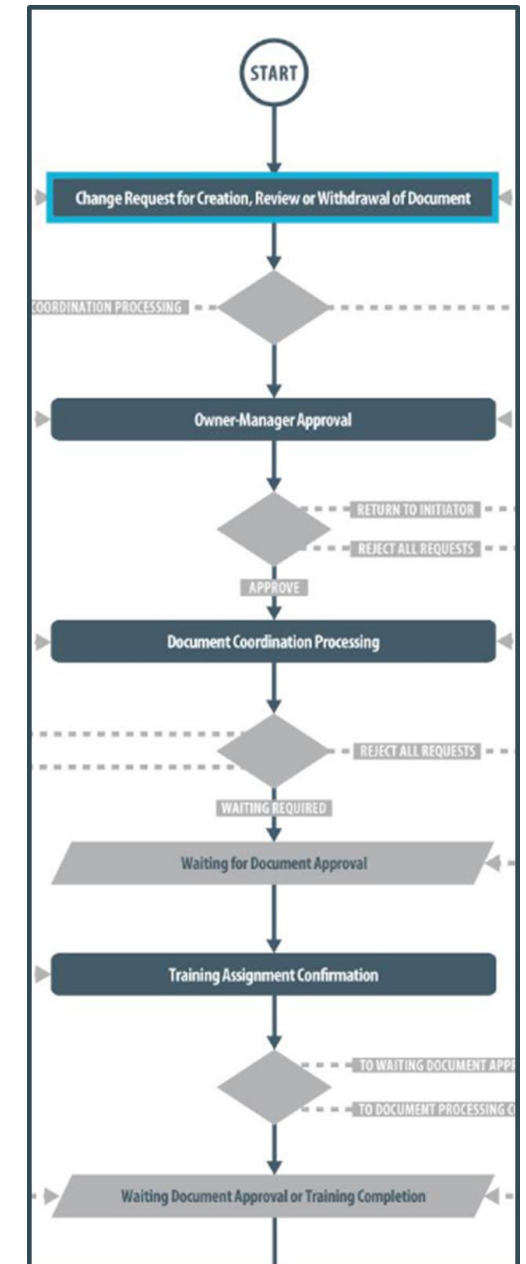




**Overview of the SOLABS QM10 Document Control Process
and Strategies for Use at your Company**

Highlights of the SOLABS QM 10 Document Control Process

- Allows any User to request new documents, revisions to existing documents or retirement of existing documents while centralizing the actual document processing tasks to Document Administrators.
- Provides a process for obtaining approval from Document Owners.
- Provides a process to coordinate creation of Training Activities with creation/revision of related documents.
- Provides a process for coordinating update of multiple documents within one Document Change Request.
- Includes Process Roles that can be assigned to allow the appropriate people to act on their part of the Process.
 - The Process Role PR_DOC_Business_Owner is assigned to anyone authorized to approve Document Change Requests at Step 2 in the Process.
 - The Process Role PR_DOC_COORD is assigned to Document Administrators who will manage the actual document processing tasks.
 - The Process Role PR_TRAIN_COORD is assigned to Training Administrators to alert them of approved documents that may require new/revised Training Activities.



Ideas for Use of the SOLABS QM 10 Document Control Process

The Document Control Process comes with the Core Software and is available for clients who might like a Document Change Control Process that is more streamlined than a full Change Control Process. It's use is optional if Document Authors are granted Modify privileges to their documents and are trained to process their documents directly in the DOCUMENT Section.



It can be useful though in the following ways:

- Use to centralize Document Management activities instead of granting Modify privileges to many Users
 - Any User can request a creation/revision/retirement of a document and obtain authorization from the Document Owner but the actual processing will be managed by the Document Coordinator.
 - The Document Coordinator can send the document, or a template, back to the requestor or make the changes and send them to requestor and Document Owner as part of an initial Review Cycle.
 - System Administrators also have the option to manage Process Privileges to limit even initiation of a Document Control Process to only certain Users through FCT or SEC Roles
- Use to help manage the Periodic Review Process for documents.
 - When documents are coming due for Periodic Review, the Document Coordinator can initiate a Document Control Process, attach the current version of the document and choose the related Owner-Manager.

Ideas for Use of the SOLABS QM 10 Document Control Process

It can be useful though in the following ways (continued):

- Link a Document Control Process to another Quality Process as a Dependent or a Related Process
 - Most steps in any of the other SOLABS Process APPs include an option to initiate a Document Control Process as a “Child Process”. It can be established as Dependent or as Related. If Dependent, it will ensure the documents are updated before the “Parent Process” can be closed.
 - The Document Control Process includes an option to initiate another Quality Process (Change Control, Deviation, CAPA, etc.) if necessary – also as either a Dependent process or as a Related process.
- Very useful for situations where multiple documents may need to be Effective together on a future date, such as for Compendial changes, new equipment installations, etc.
- Add additional coordination with the Training Administrator
 - Consider adding the Document Coordinator as the last level Approver on the document. That will allow them to control exactly when the Doc Control Process moves to Step 4.
- Update the Custom List for Percentage Training Completion at Step 4 to add “0” percent
 - This is useful for Training Administrators when training is required, and may have been automatically created/assigned based on Recurrence settings, but where there is no dependency on the level of training completion prior to the document Effective Date.



Things to Consider before Using the Document Control Process

There are some Document Type settings that are necessary when using certain steps in the Document Control Process so need to be considered ahead of time.

What types of documents do you have at your company?

- *SOPs, Specifications, Policies, Forms, Master Batch Records, etc.*

Which of those document types require Owner-Manager approval prior to a change?

- *Who are those people?*

Do any of those documents have official templates that must be used?

Which of those document types typically require training?

Which of those document types have a Periodic Review Cycle?

Do you want to centralize document processing activities? To how many people?

Do you want to allow access for some Users to process their own documents?

Do you want to limit initiation of a Document Change Request to only some Users?

Based on your answers to some of these questions your Solabs Product Specialist can work with you to suggest an approach that will work best for your company.

