

Page 1 of 4

## **Considerations for Configuration of the Training Section**

#### **Table of Contents**

Purpose of this Guide	1
Considerations for Configuration	1
Scenario 1 – All Training Activities in my Curriculum need to be assigned with every revision of the Curriculum Document	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.	3

### **Purpose of this Guide**

This guide provides considerations for determining the best way to organize Curriculums when more than one Training Activity is related to a Curriculum Document set for a Recurrence based on Document Revision.

When a Curriculum is set for a Recurrence based on revision of the Curriculum Document, all Training Activities within the 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, use of the "No Assignment" option needs to be considered with caution.

If you have multiple Training Activities that are related to a document such as an SOP, but either the frequency of assignment or the assignees are different, you may need them to be in separate QM10 Curriculums.

### **Considerations for Configuration**

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 <u>only one</u> Curriculum and a Curriculum can include <u>only one</u> 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.



Page 2 of 4

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					
Recu	rrence: Document revision				
Assig	nment After Creation:	Status After Creation:			
$\bigcirc$	No assignment	۲	Not Started		
۲	Assign based on profile	$\bigcirc$	Active		
$\bigcirc$	Assign based on previous assignments				
$\bigcirc$	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:	Status:
Classroom Training	Not Started
	<ul> <li>Active</li> </ul>
	On Hold
	Closed



Page **3** of **4** 

**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 onetime-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.



Page **4** of **4** 

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

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

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