

SOLABS QM10: Initiating a Document Control Process

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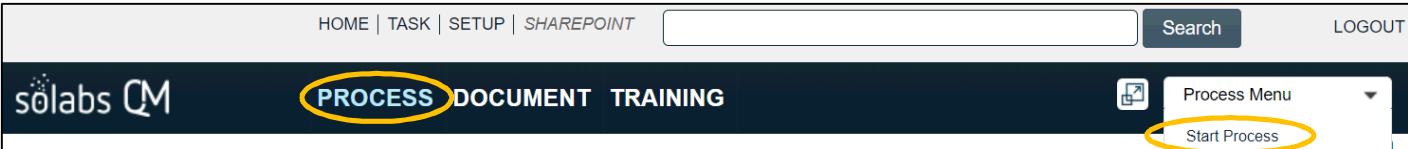
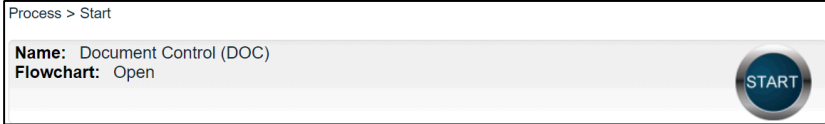
Document Control Process Step 1: Change Request for Creation, Revision or Retire of Document..... 1

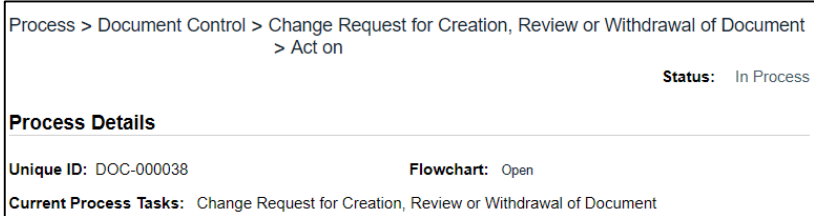
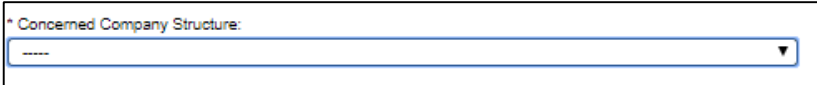
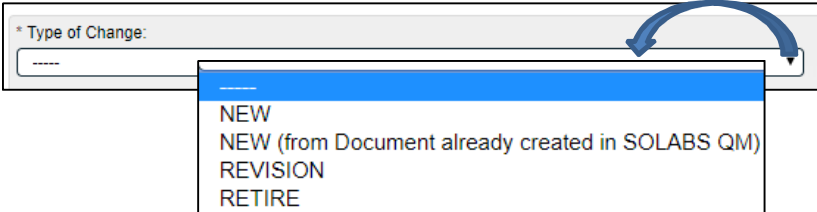
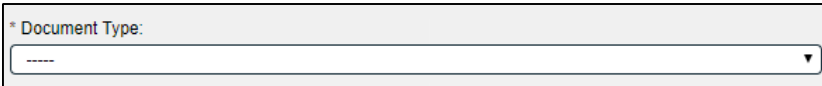
Introduction

Any User in SOLABS QM10 can initiate a Document Control Process to request a new document, revision of an existing document or retirement of a document. More than one document can be included in a Document Control Process. Initiators will **START** the Document Control Process and complete **Step 1 – Change Request for Creation, Revision or Retire of Document**.

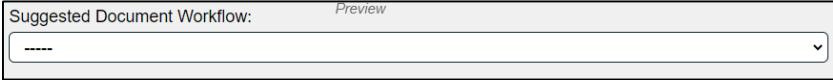
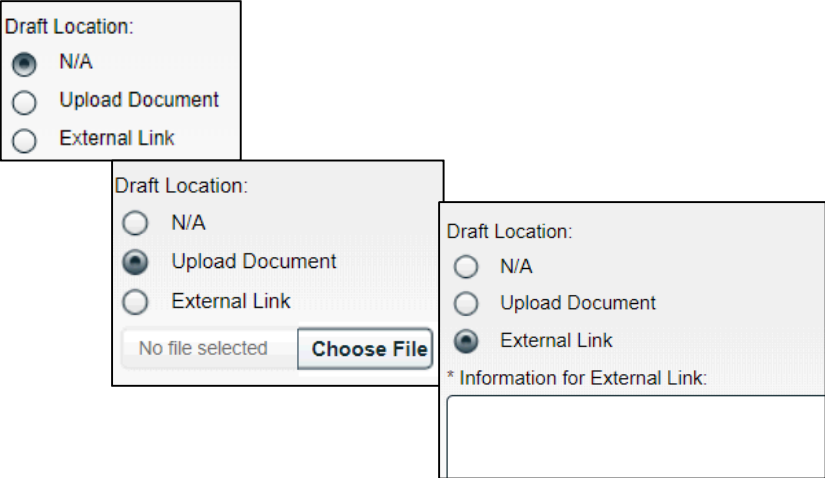
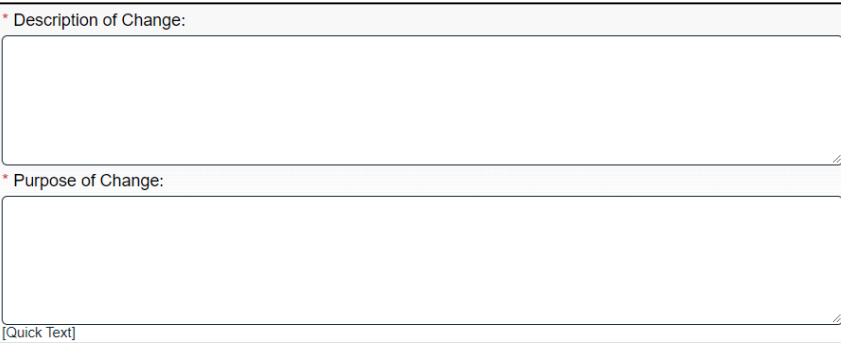
If there is a need to restrict some users from being able to initiate a Document Control Process, a System Administrator can use Manage Privileges in the Process Section to replace the SOLABS General User Role with Function Roles and/or Security Roles associated with the users who WILL have the ability to initiate a Document Control Process. That said, one of the advantages of the Document Control Process is the ability to centralize processing of documents to Document Administrators while allowing all users to request changes to documents and obtain approval from the document owners.

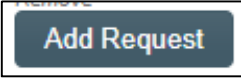
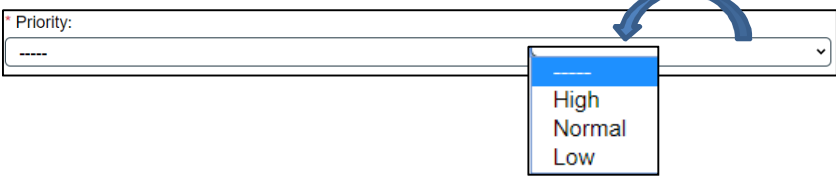
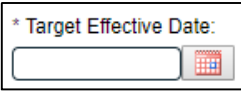

Document Control Process Step 1: Change Request for Creation, Revision or Retire of Document

Step Description	Visual Guide
<p>1. Requestor chooses PROCESS from the main menu, then Start Process from the Quick Access Process Menu on the right-hand side.</p>	
<p>2. Requestor clicks the START button to the right of the listing for Document Control and then clicks Confirm.</p>	

Step Description	Visual Guide
<p>The process is initiated, and a Unique ID is assigned. The Document Control Process Status is now “In Process”.</p> <p>NOTE: The process abbreviation and the Unique ID prefix is DOC but something different can be requested by clients during initial configuration. DCR is a common example of other prefixes used by clients. Screenshots in this User Guide may include different ones.</p>	
<p>3. The Author completes the following fields in the Process Task Form:</p>	
<ul style="list-style-type: none"> Concerned Company Structure: This is a list of any Organizational Security (SEC) Roles established for your company, along with an option for “All”. If your company uses Organizational Roles to differentiate between parts of the company, choose the applicable one, especially if there may be different Document Coordinators for each one. Otherwise choose “All”. 	
<ul style="list-style-type: none"> Type of Change: Choose NEW for <i>new</i> documents that will be imported from outside SOLABS QM. Choose NEW (from Document already created in SOLABS QM) if you have already initiated the Authoring process in SOLABS QM. Choose REVISION for revisions to existing SOLABS QM documents. Choose RETIRE to request retirement of a document. 	
<ul style="list-style-type: none"> Document Type: Choose the applicable Document Type from the drop-down list of Document 	

Step Description	Visual Guide
<p>Types created for your company. This will ensure that the document will have the correct Standard Attribute, System Attribute and Document Ownership settings.</p>	
<ul style="list-style-type: none"> Document Name: If the Request is for a New document enter the proposed name (title) of the new document. This field can be up to 256 characters. For all other Change Types start typing the existing Document Name or Control number. Documents matching the entered text will appear for selection. Select the desired document by clicking on the title. Verify that it is then listed below and note the color of listing text and box. maroon = requested document is now linked to this DCR Process and is at the Authoring status for further processing. orange = there is already a revision of this document at the Authoring status. A new request should not be started. green = there is already a revision of this document at the Review or Approval status. A new request should not be started. 	<div data-bbox="662 520 1490 625"> <p>* Document Name:</p> <input type="text"/> <p>Type document name here</p> </div> <div data-bbox="662 699 1490 877"> <p>* Document Name or Control Number:</p> <input type="text"/> <p>Start typing name or control number in the field, matching documents will be loaded.</p> </div> <div data-bbox="662 888 1490 1024"> <p>* Document Name or Control Number:</p> <input type="text" value="QA"/> <p>QADT-001 / 4.0 (4.0) / Training Program [Approved & Effective] QAC-001 / 5.0 (5.0) / Internal Audit Program [Approved & Effective]</p> </div> <div data-bbox="670 1066 1490 1119"> <p>FP-001 / 2.0 (2.0) / 0.9% Sodium Chloride Injection USP [Approved & Effective] View Open</p> </div> <div data-bbox="670 1224 1490 1287"> <p>CAL-001 / 2.0 (1.2) / Calibration Checklist - Packaging Line Checkweighers [Authoring] View Open</p> </div> <div data-bbox="670 1350 1490 1402"> <p>QAC-003 / 2.0 (1.2) / Supplier Management [Pending Review] View Open</p> </div>
<ul style="list-style-type: none"> Cosmetic Change: The default selection is No. Check with your Document Coordinator regarding business practices for this section. 	<div data-bbox="959 1556 1198 1692"> <p>Cosmetic Change:</p> <p><input checked="" type="radio"/> No</p> <p><input type="radio"/> Yes</p> </div>

Step Description	Visual Guide
<ul style="list-style-type: none"> Suggested Document Workflow: This is a drop-down list of available Document Workflow Templates created at your company. If you know the one that is applicable for your request, select it from the list. You can use the “Preview” option if you’re not sure and want to view it. Otherwise, it can be left blank for the Document Coordinator to complete. 	
<ul style="list-style-type: none"> Draft Location: If you have already linked a document from within SOLABS QM, leave this as N/A. If you are importing a new document that was created outside SOLABS QM, choose Upload Document to bring up a Choose File button. A choice of External Link brings up a text box for you to provide information regarding an external link to the document. 	
<ul style="list-style-type: none"> Description of Change: Describe WHAT is being changed, in sufficient detail for an objective person to understand the changes being proposed. Purpose of Change: Describe WHY this change is required, in sufficient detail for an objective person to understand why these changes are being proposed. If the request is to Retire a document, clearly explain why this is needed. 	

Step Description	Visual Guide
<ul style="list-style-type: none"> Add Request button: Click the Add Request button to add additional document(s) to the same Document Change Request. This brings up another set of fields for requesting another new/revised/retired document. The Description and Reason for Change fields will be pre-populated with the values from the initial Request but can be edited as needed. 	
<ul style="list-style-type: none"> Priority: Choose a priority for document processing, adhering to any applicable business practices for your company. 	
<ul style="list-style-type: none"> Target Effective Date: Choose a Target Effective Date for the new/revised/retired document(s). The Target Effective Date should be in line with the priority given above. 	
<ul style="list-style-type: none"> Owner-Manager Assignment: For Document Types that require Owner-Manager Approval, this drop-down list will be enabled and will be populated with a list of users who are assigned the Process Role PR_DOC_Business Owner. Contact your System Administrator if the Owner-Manager for your document is not listed. For Document Types that do not require Owner-Manager Approval, this field will be grayed out. 	

Step Description	Visual Guide
<ul style="list-style-type: none"> Related Processes: This section allows initiation a Related Process. Selecting this option will bring up a list of other SOLABS QM APPs deployed at your company. You can choose one and link it as a Dependent Process (to be completed before this Document Control Process can be completed) or a Related Process. You can choose who to assign it to from the Initiator drop-down list, which includes all SOLABS QM Standard users. 	
<ul style="list-style-type: none"> Submit and Confirm. Click the Submit button when all of the above fields are complete. Enter your Password and then click the Confirm button. Clicking Confirm sends the Process to the Owner-Manager for documents requiring approval or to the Document Coordinator for those that don't. The Related Items section will list the linked document(s), which is/are now at the Authoring stage. 	