SOLABS QM10: Guide for Document Treeview Folder Structure

Table of Contents

Purpose of this Guide

This document provides considerations for determining the best Treeview Folder Structure to support management of your documents using SOLABS QM10.   Various options are presented so that you can identify what will work best for your organization.

Document Folders – Document Treeview

The Document Treeview in SOLABS QM10 is the Document Folder Structure that will be used to store documents. The folder structure needs to be defined and created before any document migration into the system. It should also be created before any Document Types are created, so that a Default Location (folder) attribute can be defined for each Document Type.

When considering options for setting up a folder structure, keep in mind that the SOLABS QM10 Document Section is used to manage the lifecycle – Authoring, Review, Approval, Retirement – of controlled documents and for assigning related Privileges/Permissions for access to those documents. Since it is an integrated system, these documents can easily be linked to Training Activities, to other Documents and to Process Workflows. Therefore, document ownership, document use and document access will be the key considerations in identifying the best structure.

The Document Treeview folder structure will be used mostly by your Document Administrators and your Document Authors since they are responsible for document management and for identifying those people in the organization who need access to the documents.

End users will typically not use the Document Treeview.   They will use available Search capabilities to find documents and they will get email notifications regarding the need to view documents for training purposes or to perform review/approval tasks on in-process documents. Email notifications provide a link directly to the user's Home Page where they will find documents they then need to act on in any way.

November 2021

Document Privileges (Permissions)

Document Privileges (Permissions) are set up using the Treeview.   Therefore, this is a consideration when thinking about how to set up folders. Document privileges for a new folder are initially inherited from the Root folder and can then be can be customized by removing that inheritance relationship and adding additional Functional or Security Roles for the Users or groups of Users that will need access to documents in the folder. Document privileges for subfolders are initially inherited from the parent folder

There are four levels of document privileges:

- **Read Only** – This level provides access only to view Approved & Effective documents or to view Approved, Not Effective documents if assigned for training purposes. This is the default level for the SOLABS General User role that is assigned to all Users. It is also the only level provided to users with a Train ID Account Type.

- **Review/Approve** – This level provides access to view in-process documents and also to act on an assigned review or approval task related to those documents. Assigned Reviewers or Approvers of documents need to have at least **Review/Approve** privileges to the folder in which those documents reside.

- **Modify** – This level provides access to create documents, to modify documents and to assign Review/Approval cycles for those documents. Document authors need to have at least **Modify** privileges to the folder in which those documents reside.

- **Administer** – This level provides full access to all of the above activities, as well as access to set and modifying the privileges on folders and documents.

Before considering the best folder structure for the documents you plan to maintain in SOLABS QM10, ask the following questions about the controlled documents used at your organization:
- Which individuals or departments "own" the documents and therefore need to create and modify the documents?
- What individuals or departments are typically asked to review or approve the documents?

As mentioned previously, individuals and departments who are just users of Approved & Effective documents have Read Only privilege by default, can search for documents by their metadata attributes or are assigned the documents to act on. They do not need to use the Treeview folder structure and therefore should not be a consideration in designing it.

There are various ways to search for documents within SOLABS QM10 – left-hand Dashboards, Search fields, Saved Search Queries – so you don't necessarily need the Treeview structure to be as intuitive to General Users as a paper file cabinet might be.

Considerations in Determining the Treeview Folder Structure

Folders are created to organize how documents will be stored in the Treeview and to manage permission levels related to the documents. Although permissions can be granted on individual documents, it is much easier to manage that process by groups of documents – folders.

Documents that are typically used together (such as Specifications & Test Methods or SOPs & Forms) or that may later become part of a larger document group (such as a Regulatory Submission or a Clinical Trial

November 2021

Master File) do not need to be stored in the same Treeview locations nor should they be duplicated in multiple folders. Carefully setting up Document Types and related System Attributes will help with this.

System Attribute fields can be created in SOLABS QM10 and then shared across multiple Document Types. These become metadata fields that will allow a user to search for all documents by a common attribute – product name, submission location, etc. – and retrieve all related documents, no matter where they are stored in the Treeview folder structure. Where documents share common attributes or information, create those as System Attributes use them in each of the various Document Types. Setting them as mandatory fields for the authors of those documents, ensures that later searches will successfully retrieve all related documents.

Examples of Document Treeview Folder Structures

Organizing by Document Type

In most organizations, there is department ownership for various Document Types. For example:
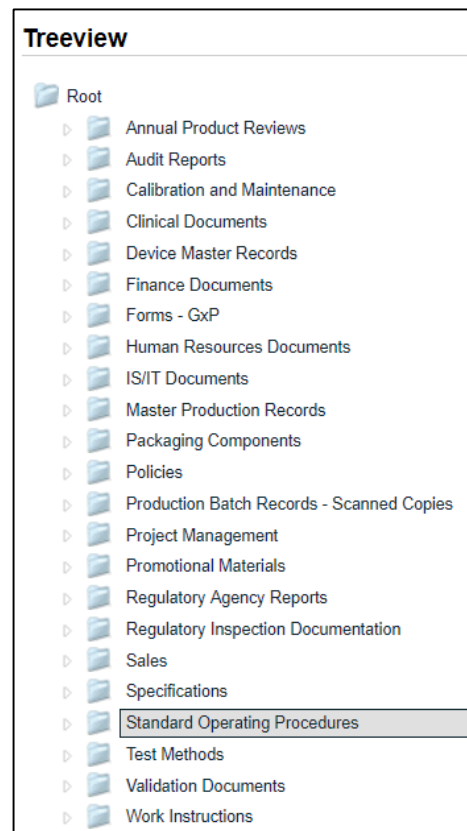- Quality Control manages Specifications and Test Methods
- Clinical Operations manages Clinical Trial Protocols
- Each department manages their own Standard Operating Procedures
- Human Resources manages Employee Hiring Policies
- Regulatory Affairs manages various regulatory submission types

In each of these cases, certain individuals in the departments are given the responsibility to create and modify those documents. Higher level personnel in that department, as well as members of other impacted departments, may be asked to review or approve new/revised documents.

Each Document Type will likely require different types of information, which can be set as required System Attributes and become searchable metadata. In SOLABS QM10, each Document Type can also be linked to default Review/Approval Workflow Templates and can even have unique PDF Rendering Templates.

To the right is an example of a Document Treeview set up mostly by Document Type, while still allowing some folders to be set up by area.

NOTE: In this example there is a folder for Production Batch Records – Scanned Copies. When considering whether to use SOLABS QM10 to simply import and store documents, realize that it is designed to manage controlled document life cycles. Therefore, you will need an Approval Cycle with at least one assigned approver in order to import and store a document. If these documents require frequent access and use, need to be linked to Training Activities or used as Related Documents in a Process (Change Control, Deviation, etc.) this may be fine, and can be imported with just one approval. If they simply need to be archived, and rarely used, there may be solutions and services other than SOLABS QM10 that can meet that need more easily for you.
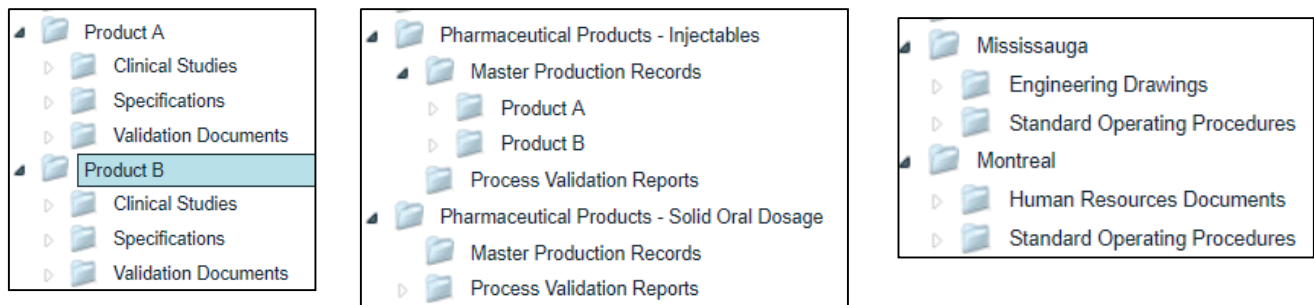
Treeview

- 📁 Root
  - ▷ 📁 Annual Product Reviews
  - ▷ 📁 Audit Reports
  - ▷ 📁 Calibration and Maintenance
  - ▷ 📁 Clinical Documents
  - ▷ 📁 Device Master Records
  - ▷ 📁 Finance Documents
  - ▷ 📁 Forms - GxP
  - ▷ 📁 Human Resources Documents
  - ▷ 📁 IS/IT Documents
  - ▷ 📁 Master Production Records
  - ▷ 📁 Packaging Components
  - ▷ 📁 Policies
  - ▷ 📁 Production Batch Records - Scanned Copies
  - ▷ 📁 Project Management
  - ▷ 📁 Promotional Materials
  - ▷ 📁 Regulatory Agency Reports
  - ▷ 📁 Regulatory Inspection Documentation
  - ▷ 📁 Sales
  - ▷ 📁 Specifications
  - ▷ 📁 Standard Operating Procedures
  - ▷ 📁 Test Methods
  - ▷ 📁 Validation Documents
  - ▷ 📁 Work Instructions

November 2021

Organizing by Product, Process or Site

For some larger organizations, responsibility for document management may be split up by Product, by Process or by Site.

- Product A vs. Product B
- Injectables vs. Solid Oral Dosage
- Mississauga vs. Montreal

In each of these cases, the related documents may be owned and managed by different areas of the organization, even with different Document Administrators. The highest-level folders may be organized that way but likely the subfolders will then start to fall into a Document Type structure at this point, since this is usually how document management responsibilities are split up and therefore how the SOLABS QM10 Document Management Setup is designed.

Summary

In summary, SOLABS QM10 provides the following Setup Activities to support Document Management for your organization, no matter how you may choose to set up your Document Treeview Folder Structure:

- Creation of **Document Types** to differentiate the requirements for any types of controlled documents you choose to manage using the software. Examples:
    - Whether or not training is typically required
    - Control Numbering schemes
    - Effective Dating requirements
    - Periodic Review requirements
    - System Attributes
    - Document Ownership

- Creation of **System Attributes** (metadata fields) and the ability to link those to Document Types to facilitate searching and retrieval of documents. Examples:
    - Date fields
    - Numeric fields
    - Free text fields
    - Single Item Selection lists
    - Multiple Item Selection lists

- Creation of **Document Workflow Templates** and **PDF Rendering Templates**, and the ability to link those to specific Document Types further facilitate processing and format of your controlled documents.

Solabs personnel assist you in the initial configuration of SOLABS QM10, including the Document Treeview Folder Structure, to ensure that it will best meet your document management needs.