

SOLABS QM10: Guide for Training Administrators

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Purpose of this Guide

This guide is intended for “Super-Users” who are assigned the **SOLABS Training Administrator** Role and who manage Curriculums, Training Activities and Training Assignments in **SOLABS QM10**.

Administration Tasks in the TRAINING Section

Considerations for Configuration of the Training Section

A **Curriculum** is a grouping of related **Training Activities** (e.g.: training for all new employees, training related to SOP QA-023). It is where default settings for the included Training Activities are defined. The Curriculum cannot be assigned as a grouping. The individual Training Activities are assigned separately, or as a grouping by linking them to a Function Role assigned to one or more users. This defines required training for that function, against which training compliance will be measured and reported.

When a **SOLABS QM10 Document** is linked to a Curriculum as the **Curriculum Document**, the Training Activities within that Curriculum can be set to recur whenever that document is revised. A SOLABS QM10 Document can be linked as a Curriculum Document to only one Curriculum and a Curriculum can include only one linked Curriculum Document. Training Activities can include other documents or Related Documents but revision to *those* documents won’t initiate recurrence of the Training Activity.

When a Curriculum is set for a Recurrence based on revision of the Curriculum Document, all Training Activities within that Curriculum are automatically versioned, even if some are intentionally set as “No Assignment” after Recurrence. The previous versions of all Training Activities are also automatically closed.

Training Compliance percentages can be negatively impacted by “Unassigned” Training Activities, even where the choice not to assign them was intentional. Therefore, some considerations need to be made before grouping multiple Training Activities into one Curriculum that is set for a Recurrence on the Curriculum Document.

It is important to consider a training assignment strategy that aligns with this functionality.

Scenario 1 – All Training Activities in my Curriculum need to be assigned with every revision of the Curriculum Document

This is the most straightforward situation. The **Assignment After Creation** section is used to decide what you would like to happen upon revision of the Curriculum Document.

If all Training Activities need to recur when the linked Curriculum Document is revised, set them all to one of the three “Assign” options – based on profile, previous assignments or previously trained, whichever you prefer.

Recurrence	
Recurrence: Document revision	
Assignment After Creation:	
<input type="radio"/> No assignment	Status After Creation:
<input checked="" type="radio"/> Assign based on profile	<input checked="" type="radio"/> Not Started
<input type="radio"/> Assign based on previous assignments	<input type="radio"/> Active
<input type="radio"/> Assign based on previously trained	

When Training Activities are linked to a Function Role, **Assign based on profile** would be the appropriate setting.

When it is desired to measure Training Compliance for your users, always use the **Add Activity to Profile** option after creating a new Training Activity and then Assign End Users by filtering on those Profiles (Function Roles). For the Recurrence settings, use the **Assign based on profile** (Function Role) option.

It is also helpful to set **Status After Creation** to “**Not Started**” so that you can change settings after the Training Activities are recreated, even if it is just to set new Due Dates for your assigned users through **Schedule Users Activity** or to update a linked Training Assessment.

What if I need to remove one of the Training Activities in the Curriculum?

If you have linked multiple Training Activities within a Curriculum set for Recurrence Based on Document Revision and then decide that one of the Training Activities does not need to recur each time the Curriculum Document is revised, you can Modify that Training Activity to **change the Status to Closed**. However, this must be done **BEFORE the next revision of the Curriculum Document**.

Training Activity Details	
* Name:	GDP Validation Program
Category:	Classroom Training
Status:	<input type="radio"/> Not Started <input type="radio"/> Active <input type="radio"/> On Hold <input checked="" type="radio"/> Closed

CAUTION: If there are Assigned and Untrained users when the Training Activity is put to a Status of “Closed”, those activities will show as Not Trained on some Training Compliance Reports. The Training Activity will clearly be identified as “Closed” but can result in questions upon review of such reports. If you know the Curriculum Document will soon be revised, and that you plan to close one of the related Training Activities, check for Untrained Users on all related Training Activities and ask them to complete the assignments.

What should I do if I’ve decided that a Training Activity *is* related to the document but does not need to recur every time the document is revised?

Whether you decide this up front – and therefore don’t include it in the same Curriculum as the document – or you identify this after the fact and remove it from the Curriculum, see Scenario 2.

Scenario 2: I have Training Activities Related to a Curriculum Document but don’t assign them every time the document is revised, or don’t need the same people to train on them.

What if I have Classroom Training or On-the-Job Training for new personnel that is intended as a one-time-only assignment?

In this case, the assignees may be the same, but the frequency of assignment is different.

If you may need future users to complete one-time-only Training Activities, they should be in a separate Curriculum from the related document. They can be linked to the same Profiles (Function Roles) but be set up with No Recurrence and assigned as needed, as new people come into the organization.

If you occasionally need to make modifications to this Training Activity, you can choose to manually Modify it for subsequent assignments.

What everyone needs to read the SOP for awareness, but some also need related Classroom Training or On-the-Job Training due to the nature of their job?

In this case the assignees are different between the related Training Activities.

If some users need complete more Training Activities than others, those Training Activities should also be in a separate Curriculum from the related document. They can then be linked to only those Profiles (Function Roles) that need them. You may need to consider creating additional Function Roles in this situation.

Example: Everyone in GMP Job Roles needs to know what to do if they identify a deviation from an approved process but only certain people are responsible for then managing those deviation investigations.

- The Training Activity for the SOP can be set up in a Curriculum with Recurrence Based on Document Revision and linked to Function Roles for everyone's Job Title.
- The Training Activity for Managing Deviation Investigations can be set up in a Curriculum with No Recurrence and linked to a Function Role such as FCT_Managing Deviation Investigations. That Function Role will only be assigned to users who are actually involved in managing and approving the related investigation.

If you occasionally need to make modifications to this Training Activity, you can choose to manually Modify it for subsequent assignments.

If I have Training Activities associated with the same SOP but they are in separate Curriculums, how can I be sure my Training Administrators are aware of this?

Use similar naming conventions and use the Description section of both the Curriculum and the Training Activities help identify the relationships.

For Example:

- Curriculum 1 is named SOP-QA-027, Deviation Reporting & Management and includes only the SOP
- Curriculum 2 is named SOP-QA-027, Managing Deviation Investigations and includes classroom and/or OJT training for deviation investigators and approvers

Create a Curriculum

Curricula can be created only by Users who have been assigned the **SOLABS Training Administrator** Role. A curriculum is used simply to define defaults for the one or more Training Activities that will then be created within it and assigned to users.

From the **TRAINING** Section, access the Quick Access **Training Menu** at the top right of the screen and choose the **Create Curriculum** option. The **Training > Create** screen will be displayed. It includes the following sections, each of which will be described starting on the next page.

- Curriculum Details
- Recurrence (requires selection of a Curriculum Document, and defaults for Creation and Reassignment of the Training Activities)
- Completion Requirements
- Suggested Trainers

Curriculum Details:

The first section on the Training > Create screen is **Curriculum Details**.

Training > Create

Status: Open

Curriculum Details

Auto-populate fields from: Open

* Name:

Categories (Activities):

Classroom Training

Read and Confirm

Configurable Custom List
System_List_Training_Activity_Categories

Expand

Description:

* Start Date: 17-Oct-2017

End Date:

Created by: gdixson (Gretchen Dixson)

Creation Date: 17-Oct-2017

Auto-populate fields from: Open

MFG-002 In-Process Controls for Check Weighers

QAC-001 Internal Audit Program

Introductory Training for Microbiology Lab Personnel

Categories (Activities):

Classroom Training

Read and Confirm

On-the-Job Training

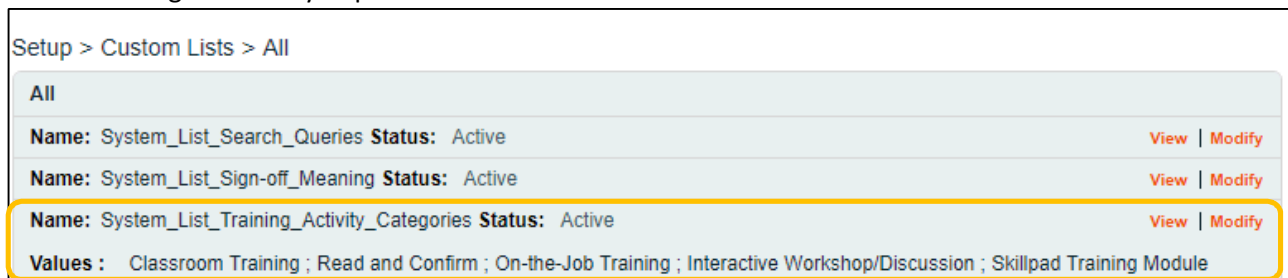
Interactive Workshop/Discussion

Skillpad Training Module

An **Auto-populate fields from** option is available if the new Curriculum will be similar to one that already exists. This can be helpful in that some of the fields will already be populated, but requires caution to ensure that any fields that need to be different are edited.

The **Name** field is mandatory. Choose a meaningful and intuitive name, such as one that describes either the purpose of the Curriculum – New Employee Training – or the Curriculum Document it is associated with – QA-001, Batch Review and Release – Pharmaceutical Products. You may want to think ahead of time about a strategy for Curriculum naming conventions. A Curriculum for SOP QA-001 could be named CUR QA-001 for example.

The **Categories (Activities)** field is a multi-select field populated with values from a Custom List that can be configured to include training category terminology for your organization. Choose the categories appropriate for the Training Activities you plan to create in this Curriculum.



The **Description** field is an optional free-text field but can be helpful as a place to include information on the purpose of the Curriculum. This is helpful if you have multiple Training Administrators.

The **Start Date** field is mandatory date field that can be populated with a calendar. It will default to the creation date but can be edited. The **End Date** field is optional and, in most cases, should be left blank to prevent situations where trainees cannot access their training assignment. It acts as an expiry date so is useful when a Training Curriculum may have a definite End Date – such as 2021 Safety Training – and will be replaced by something else after that date. It can also be useful when initially assigning a new Training Activity to many users because it will act as a Due Date, in lieu of using the **Schedule Users Activity** option after assigning End Users. In this case though, you must remember to remove the **End Date** after the initial user population is trained or it won't be available for future assignees.

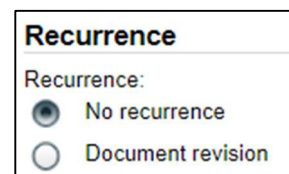
The **Created by** field and the **Creation Date** field default to the person creating the Curriculum and the date they initially create it. They are not editable fields.

Recurrence:

The next section on the Training > Create screen is **Recurrence**.

When a Curriculum is created, it must be established whether you will link a Curriculum Document and whether or not you would like recurrence (recreation) of Training Activities in that Curriculum when that document is revised.

- If you are creating a curriculum for training activities **that do not relate to a document**, you would choose a **Recurrence Type** of **No recurrence**.



- If you are creating a curriculum for training activities **relating to a SOLABS QM10 document** (such as an SOP), and would like any of the training activities to recur (be recreated and reassigned) upon revision of that document, you would choose a **Recurrence Type** of **Document revision**. This will allow you to select that document as the **Curriculum Document**, and to set one or more Training Activities within the Curriculum to recur upon revision of that document.

When a **Recurrence Type** of **Document revision** is selected, additional options are displayed for the future **New Activities** and for the linked **Curriculum Document**.

New Activities:

This section establishes **defaults** for the creation and assignment of the Training Activities that will be re-created upon Document Revision.

They can be edited for each Training Activity if needed.

Recurrence

Recurrence:

No recurrence

Document revision

New Activities

New Activities Created Based On:

Activities linked to a profile

All

Default Assignment After Creation:

No assignment

Assign based on profile

Assign based on previous assignments

Assign based on previously trained

Default Status After Creation:

Not Started

Active

Curriculum Document

Filter by:

Document Name and/or Control Number

Location

<empty>

New Activities Created Based on:

- With a choice of **Activities linked to profile**, only the Training Activities linked to Job Profiles (Function Roles) will be re-created upon revision of the document.
- With a choice of **All**, all the Training Activities in the Curriculum will be re-created upon revision of the document.

New Activities

New Activities Created Based On:

Activities linked to a profile

All

Default Assignment After Creation:

- With a choice of **No Assignment**, the Training Activities that are re-created will not be automatically re-assigned. This choice may be helpful if you would prefer to make that decision one-by-one for each of the Training Activities within the Curriculum. See NOTE on next page however.

Default Assignment After Creation:

No assignment

Assign based on profile

Assign based on previous assignments

Assign based on previously trained

NOTE: If the Training Activity is linked to a Function Role, it will still be a requirement for that Function Role, just not assigned. This can result in Training Compliance Reports based on Job Profile to show less than 100% completion rates, even if the Training Activities are intentionally not assigned.

- With a choice of **Assign based on profile**, the Training Activities that are re-created will be assigned based on the Job Profiles (Function Roles) that they are linked to.
- With a choice of **Assign based on previous assignment**, the Training Activities that are re-created will be assigned to those Users with a current or past assignment of the previous version.
- With a choice of **Assign based on previously trained**, the Training Activities that are re-created will be assigned to all Users who completed the previous version, whether it is still an active assignment or not.

Default Status After Creation:

With a choice of **Active**, the Training Activities that are re-created will be automatically Active upon their re-creation so reassignments will happen immediately. A choice of **Not Started** should be used if there may be a need to make any changes such as additional assignments, Due Dates for assigned users, adding a Related Item, adding a Training Assessment, etc. The Training Activity can then be manually changed from Not Started to Active.

Default Status After Creation:

Not Started

Active

Curriculum Document

This section is used to make the link with the SOLABS QM10 Document which, when revised, will trigger the Recurrence activities to be initiated.

Curriculum Document

Filter by:

Document Name and/or Control Number

Location

<empty>

Filters are available to search for the Document by Name, Control Number or Location. Documents meeting the filter criteria will be listed. Select the one that you want to link.

Filter by:

Document Name and/or Control Number

Location

Number of levels to display:

Available Folders:

Filter

Available:

Name	Control Number	Status
Internal Audit Program	QAC-001	Approved & Effective
Managing Product Complaints	QAC-002	Approved & Effective

November 2021

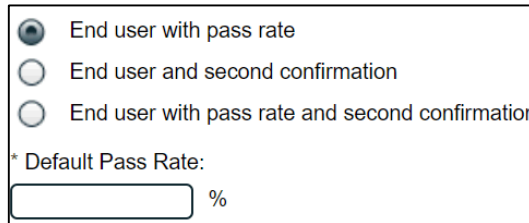
QAC-002 / 3.0 (3.0) / Managing Product Complaints

Completion Requirements:

The next section on the Training > Create screen is **Completion Requirements**.

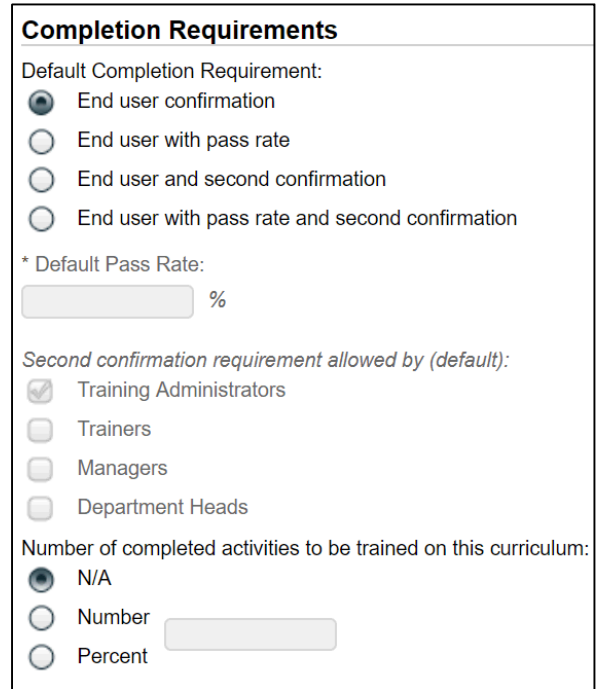
This section establishes **Default Completion Requirements** for the Training Activities within the Curriculum. They can be overridden for each Training Activity if needed.

- With a choice of **End user confirmation**, the trainee will confirm their completion with entry of their e-Signature to achieve a status of Trained.
- With a choice of **End user with pass rate**, the field for **Default Pass Rate** will be enabled and a value must be entered.



End user with pass rate
 End user and second confirmation
 End user with pass rate and second confirmation
 * Default Pass Rate:
 %

The trainee will confirm their completion with entry of their e-Signature but the assignment will not go to a status of Trained until the Training Administrator Grades the confirmed activity with a score that meets or exceeds the Pass Rate. If the score does not meet the requirement, the Training Activity will automatically be reassigned to the trainee.



Completion Requirements

Default Completion Requirement:

- End user confirmation
- End user with pass rate
- End user and second confirmation
- End user with pass rate and second confirmation

* Default Pass Rate:
 %

Second confirmation requirement allowed by (default):

- Training Administrators
- Trainers
- Managers
- Department Heads

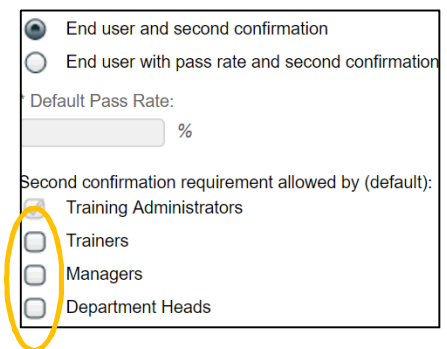
Number of completed activities to be trained on this curriculum:

- N/A
- Number
- Percent

If you are using the **Questionmark OnDemand** feature for online Training Assessments, the **Default Pass Rate** field will be grayed out because it will be auto-populated with the Pass Rate set in that software. Refer to the following two document in the SOLABS Knowledge Base for more details on that feature: **SOLABS QM10 - Questionmark OnDemand Interface Feature - User Guide**

- With a choice of **End user and second confirmation**, the fields for **Second confirmation requirement allowed by (default):** will be enabled and one or more selections can be made. The Training Administrator is always selected by default but other options can be selected as well.

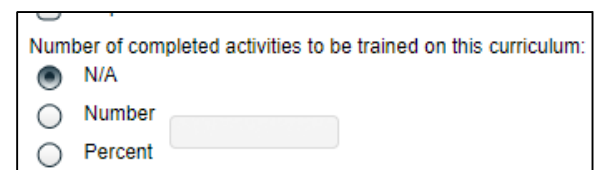
The trainee will confirm their completion with entry of their e-Signature but the assignment will not go to a status of Trained until the Training Administrator, Trainer, Manager or Department Head provides a Second Confirmation of the confirmed activity.



End user and second confirmation
 End user with pass rate and second confirmation
 Default Pass Rate:
 %
 Second confirmation requirement allowed by (default):

- Training Administrators
- Trainers
- Managers
- Department Heads

- With a choice of **End user with pass rate and second confirmation** both of the previous two situations will be required.
- The section for **Number of completed activities to be trained on this curriculum** is optional for situations where, for a Curriculum that includes multiple Training Activities, not all of them need to be completed. It can be left at the default of N/A if the intent is for all assigned Training Activities to be completed.

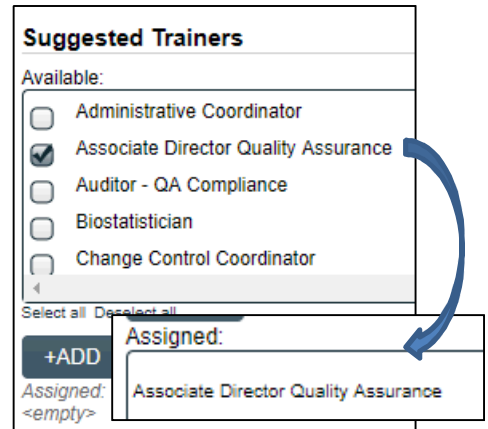


Number of completed activities to be trained on this curriculum:

- N/A
- Number
- Percent

Suggested Trainers:

The next section on the Training > Create screen is **Suggested Trainers**. This section is optional unless a Completion Requirement of Second Confirmation by a Trainer was selected above, or if you wanted Trainers to confirm completion as a “Trainer” vs. a “Trainee”. In that case at least one Trainer must be selected. To select a Trainer, check the box in front of the appropriate Function Role(s) and then click the **+ADD** button.

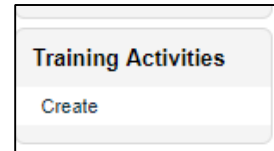


Submit and Confirm

To save the new Curriculum, click the **Submit** button, review and confirm the selections made and then click the **Confirm** button.

Create Training Activity

After a **Curriculum** is created, a **Training Activity** can be created. The Curriculum must be created first and can contain one or more Training Activities.



From the **Curriculum View** screen choose the **Training Activity > Create** option from the right-hand menu.

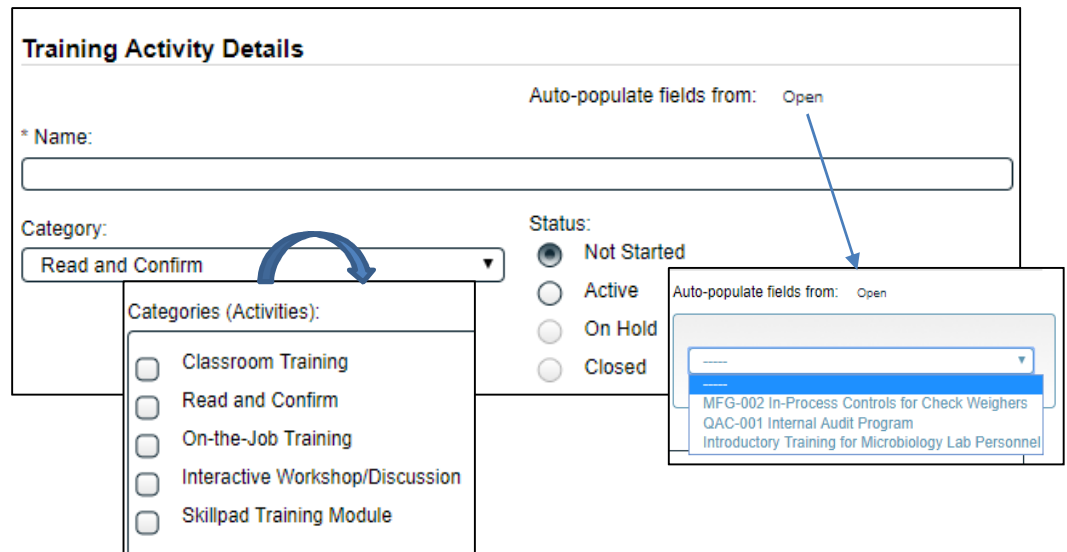
The **Training > Create** screen will be displayed. It displays the Curriculum Details and includes the following sections for creation of a Training Activity, each of which will be described starting below.

- **Training Activity Details** (will default to Curriculum setting but can be changed at the Training Activity level)
- **Recurrence** (will default to Curriculum settings but can be changed at the Training Activity level)
- **Training Activity Assessment** (used to link a Questionmark OnDemand Training Assessment)
- **Completion Requirements** (will default to Curriculum settings but can be changed at the Training Activity level)
- **Trainers** (will default to Curriculum settings but can be changed at the Training Activity level)

Training Activity Details:

The first section on the Training > Create screen is **Training Activity Details**. As with the Curriculum settings, there is an **Auto-populate fields from option**, a mandatory **Name** field and a single-item selection field for **Category**. See page 6 for more detail on these settings.

The **Status** will default to **Not Started**. It is recommended to leave the status as Not Started until all creation settings are completed, users are assigned and any due dates are set. The Modify option can then be used to change the status to **Active**.



Starting with Release 10.9 there is an optional field to use for linking **Training Video(s)** to a Training Activity. Use the full embed code for your video.

Training Video(s):

```
<iframe width="560" height="315" src="https://www.youtube.com/embed/Z1IMWKgAYIU" title="YouTube video player" frameborder="0" allow="accelerometer; autoplay; clipboard-write; encrypted-media; gyroscope; picture-in-picture" allowfullscreen></iframe>
<iframe width="1262" height="719" src="https://www.youtube.com/embed/zBz5HzrBnLU" title="YouTube video player" frameborder="0" allow="accelerometer; autoplay; clipboard-write; encrypted-media; gyroscope; picture-in-picture" allowfullscreen></iframe>
```

Enter your embedded Training Video links. Supported Type: Youtube, Vimeo, Microsoft Stream.

The optional fields for **Description, Purpose, Method of Instruction** and **Method of Evaluation** can be used to provide more information about the Training Activity. Each of these free-text fields can also be populated by **Quick Text** values.

Description:

System_List_Training_Activity_Description

[Quick Text]

Purpose :

System_List_Training_Activity_Purpose

[Quick Text]

Method of Instruction:

System_List_Training_Activity_MethodOfInstruction

[Quick Text]

Method of Evaluation:

System_List_Training_Activity_MethodOfEvaluation

[Quick Text]

Quick Text values come from configurable Custom Lists created and maintained by the SOLABS System Administrator. They can be helpful to provide standardized terminology.

The **Estimated Duration** and **Cost** fields are optional numeric fields.

Estimated Duration: hour(s)

Cost:

* Estimated Start Date:

Estimated End Date: Clear

Created by:

Creation Date:

The **Estimated Start Date** field is mandatory and will default to the creation date but can be changed.

The **Estimated End Date** is optional and is best left blank unless the Training Activity will have a planned retire date (after which it will no longer be used). It can also be useful when initially assigning a new Training Activity to many users because it will act as a Due Date, in lieu of using the **Schedule Users Activity** option after assigning End Users. In this case though, remember to remove the **End Date** after the initial training or it won't be available for future assignees.

The **Created by** and the **Creation Date** fields are not editable. They will default to the person creating the Training Activity and the date that it is being created.

The sections for **Recurrence** and **Completion Requirements** will default to what was set at the Curriculum level. See pages 6-9 for more detail on these settings.

- If the Curriculum is set with a Recurrence based on Document Revision, and the Training Activity created for the Curriculum document is the only Training Activity that the Curriculum will include, the settings should remain at the defaults from the Curriculum.
- If there are additional Training Activities within the Curriculum, some of which have Categories other than Read and Confirm, and/or do not need to recur (be recreated/reassigned) when the Curriculum Document is revised, the settings for those activities can be edited accordingly.

The section for **Training Activity Assessment** is used to link Training Assessments that were created in **Questionmark OnDemand**. See the separate document **SOLABS QM10 Questionmark OnDemand Interface Feature – User Guide** for more information on those settings.

Training Activity Assessment

Assessment Required?:

Yes

No

Assessment ID:

Start typing assessment name or ID in the field, matching assessment will be loaded.

There are two additional settings at the **Completion Requirements** section for a Training Activity.

- The section for **Exceptions (Automatic Records)** can be used to automatically grant a status of Trained for the Author of the Curriculum Document or both the Author and Approvers of that Document.
- The **Dismiss with Justification** section can be used to allow trainees to opt out of an assigned Training Activity, with appropriate justification. When the **Yes** option is selected, trainees will see an option to Dismiss with Justification. If they choose that option, they will be required to complete a mandatory Justification field.

Exceptions (Automatic Records):

N/A

Author only

Author and Approvers

Dismiss with Justification:

Yes

No

The final section on the Training > Create screen is **Trainers**. This section will be enabled only if the Curriculum was set to include Trainers. It is used to identify whether the Trainer or both the Trainer and Training Administrator, must also complete the Training Activity.

Trainers

Completion Requirement:

Trainer

Trainer and Training Administrator

Submit and Confirm

To save the new Training Activity, click the **Submit** button, review and confirm the selections made and then click the **Confirm** button. To create additional Training Activities for the Curriculum, choose the Training Activities > Create option again from the Curriculum View screen and repeat the above settings for those activities.

Once Training Activities are saved, the following actions can be performed:

- Links to **Related Items**, such as documents or processes, that will then be available for the trainee to view.
- Links to a **Job Title Profile** (Function Role)
- **Assign End Users**

Linking Related Items to a Training Activity

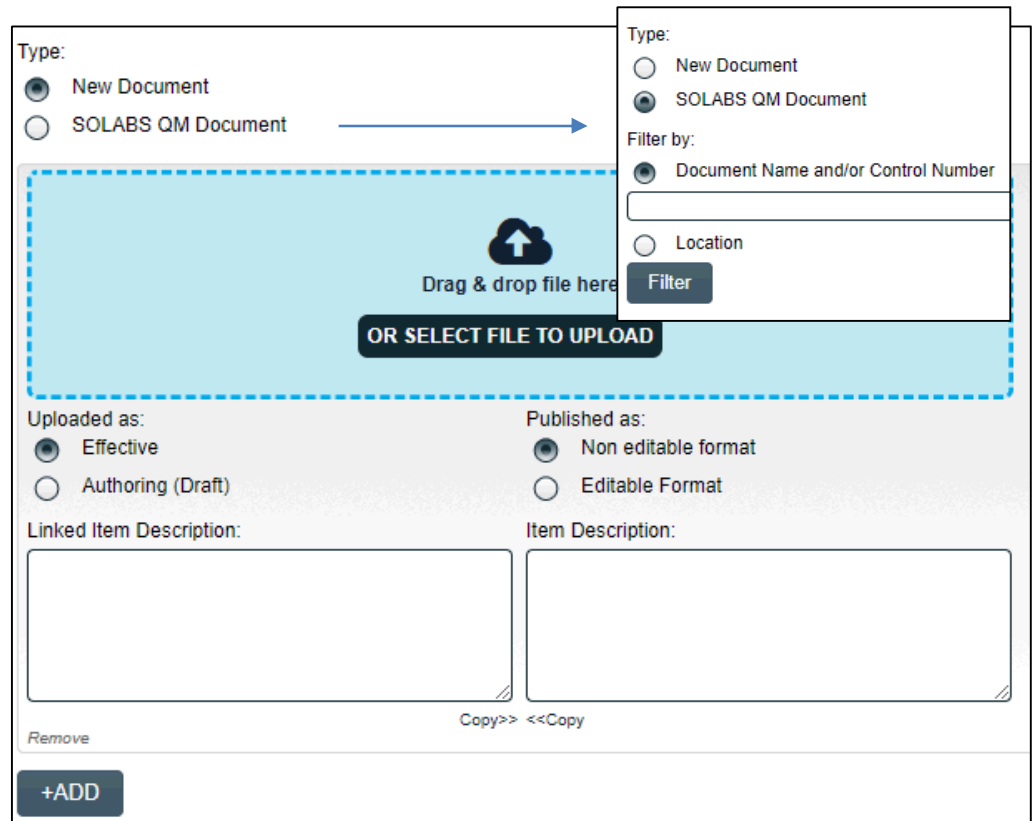
Related Items

Link Documents

Link Processes

The **Link Documents** option allows linking of an existing **SOLABS QM10 Document** or a **New Document** from outside SOLABS QM10. The maximum file size for each Related Item is 50MB. The search functions are the same as in other sections of SOLABS QM10. Multiple documents can be linked by using the **+ADD** button but the file size total cannot exceed 200MB. If the total size of all documents is >200MB, add them in sets.

A Document or a Process can be linked to any Training Activity using the **Related Items** section in the right-hand menu of the Training Activity View screen.



The screenshot shows a form titled "Related Items" with the following sections:

- Type:** Radio buttons for "New Document" (selected) and "SOLABS QM Document".
- Upload Area:** A dashed blue box containing a cloud icon with an upward arrow and the text "Drag & drop file here" and "OR SELECT FILE TO UPLOAD".
- Filter by:** Radio buttons for "Document Name and/or Control Number" (selected) and "Location". A "Filter" button is below.
- Uploaded as:** Radio buttons for "Effective" (selected) and "Authoring (Draft)".
- Published as:** Radio buttons for "Non editable format" (selected) and "Editable Format".
- Linked Item Description:** A text input field with a "Remove" link below it.
- Item Description:** A text input field with "Copy>>" and "<<Copy" links below it.
- +ADD** button at the bottom left.

All linked documents will be displayed as **Related Items** within the Training Activity when it is opened by the trainee. This can be useful for reference information, such as a compendial reference for a laboratory test method.

The **Link Processes** option allows linking of an existing SOLABS QM10 Process by searching using the **Unique ID**. Any linked processes will also be displayed as Related Items within the Training Activity when it is opened by the trainee. Linking a process could be useful when the Training Activity may be assigned as a requirement of a Deviation or CAPA.



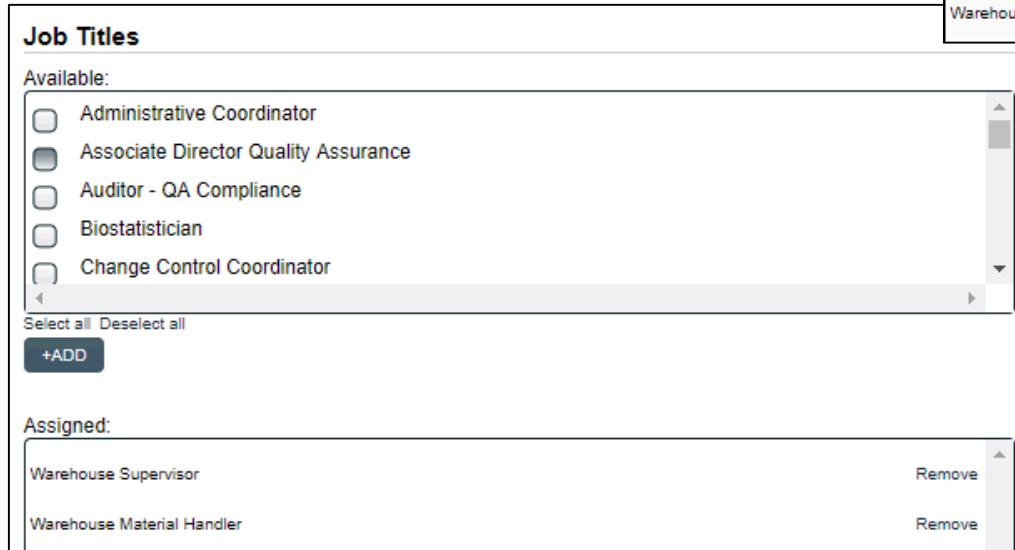
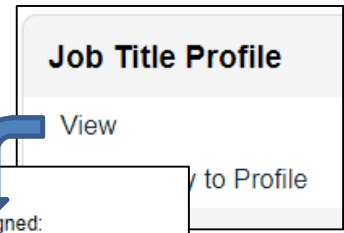
The screenshot shows a form titled "Related Items" with the following sections:

- Filter by:** Radio button for "Unique ID" (selected).
- Input Field:** A text input field for entering the Unique ID.
- Filter** button below the input field.

Adding/Linking a Training Activity to a Job Title Profile (Function Role)

A Training Activity can be linked to any Function (FCT) Role, using the **Job Title Profile** section in the right-hand menu of the Training Activity View screen.

The **View** option displays a list of Function Roles to which the Training Activity is already linked. The **Add Activity to Profile** option brings up other **Available** Function Roles that can be selected and add to the **Assigned** list using the **+ADD** button.



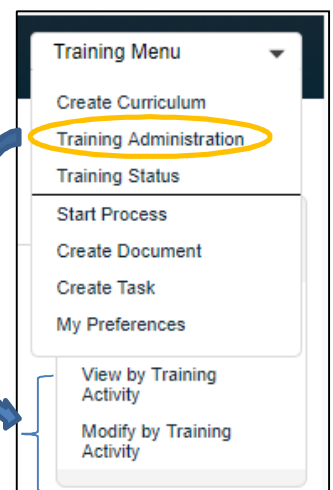
Linking a Training Activity to Function Roles establishes required training for Users who have those Function Roles assigned. It also assists in the Training Activity assignment process, through the **Assign End Users** option, because it creates a filter that will display only Users with those Function Role assignments.

The above actions can also be accessed through the Quick Access **Training Menu**, using the **Training Administration** option.

- The **View by Training Activity** option will display the list of Function Roles to which the Training Activity is already linked.
- The **Modify by Training Activity** option brings up other **Available** Function Roles that can be selected and add to the **Assigned** list using the **+ADD** button.

NOTE: Linking a Training Activity to a Function Role will **NOT** automatically assign the Training Activity to users with that Function Role. Assignments still need to be made through the **Assign End Users** menu option. At that point the chosen Function Roles act as a Filter, bringing up only the users with those Function Roles.

Training Activity assignment is covered starting on Page 16.



Accessing a Saved Training Activity

Users with the **SOLABS Training Administrator** Role can view the list of Curricula from the **Navigation** tab within the TRAINING Section. Clicking on a Curriculum Name expands the listing to display the related Training Activities. Access the **Training Activity** by using the View option to the right of the listing.

Alternatively, the **View** option to the right of the **Curriculum** listing can be used to get to the **Curriculum View** screen. Training Activities are listed at the bottom of the Curriculum View screen.

There is a **View** option next to each of the listed Training Activities there too.

From the Training Activity View screen, Training Administrators can perform the following administrative actions described starting on the next page.

- Assign Trainers to a Training Activity
- Assign Users to a Training Activity
- Schedule User Activity (Due Dates)
- Second Confirmations
- Grade End Users
- Record from External Record

All of those activities are covered later in this User Guide.

Training Activity Assignment

As mentioned above, linking a Training Activity to Function Roles makes the Training Activity Assignment process easier because the list of possible assignees will be limited only to Users who have those Function Role assignments in SOLABS QM10. Especially for a large organization, this can help ensure the accuracy of the assignment process. Similarly, the Function Role selections made for Suggested Trainers at the Curriculum level will limit the list of possible trainers to only those Users who have those Function Role assignments in SOLABS QM10. Linking Training Activities to Function Roles also establishes a list of required training. Training Compliance Reports will measure compliance against this list.

Assigning Trainers to a Training Activity

The **Training Activity Assignment** menu is part of the right-hand menus available in the Training Activity View screen. The first two options of **View Trainers** and **Assign Trainers** will only be present in this menu for Training Activities that include Suggested Trainers. The options for Training Activities set up as Read and Confirm, will have only the last three options on this menu.

- The **View Trainers** option will display the list of Users who are already assigned as trainers.
- The **Assign Trainers** option will bring up filter criteria to add additional Trainers. If the Curriculum was set up to include **Suggested Trainers**, that option can be chosen. When the list is displayed in the Available sub-filters box, clicking on Select all will display any other **Available** Users that have one of those suggested Function Roles. They can then be selected and added to the **Assigned** list using the **+ADD** button.

The screenshot shows the 'Training Activity Assignment' menu with options: View Trainers, Assign Trainers, View End Users, Assign End Users, and Schedule Users Activity. Below it is the 'Assigned Trainers' list containing: hsimmons (Helen Simmons), rcox (Roger Cox), and tgarcia (Theresa Garcia). A 'Manage Trainer Assignments' dialog is open, showing filter criteria: Suggested trainers (selected), Document Author, Active users, and All Job Titles. Available sub-filters include Manager Quality Control, Supervisor Quality Control, and Quality Control Chemist. An 'Available' list shows bgreen (Bonnie Green). A blue arrow points from the 'Assign Trainers' option to the dialog.

Assigning Users to a Training Activity

Viewing Users already assigned to a Training Activity and assigning additional Users to a Training Activity can be accomplished from either the Quick Access **Training Administration** menu or from within the **Training Activity Assignment** menu within the Training Activity View screen.

The screenshot shows the 'Training Menu' with 'Training Administration' selected, leading to 'End User Assignment Actions' (View by End user, Assign by End User). The 'Training Activity Details' panel shows: Name: SOP MFG-SC-001 Receiving, Category: Read and Confirm, Description: Reading of SOP MFG-SC-001 Receiving, Purpose: Required Knowledge, Method of Instruction: Read and Confirm. The 'Training Activity Assignment' menu is highlighted, showing 'View End Users' and 'Assign End Users' circled in yellow. Below is the 'Assigned Users' table:

User	Estimated Start Date
aingram (Abel Ingram)	2017-11-03
bgregory (Brandon Gregory) - [Author]	2017-11-03
npittman (Neil Pittman)	2017-11-03

In either case, the **View End Users** option will display the list of **Assigned Users** and their **Estimated Start Date**.

In either case, the **Assign End Users** option will bring up the options to **Manage End User Assignment**. The filter options will default to **Job Title Profile** (list of Function Roles) and the linked Job Title Profiles will be displayed in the **Available sub-filters** box. Selecting all of the Available Job Title Profiles will bring up a list of **Available** users who have that Function Role but are not yet assigned the Training Activity. Selecting those Users will add them to the **Assigned** list.

As mentioned previously, linking Training Activities to Job Profiles helps to limit the list of **Available** users to the people assigned those Function Roles. This does not prevent the option to assign the Training Activity to additional Users. To assign to additional Users, the other **Filter by** options can be chosen:

- **Assigned trainers** – will bring up the list of any assigned trainers for the Training Activity
- **Active users** – will bring up the entire Active Users list within SOLABS QM10
- **All Job Titles** – will bring up all remaining Active Function Roles within SOLABS QM10

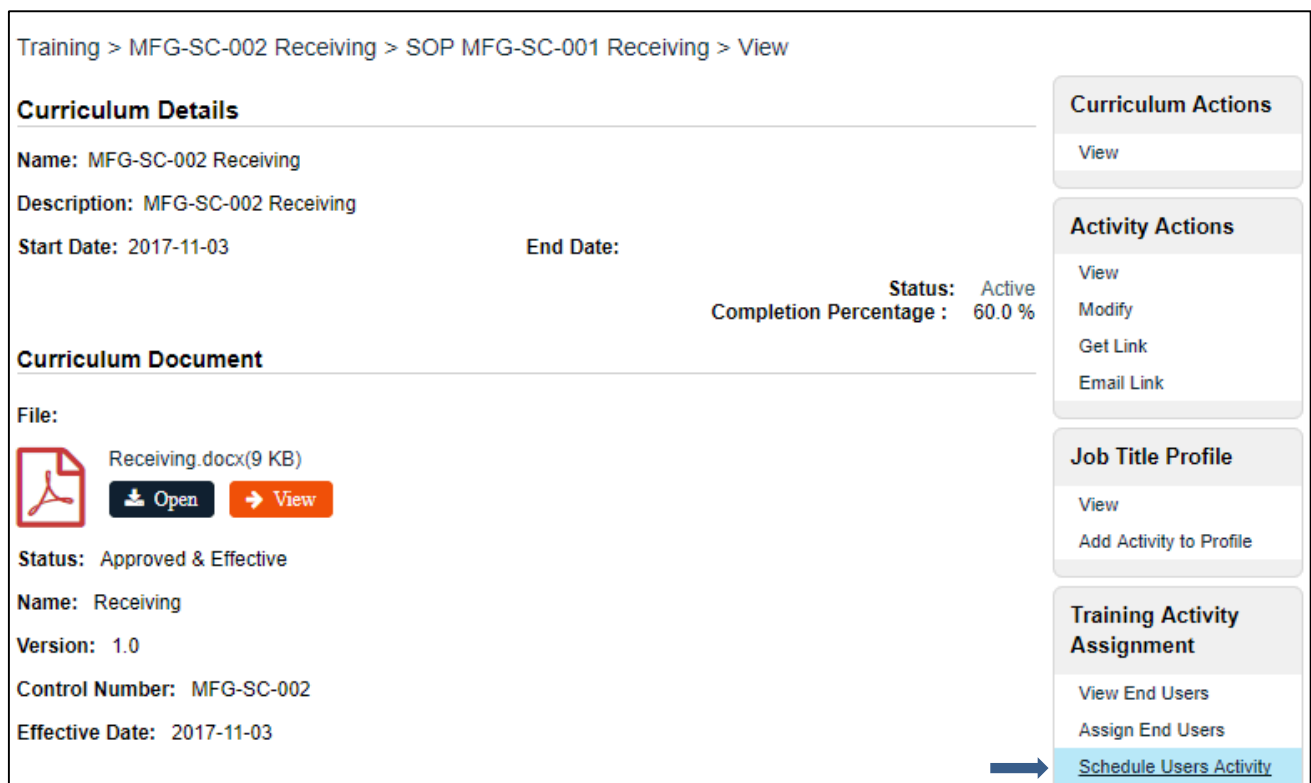
Schedule User Activity

After a Training Activity is assigned to a User, the **Schedule Users Activity** option can be used to **Schedule Due Dates** for their assignment. Scheduling an activity is mainly used to set or change the time allowed for a user to complete an activity. Changes to the Start Date can also be made.

Setting Due Dates at the Training Activity Assignment level is helpful when the Curriculum and Training Activity itself are set with no End Date. As mentioned previously, setting an End Date at the Curriculum/Training Activity level can be helpful to apply an initial due date for a new assignment but it acts as a retirement date for the Training Activity itself so must be used with caution.

If there are no due dates for assignments, there can be no calculations for status – such as Last Week/This Week, +/- 30 Days, +\ -90 Days, etc. Assignments with no due date immediately fall into a status category of Overdue, which can be confusing to the trainees and when running Training Reports. Setting due dates can also be helpful for new employees with many assignments, in order to help stagger them or put them in order by urgency.

To set assignment due dates for Users, go to **Training Activity Assignment > Schedule Users Activity** in the right-hand menu of the Training Activity View screen. This displays the **Schedule Due Dates** screen.



The screenshot shows the 'Training Activity View' screen for 'MFG-SC-002 Receiving'. The breadcrumb trail is 'Training > MFG-SC-002 Receiving > SOP MFG-SC-001 Receiving > View'. The main content area is divided into three sections: 'Curriculum Details', 'Curriculum Document', and 'Curriculum Actions'. The 'Curriculum Details' section shows 'Name: MFG-SC-002 Receiving', 'Description: MFG-SC-002 Receiving', 'Start Date: 2017-11-03', 'End Date:', 'Status: Active', and 'Completion Percentage: 60.0 %'. The 'Curriculum Document' section shows a file named 'Receiving.docx (9 KB)' with 'Open' and 'View' buttons, and a status of 'Approved & Effective'. The 'Curriculum Actions' section is on the right and contains several sub-sections: 'Curriculum Actions' (View), 'Activity Actions' (View, Modify, Get Link, Email Link), 'Job Title Profile' (View, Add Activity to Profile), and 'Training Activity Assignment' (View End Users, Assign End Users, and **Schedule Users Activity**, which is highlighted with a blue arrow).

The Available sub-filters list will default to the Job Title Profile (Function Role) filter. Changing that to **Filter by Assigned Users** is helpful because it will bring up only Users who have are assigned the Training Activity but have not yet completed it.

Schedule Due Dates

Filter by:

Job Title Profile
 Assigned Users
 All Job Titles

Available sub-filters:

Clinical Operations

Select all Deselect all

Available:

Start Date and Due Date: 1

Select all Deselect all

+ADD

Schedule Due Dates

Filter by:

Job Title Profile
 Assigned Users
 All Job Titles

Available sub-filters:

Select all Deselect all

Available:

Start Date and Due Date: 17-Jun-2020 UTC-04:00 Clear

User	Start Date	Due Date
<input type="checkbox"/> ariver (Alan River)	17-Jun-2020 UTC-04:00	30-Jun-2020 UTC-04:00
<input type="checkbox"/> dthomas (Daniel Thomas)	17-Jun-2020 UTC-04:00	30-Jun-2020 UTC-04:00
<input type="checkbox"/> jbecket (Jennifer Becket)	17-Jun-2020 UTC-04:00	30-Jun-2020 UTC-04:00
<input type="checkbox"/> jtolbert (Jim Tolbert)	17-Jun-2020 UTC-04:00	30-Jun-2020 UTC-04:00
<input type="checkbox"/> kharrison (Ken Harrison)	17-Jun-2020 UTC-04:00	30-Jun-2020 UTC-04:00
<input type="checkbox"/> chopkins (Olivia Hopkins)	17-Jun-2020 UTC-04:00	30-Jun-2020 UTC-04:00

Select all Deselect all

+ADD

Select one or more **Users**, enter a **Due Date**, change the **Start Date** (if applicable), and click **+ADD**. If you need different dates for different Users, add a set of Users for one date, then add another set. As you add User End Dates, they will be listed in the Assigned section. When you are done, click **Submit**, then **Confirm**.

Assigned:			
User	Start Date	Due Date	
ariver (Alan River)	17-Jun-2020 UTC-04:00	28-Aug-2020 UTC-04:00	Remove
dthomas (Daniel Thomas)	17-Jun-2020 UTC-04:00	28-Aug-2020 UTC-04:00	Remove
jbecket (Jennifer Becket)	17-Jun-2020 UTC-04:00	28-Aug-2020 UTC-04:00	Remove

This can also be done using the Training > Training Administration > Assign by End User option by changing the default to Set specific dates.

Use activities estimated start and end dates
 Set specific dates

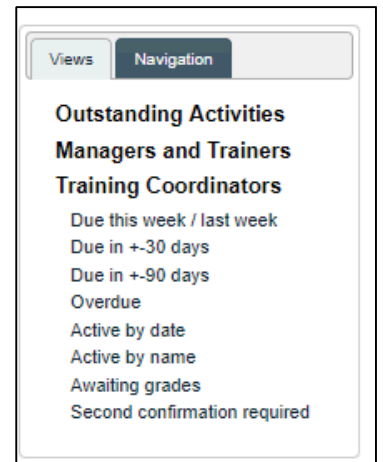
Available:

Start Date and Due Date: Clear

Training Coordination Activities

Users who are assigned the System Role of **SOLABS Training Administrator**, have additional menu options for **Training Coordinators** on the left-hand side of the Home Page from within the TRAINING Section. These menu options allow the Training Coordinator to monitor the status of Training Activities for their entire organization.

There are also options for the Training Coordinator to display a list of Training Activities that are **Awaiting Grades**, and a list of Training Activities that have **Second confirmation required**. The Excel Workflow Report can be used to get the list of Training Activities actually **awaiting** Second Confirmation.



Second Confirmation

Training Activities can be created with the option to require a **Second Confirmation**. That Second Confirmation can always be made by a Training Administrator. It can also be made by a Trainer, Manager or Department Head if those options are selected when creating the Training Activity.

To see the list of Training Activities that were created requiring a Second Confirmation, choose the **Second confirmation required** option on the above Training Coordinators menu.

Training > Training Coordinators	
Second confirmation required	
Name: OJT QC-001 HPLC System Suitabi[...] Due: Completion: 0.0 % Status: Active	View Second Confirmation
Name: Aseptic Technique Due: Completion: 42.9 % Status: Active	View Second Confirmation
Name: Media Preparation Due: Completion: 25.0 % Status: Active	View Second Confirmation

Click on **Second Confirmation** next to a listing to display the Second Confirmation screen. The **Filter by** will default to **Assigned Users**. Changing the filter to **Confirmed Users** will display the list of Users who have confirmed completion of the Training Activity but whose training status is Awaiting Second Confirmation.

In the **Available** box, select the **Confirmed Users** for whom you would like to provide a Second Confirmation and click **+ADD** to move them to the **Assigned** box.

Click **Submit** and then **Confirm** the selection. Confirmed Users will then move to a status of Trained on the activity (unless it also requires Grading – see next section).

Second Confirmation

Filter by:

- Assigned Users
- Confirmed Users
- My assigned employees
- My employees who have confirmed activity
- All Job Titles ▼

Available sub-filters:

Select all Deselect all

Available:

- hsimmons (Helen Simmons)
- jwatson (Joyce Watson)

Select all Deselect all

+ADD

Assigned:
<empty>

Grading End Users

Training Activities can be created with the option to require a **Pass Rate**. The required Pass Rate is established during creation of the Training Activity when manual entry of a grade is planned, either from an assessment that may be added as a Related Item or one completed during a classroom training session. Grading of End Users must be made by a Training Administrator (or will be automatically entered through the interface with Questionmark OnDemand, if online assessments are being used).

To see the list of Training Activities that are waiting to be graded, choose the **Awaiting grades** option on the above Training Coordinators menu.

Training > Training Coordinators	
Awaiting grades	
Name: Introduction to GMPs Due: Completion: 82.4 % Status: Active	View
Name: Labor Law Regulations Due: Completion: 89.7 % Status: Active	View
Name: Safety Orientation Due: Completion: 85.3 % Status: Active	View

Click on **View** next to a listing to display the **Training Activity View** screen. From that screen, choose the **Grade End Users** option in the right-hand Activity Confirmation menu.

- **NOTE:** If that menu also includes the **Provide Second Confirmation** option, that must be done **FIRST** before the Users will show up for Grading.

Activity Confirmation

[Provide Second Confirmation](#)

[Grade End Users](#)

The **Available** box includes the list of Users who are awaiting Grading.

Below that box is a field to enter the **Grade**. One Grade can be entered at a time for one or more Users who achieved that. After selecting one or more Users and entering the Grade, click **+ADD** to move them to the Assigned section at the bottom.

When all End User Grades have been entered, click **Submit** and then **Confirm** the selection. Confirmed Users will then move to a status of Trained on the activity.

November 2021

Grade End Users

Filter by:

Assigned Users

All Job Titles

Available sub-filters:

Select all Deselect all

End User Grades

Available:

kkirby (Kristopher Kirby)

Ispears (Louis Spears)

myoung (May Young)

Select all Deselect all

Grade: %

Assigned: <empty>

If grades are entered for Assigned Users who have not yet Confirmed, User Confirmation will be required before their training status goes to Trained. If the Grade entered does not meet the minimum established for the Training Activity, that Training Activity will automatically be reassigned to the User.

Assigned:			
User	Attempts	Grade	
kkirby (Kristopher Kirby)	1	95.00	Remove
lspears (Louis Spears)	1	95.00	Remove
myoung (May Young)	1	100.00	Remove

Remove all

Submit Cancel

Confirming Training Activities for End Users

Training Administrators have the ability to confirm training for assigned users through a right-hand menu option in the Training Activity called **Record Training From External Record** or from the Training Administration menu using the option **Record for End User**. This is helpful for situations such as classroom training, where the participants may have signed a Training Attendance Document and that proof of completion is submitted to a Training Administrator. It is also helpful for external training, where the participants may submit a Training Certificate.

From within a Training Activity, choose the right-hand menu option **Record Training From External Record**.

There are then options to **Filter by** either **Assigned Users** (default) or **All Job Titles** (for Available sub-filters listing all Function Roles).

After selecting the User(s) who you want to record training for, use the **Record Date** field to enter the training date listed on the external record or certificate.

Click **+ADD** to move the user to the **Assigned** box with that date. A **Remove** option is available.

Record Training From External Record

Filter by:
 Assigned Users
 All Job Titles

Available sub-filters:

Select all Deselect all

Available:
 jclark (Jaqueline Clark)
 iwalker (Irma Walker)
 tjordan (Tamara Jordan)

Record Training From External Record

Filter by:
 Assigned Users
 All Job Titles

Available sub-filters:

- Director Human Resources
- Director IS/IT
- Director Manufacturing
- Director Quality
- Director Regulatory Affairs
- Director Research & Development
- Director Safety, Health & Environment
- Documentation Coordinator
- Engineering
- Equipment Calibration Technician
- Executive Director, Product Operations

Select all Deselect all

Available:
 jclark (Jaqueline Clark)

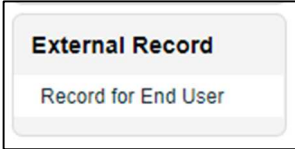
Activity Confirmation

Record Training From External Record

Assigned:

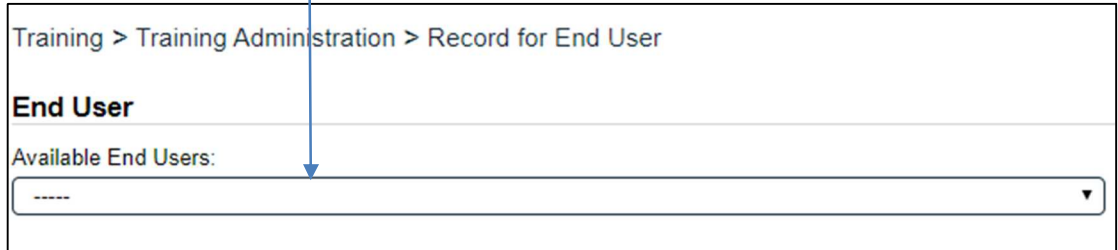
End User	Record Date	
jclark (Jaqueline Clark)	16-Sep-2019	Remove

From within the Quick Access Training Administration menu, choose the menu option **External Record > Record for End User**.

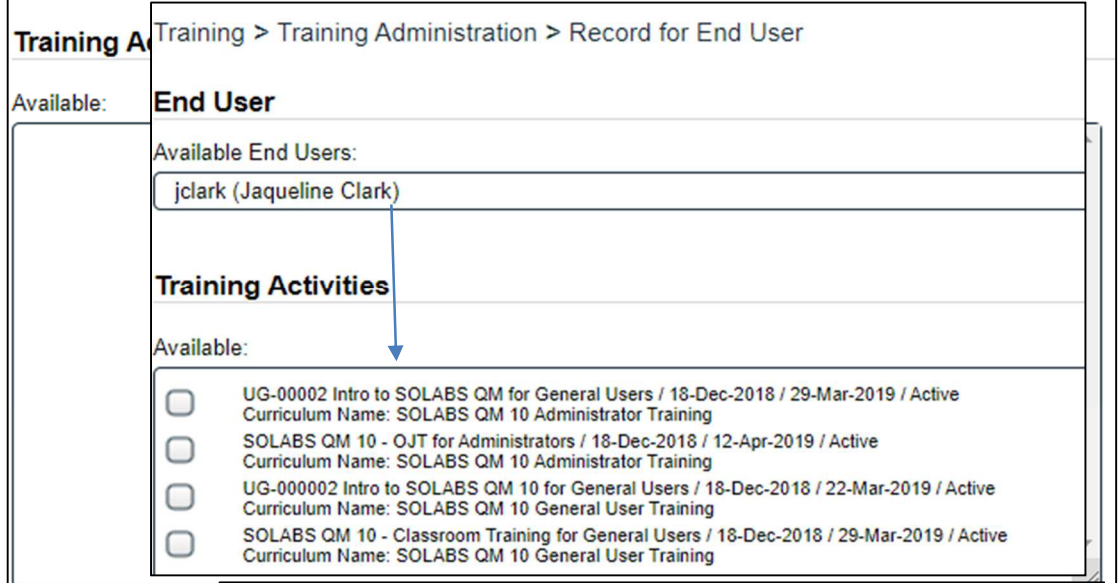


There be a drop-down list of **Available End Users**.

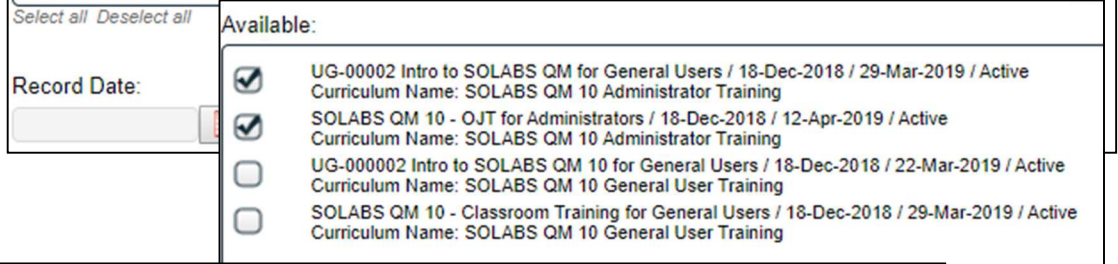
After selecting the User who you want to record training for, a list of their assigned Training Activities will be displayed in the **Available** box.



Select one or more Training Activities. This will enable the **Record Date** field.



Use the **Record Date** field to enter the training date listed on the external record(s) or certificate(s).



Click **+ADD** to move the user to the **Assigned** box with that date. A **Remove** option is available.

Training Activity	Record Date	
UG-00002 Intro to SOLABS QM for General Users / 18-Dec-2018 / 29-Mar-2019 / Active Curriculum Name: SOLABS QM 10 Administrator Training	23-Sep-2019	Remove
SOLABS QM 10 - OJT for Administrators / 18-Dec-2018 / 12-Apr-2019 / Active Curriculum Name: SOLABS QM 10 Administrator Training	23-Sep-2019	Remove

NOTE: If the Training Activity requires a **Second Confirmation** or **Grade**, that must still be entered before the trainee will be in a Trained status.

