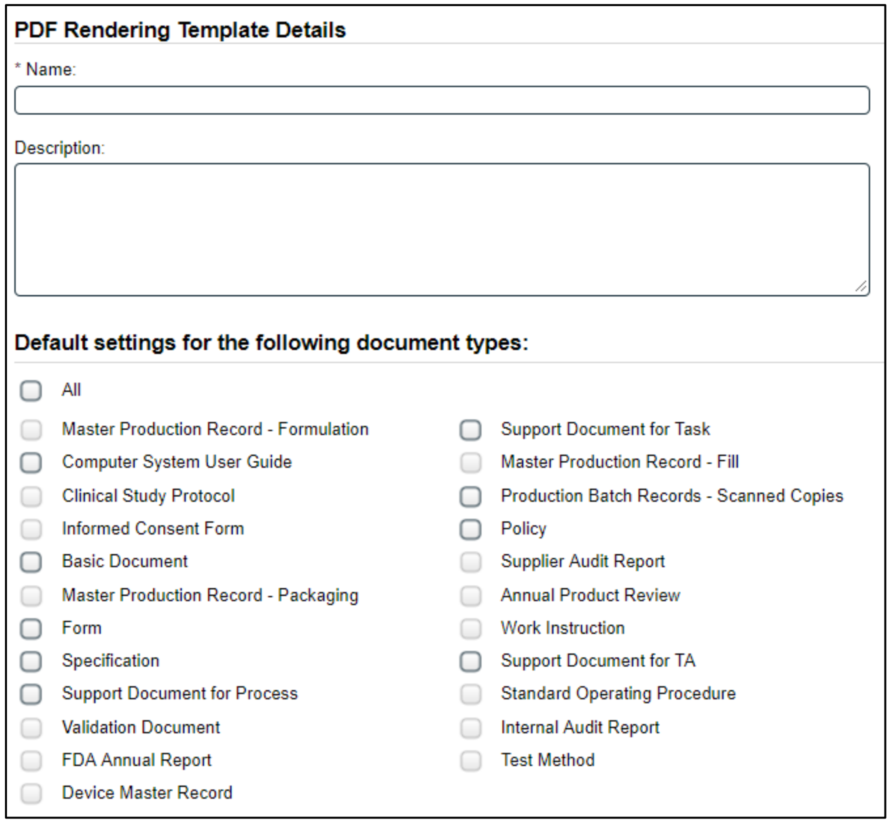
Enter a meaningful, intuitive **Name** for the PDF Rendering Template; one that easily describes the Document Type(s) that it will be used for.

The **Description** field is optional but can be useful to provide more information on how the template will be used.

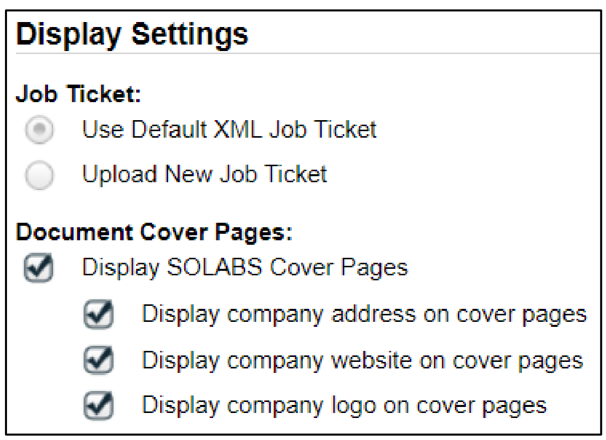
The **Default settings for the following document types** section includes a list of all active Document Types.

Document Types that are grayed out are already associated with a PDF Rendering Template.

To associate the new PDF Rendering Template with one or more existing Document Types, check the box(es) next to them.



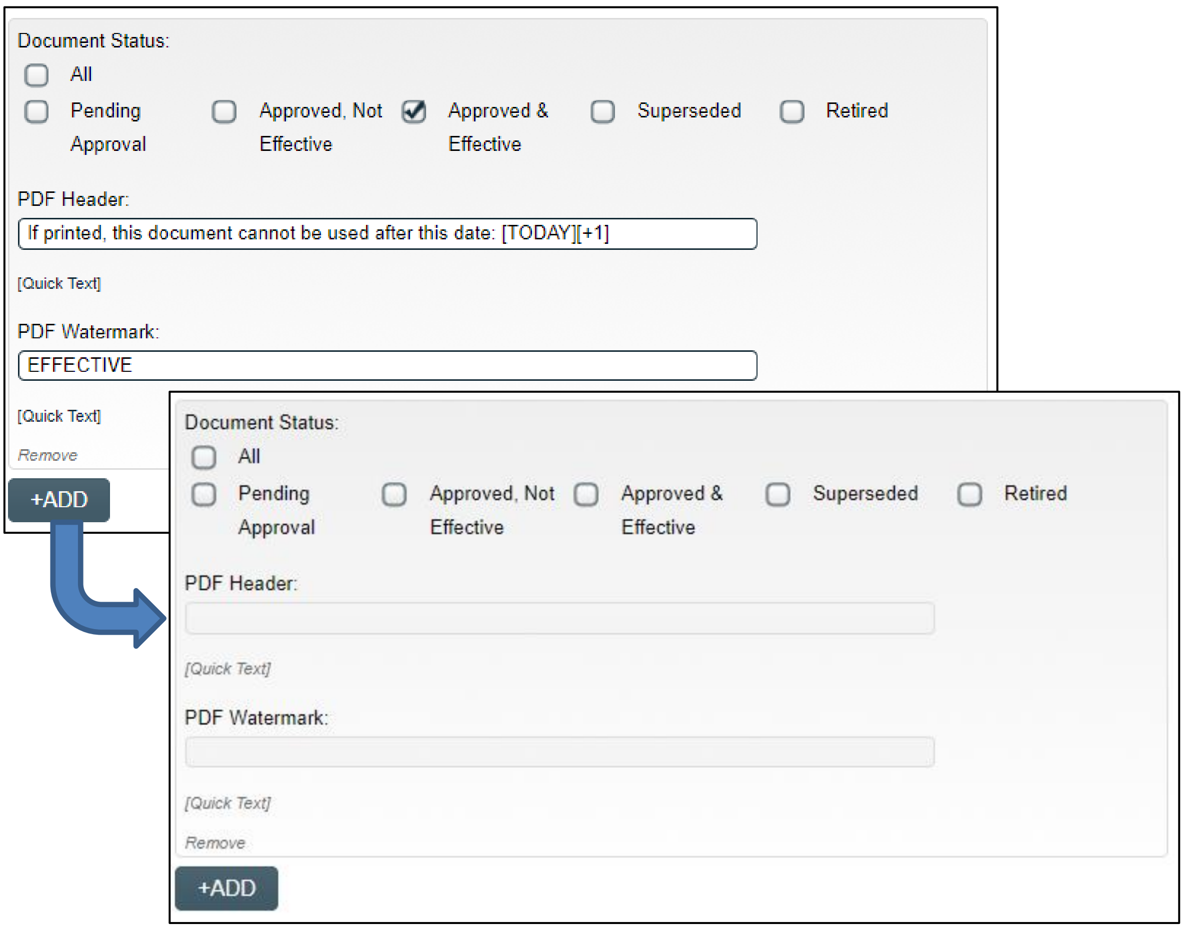
The next section on the **Setup > Administration > Document Rendering Settings > CreateModify** screen is for **Display Settings**. This is where it will be identified whether or not the SOLABS Cover Pages will be applied for PDF renditions of these Document Types. If SOLABS Cover Pages will be used, this section also defines whether they will include the company address, website and/or logo.



The **Display Settings** section is also used to define optional **PDF Headers** and **PDF Watermarks** for different document statuses.

To define a **Document Status PDF Header** or **PDF Watermark** for the PDF Rendition, check the box in front of the Document Status you would like to define a header and/or watermark for. Type the information into the related text field or use available Quick Text options to define the PDF Header and/or PDF Watermark for that particular Document Status. There are some Quick Text options that come with the core software, but those Custom Lists can be edited by the SOLABS Document Administrator to include options specific to your needs. There is a 76-character limit for the header and a 12-character limit for the watermark.

To define a PDF Header and a PDF Watermark for another Document Status, click the **+ADD** button and add another set of entries.



If the PDF Header and the PDF Watermark will be the same for all five listed document statuses, check the All option to just enter the information once.

The **SOLABS Cover Pages** are applied as the first two pages of the PDF rendition. They include a DOCUMENT INFORMATION TABLE (that include the document Standard Attribute and System Attribute metadata), a list of any RELATED ITEMS and an APPROVAL TABLE.

The PDF Header and the PDF Watermark are applied to every page of the PDF rendition.

See the next page for an example of a PDF Rendition

Example SOLABS Cover Pages – with company address, website and logo:

Page 1:

If printed, this document cannot be used after this date: 15-Oct-2017

Example Header

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

0.9% SODIUM CHLORIDE INJECTION USP

Status: Approved & Effective
Effective Date: 01-Jun-2017
Control Number: FP-001
Version: 1.0

DOCUMENT INFORMATION TABLE

Name	0.9% Sodium Chloride Injection USP
Document Type	Specification
Description	Finished Product Specifications for 0.9% Sodium Chloride Injection USP, 250mL, 500 mL, 1000mL
Unique ID	1647d3c3-da73-4320-8f4e-59c9973f3e44
Control Number	FP-001
Version (Internal Version)	1.0 (1.0)
Effective Date	01-Jun-2017
Next Review Date	01-Jun-2019
Reason for Change	New
Additional Information	Applies to all sizes
Change Request Number	CR002
Specification Type	Finished Product - Pharmaceutical
Originator (Author)	N/A
Document Owner	N/A
Document Coordinator	N/A

EFFECTIVE

Example Watermark

RELATED ITEMS
N/A

Page 2:

If printed, this document cannot be used after this date: 15-Oct-2017

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

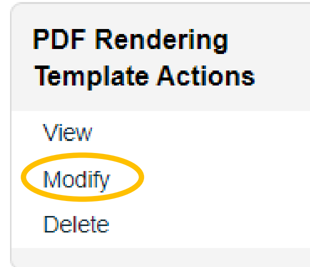
0.9% SODIUM CHLORIDE INJECTION USP

Status: Approved & Effective
Effective Date: 01-Jun-2017
Control Number: FP-001
Version: 1.0

APPROVAL TABLE

Status	Order	Approver (Role)	Approver (User)	Approved By	Meaning	Approval Date
Approved	1	FCT_Director Quality	drennold (Delores Rennold)	drennold (Delores Rennold)	Approver	01-Jun-2017 10:54:15
Approved	1	FCT_Manager Quality Control	tgarcia (Theresa Garcia)	tgarcia (Theresa Garcia)	Approver	01-Jun-2017 10:52:54

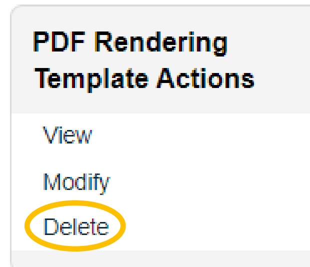
Modify a PDF Rendering Template



To modify an existing **PDF Rendering Template,** go to the **View** screen for that active PDF Rendering Template. From the top right-hand **PDF Rendering Template Actions** menu, choose the **Modify** option.

You can modify all details of the PDF Rendering Template.

Delete a PDF Rendering Template



To delete an existing **PDF Rendering Template,** go to the **View** screen for that active PDF Rendering Template. From the top right-hand **PDF Rendering Template Actions** menu, choose the **Delete** option.

You *cannot delete* a PDF Rendering Template *that is currently associated with a Document Type.*

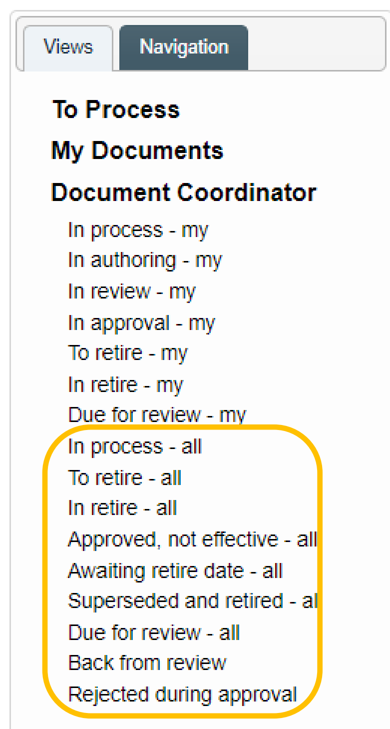
If you will no longer require this PDF Rendering Template, first assign a different PDF Rendering Template to that Document Type.

Document Administration Tasks in the DOCUMENT Section

The Document Section is used:

- To manage, process (i.e. review, approve or retire) and publish (PDF) controlled documents.
- To store documents from other SOLABS sections (support documents attached to Processes, Tasks and Training activities).

This section includes some setup and maintenance tasks that are typically performed by the SOLABS System Administrator or the SOLABS Document Administrator. See other User Guides in the SOLABS Knowledge Base for General User actions such as Creation/Revision of a Document or Review/Approval of a Document. Search by Keyword "Document" to bring up various resources.



Users who are assigned the System Role of **SOLABS Document Administrator**, have additional Views for **Document Coordinators** on the left-hand side of the Home Page from within the DOCUMENT Section.

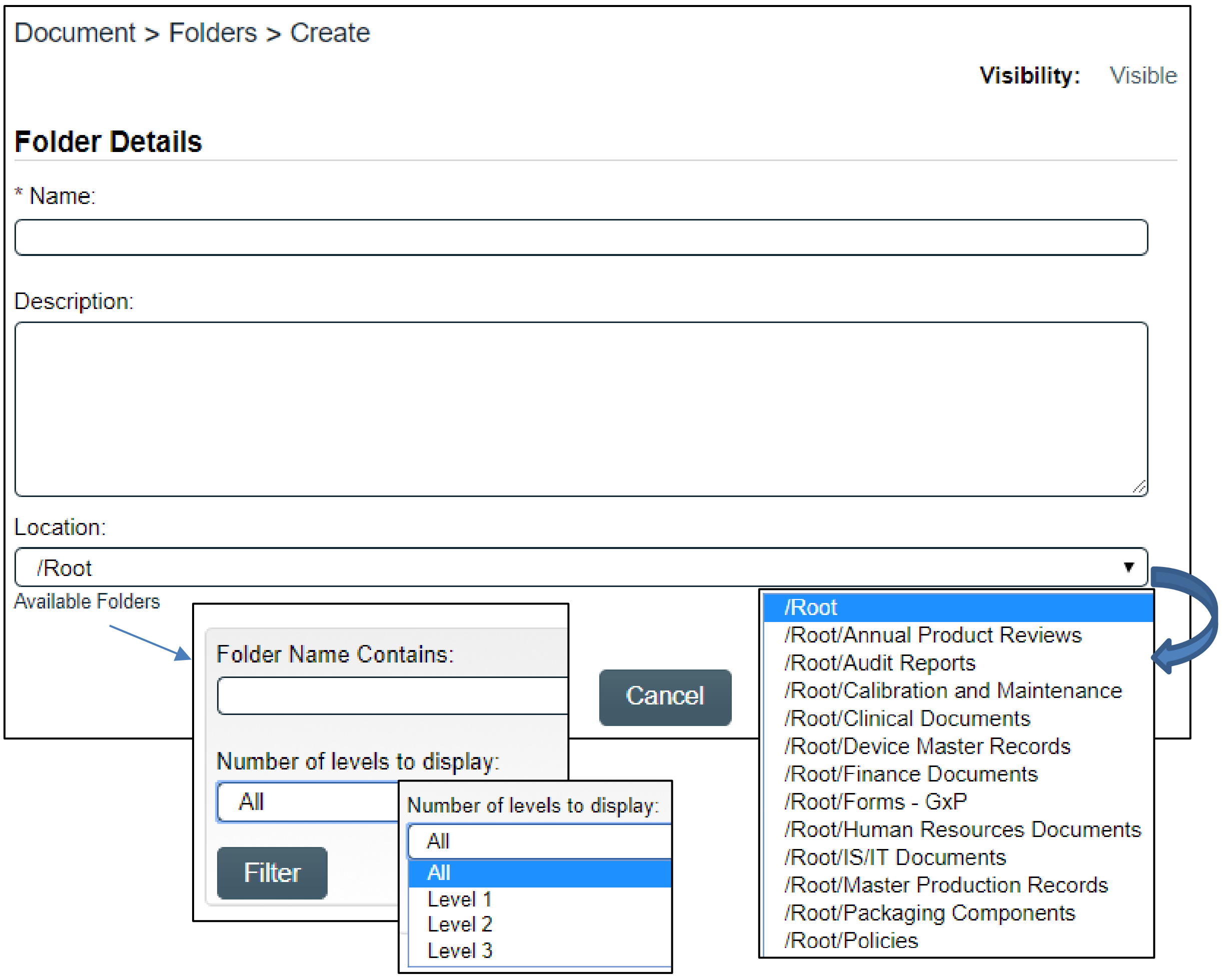
These additional Views allow the Document Coordinator to monitor the status of Document activities for their entire organization.

- The Back from review option allows quick access to a list of documents that have had comments from assigned Reviewers so are back at the Authoring status.
- The Rejected during approval option allows quick access to a list of documents that have been rejected by an Approver and are back at the Authoring status.

Add a New Folder

Folders and subfolders can be created for the beginning of a new project, the addition of a new team, etc. Once created, they appear in the Document Treeview.

From the **DOCUMENT** Section, access the Quick Access **Document Menu** at the top right of the screen and choose the **Create Folder** option. The **Document > Folders > Create** screen will be displayed.



Enter a meaningful, intuitive **Name** for the Folder; one that easily describes the Documents that will be stored in it. The Description field is optional but can be helpful to provide more information on the Documents stored within this folder.

The **Location** field is used to place the new Folder within the Document Treeview. If the parent folder was highlighted before choosing the Create Folder option from the Document Menu, this field will default to that folder location as the parent folder. Otherwise, search for the desired Location as follows:

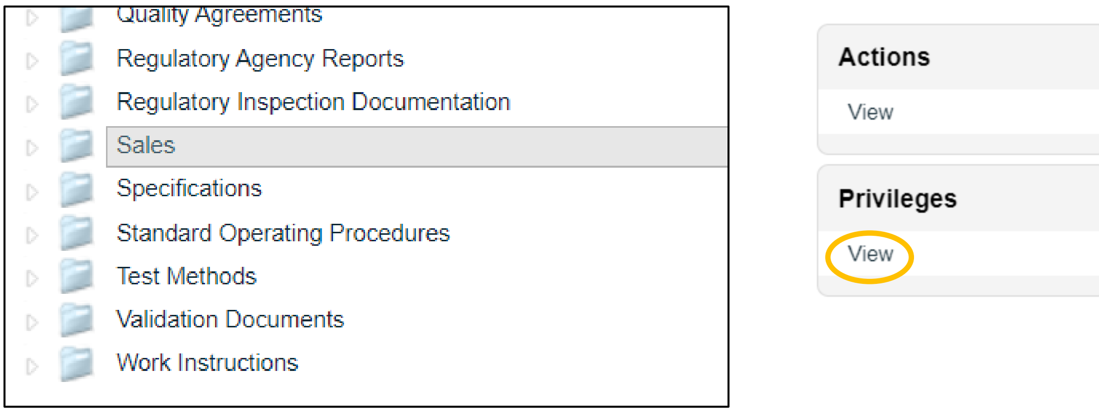
- Click on "**Available Folders**" to bring up search criteria for the Treeview folders.
- Enter the search criteria and then click on the **Filter** button. If there are many folders in the Treeview, use the **Folder Name Contains** field to limit the results to folders that include that search criteria.

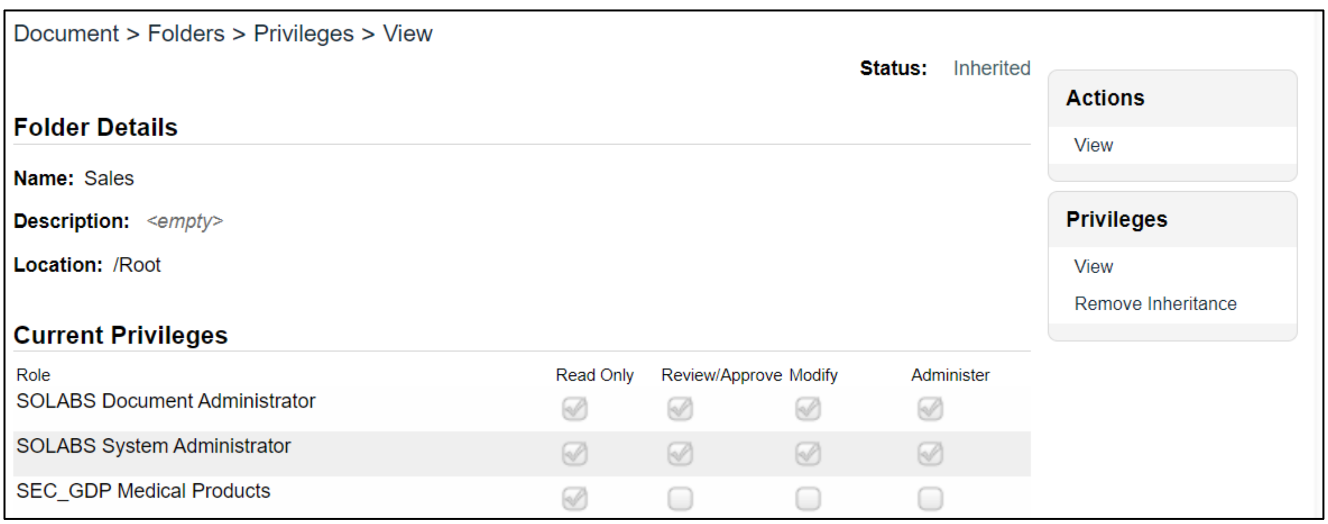
- At that point, clicking on the /Root drop-down list will bring up all the available folders that meet the search criteria.
- Click on the folder that will be the parent folder for this new one.
- Submit and Confirm the information to add the new Folder to the Treeview.

Setting Privileges for Folders and Documents

The **Privileges** settings define the type of access the Users have to the different folders and/or documents. This access is granted by Roles. When those Roles are assigned to a User, they then have the related Privileges.

To View and Modify Privileges for a Folder, highlight it within the Treeview and then choose **Privileges > View** from the right-hand menu.



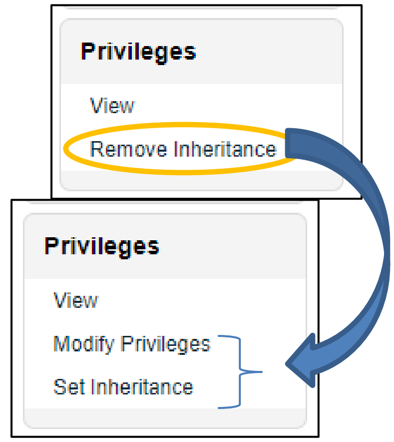


Privileges on folders are either **Inherited** from the parent folder or are individually set by choosing to **Remove Inheritance** and then **Modifying Privileges**.

By default, Users with the System Roles of SOLABS Document Administrator and SOLABS System Administrator have Administer privileges. Users with only the SOLABS General User role – Train ID Users for example – have the lowest Privilege of Read Only. That role can be replaced by one related to your company, as in the example above, saving the SOLABS General User role for outside parties.

- **Read Only** = Users with this privilege can view only Approved & Effective documents or Approved, Not Effective documents that they are assigned for training purposes.

- **Review/Approve** = Users with this privilege can view all in-process documents as well as act on Review or Approval tasks.
- **Modify** = Users with this privilege can do the above and can also create and modify documents.
- **Administer** = Users with this privilege can do all of the above and can also set privileges.



To add additional privileges, first choose **Privileges > Remove Inheritance**. After Confirming that choice, the Privileges menu will include the option for **Modify Privileges**.

Clicking on the Modify Privileges option brings up the **Document > Folders > Privileges > Modify** screen.

This screen is used to Remove or Add privileges.

All SOLABS QM10 Users have the **SOLABS General User** role by default so have **Read Only** privileges.

To add Review/Approve, Modify or Administer privileges to another Role, scroll through the list and select it. The list contains all active FCT, SEC, PR and SOLABS Roles.

After selecting the Role, select the privileges you would like to add to that Role by choosing them at the bottom of the screen and then clicking on **Update**. When you have made changes, click on **Submit**.

Any privileges you have Added, Removed or Modified will be listed for review. When you have verified the updates, click on **Confirm** to save the changes. The **Privileges > Set Inheritance** option can be used to set privileges back to those of the parent folder if/when needed