DOCUMENT NUMBER: COMM-QA-061

DOCUMENT TITLE:
MasterControl User Procedures - Documents for View-Only Users

DOCUMENT NOTES:

<table>
<thead>
<tr>
<th>Document Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision: 05</td>
</tr>
<tr>
<td>Status: Release</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation Date: 11 Aug 2015</td>
</tr>
<tr>
<td>Effective Date: 18 Sep 2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author: BJ42</td>
</tr>
<tr>
<td>Previous Number: COMM-QA-061 Rev 04</td>
</tr>
</tbody>
</table>
COMM-QA-061
MASTERCONTROL USER PROCEDURES – DOCUMENTS
FOR VIEW-ONLY USERS

1 PURPOSE
1.1 This procedure provides the details for using and navigating the MasterControl (MC) Documents application for a View-Only User.

2 INTRODUCTION
2.1 The document management system, MasterControl, will provide the View-Only User the ability to view, print documents, and sign-off on training tasks.

3 SCOPE AND RESPONSIBILITIES
3.1 This procedure covers the operational (step-by-step) instructions on how to use MasterControl as a View-Only User.
3.2 It is the responsibility of all employees using MasterControl to follow and apply these procedures as outlined.

4 DEFINITIONS/ACRONYMS
4.1 21 CFR Part 11 – Federal regulations that considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records.
4.2 Esig – Abbreviation for electronic signature that is considered as a legally acceptable and functionally binding equivalent of a paper-based signature.
4.3 InfoCard – InfoCards are the core of MC. The InfoCard controls access to documents as well as the functions available to each use.
4.4 LDAP – MasterControl Portal can accommodate users from other networks. This functionality allows network administrators to synchronize user login passwords to MasterControl with those from the network domain.
4.5 MasterControl Portal/Documents – A software product from MasterControl, which is used as the main document control agent, assisting in the automation and control of document approval, change control, and distribution processes.
4.6 PDF – Portable Document Format.
4.7 Route – A route is the workflow component of a task composed of a series of steps, which include a predefined sequence of users who must act upon the task contents. Training tasks, however, consist of only two-steps: the Trainee step and the Course Verifier step.
4.8 SOP – Standard Operating Procedure
4.9 Systems Administrator – The person or position responsible for the administration, configuration, and control of the MasterControl software.
4.10 Trainee – A user responsible for completing training requirements and keeping their Training Folder up-to-date.

4.11 Task – An assigned piece of work to be completed within a certain time period.

4.12 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are usually of three (3) common types: Draft, Release, Archive.

4.13 View-Only User – The personnel or positions designated as users who have view only (read-only) rights, printing capability, and rights to sign off on Training Tasks.

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 Computer to access MasterControl

7 SAFETY
7.1 NA

8 PROCEDURE
8.1 System Login to MasterControl Portal Home Page
   8.1.1 Click on Internet Explorer. Type in the following URL address: https://duke-mastercontrol.duhs.duke.edu/mc

The Login Screen displays.

![Login Screen](image-url)
8.1.2 In the User ID field, enter your Duke NetID.

8.1.3 In the Login Password field, enter your Duke NetID password.

**NOTE:** Login passwords are controlled by the LDAP server. This functionality allows the System Administrator to synchronize a user's NetID password to MasterControl so the user will not have to change their login password every 45 days.

**NOTE:** The login password and the electronic signature password are masked when typed in, and encrypted during any transaction in which they are utilized.

**NOTE:** The Login Password field is case-sensitive. If your password is entered while the Caps Lock is on, you will see a red wink indicating an **ERROR** that may result in an incorrect password.

![Error Message](image)

8.1.4 Since login passwords are synchronized, the functionality for the **Forgot your password?** link is turned off.

8.1.5 When finished, click the **Log In** button. The MasterControl Portal Home Page displays.
8.2 My MasterControl

8.2.1 The **My MasterControl** menu is located on the left side of the top navigation menu. **My MasterControl** is intended to give ready access to the areas of the system that are accessed the most. Items in this menu include My Tasks, My Links, My Recent, My Files, My Organizers, My Training Folder, and My Settings.

8.3 My Settings

**NOTE:** When you are logged in to MasterControl Portal, the main application header contains a number of items to facilitate use of the system. The **MasterControl** icon in the top-left of the header will return to the MasterControl Portal Home Page from any other page. The **Log Out** link will log you out of
MasterControl Portal. You may also change your esig password (Section 8.4) and select skins (Section 8.5) for MasterControl.

8.4 Changing Passwords

8.4.1 Click Change Passwords from the My Settings menu. The Change Passwords window displays.

Fields are grayed-out, this indicates your Login Password is synchronized with the LDAP Server, and cannot be changed.

8.4.2 Type your current password in the appropriate Current field of the password type you are changing (Login or Electronic Signature).

Minimum length of passwords:
Login – 8 characters
Esig – 5 characters (requires alpha/numeric combination)

8.4.3 Type the new password in the appropriate New field and the Confirm field.

8.4.4 Click the Save button to save your changes.

8.4.5 The Change Reason window will display for you to include a brief reason for the change; then click the Save button. (A message will display confirming the success of the password change.)
NOTE: All users of MasterControl will be trained and have records maintained which indicate the usage of their Unique User ID and Electronic Signature as a legal and binding signature.

8.5 Choosing a Skin

NOTE: MasterControl Skins let you define how you want your home page to look, what type of menu buttons you want to see, etc. You can switch between multiple skins to modify your settings. To do this:

8.5.1 Click the My Skins item from the My Settings menu in the My MasterControl menu.

8.5.2 Select Default or Classic.

8.5.3 Select a skin from the Menu Skin drop-down list.
8.5.4 Select a skin from the **Border Skin** drop-down list.

8.5.5 Click **Change Skin**.

8.6 My Tasks

8.6.1 MasterControl has replaced the old “In Box” on your desk with a handy repository for all the tasks that require your attention. This is the **My Tasks** page, where you open the document you need to complete and sign off on tasks requiring your approval.

8.7 My Links

8.7.1 **My Links** is a links section that provides quick access to different landing pages or actions within the MasterControl system.

8.8 My Recent

8.8.1 The **My Recent** menu item allows you to instantly retrieve any of the last 15 InfoCards with which you have viewed. Mouse over the menu and select the desired InfoCard. The system will navigate directly to it.

8.8.2 Clicking the **Recent Messages** link in the menu will show you the last ten messages displayed by MasterControl since you last logged in.

8.9 My Organizers

8.9.1 **My Organizers** gives quick access to all organizers to which you have rights. This page provides visual access to organized InfoCards in an HTML view. You can view the contents of an organizer in this view but cannot edit them.

8.9.1.1 In **My MasterControl**, click the **My Organizers** link in the main navigation menu to reveal a list of Organizers that you have the rights to view.

8.9.1.2 Click the Organizer (🗂️) to display a Subfolder(s) (🗂️).

8.9.1.3 Select the Subfolder to view by clicking.

8.9.1.4 A list of documents contained in the subfolder populates. Click the document to view.

8.10 My Training Folder

8.10.1 **My Training Folder** is a listing of every training task that has ever crossed your path. Anything you want to know about your training record can be found here, from task statuses, past and future due dates, completion dates, when retraining will be required, and who verified your training.

8.11 My Settings (see Section 8.3)

8.12 Links

**My Links** is a links section that provides quick access to different landing pages or actions within the MasterControl system. You can make any page in
MasterControl the home page the system will open after you log in. To set your home page:

8.12.1 Navigate to the page you wish to set as your home page.
8.12.2 Click **Make Current My Home Page** from the **My Links** menu.
8.12.3 Click **Confirm Change** to change the home page or **Cancel Change** to leave the current home page as it is.

8.13 **Help Icon**

8.13.1 From the Portal Home Page, click on the **question mark icon** for quick help navigating the system.

8.14 **System Logout**

8.14.1 To end your session, click on the **Log Out** in the upper right-hand corner. Do not close your browser to log out. Clicking the **Log Out** link closes the “loop” completely and ensures a session is available for another user(s).

8.15 **Portal Search**

**NOTE**: A Portal Search can be performed by entering information in the **Portal Search** field (white space window) located directly under the login name.

8.15.1 Type in the search information in the **Portal Search** field. You can enter an InfoCard number or part of a title to access a document.

8.15.2 Press **Enter** or click the **GO** button.

8.15.3 The InfoCard(s) results display.

8.15.3.1 Results are organized by Module in folders for easy navigation.

8.16 **Searching and Viewing**

8.16.1 For a more specific search, the word “**Search**” next to the Portal Search field is hyperlinked. Clicking on it will open a search window with the **Simple**, **Basic** and **Advanced** search tabs.
8.17 Search Methods

**NOTE:** By default, List Page returns only InfoCards that belong to Vaults for which you have access rights.

8.17.1 Simple Search

**NOTE:** The Simple search provides you with a single field and allows you to enter a word, phrase, or document number on which to search.

8.17.1.1 Click an InfoCard list from the main navigation menu. For example, in the DOCUMENTS Module, click on Documents to display Document InfoCards to which you have access.

8.17.1.2 Click the Search button in the toolbar.

8.17.1.3 Select the Simple tab.

8.17.1.4 Enter search data in the Search For field.

8.17.1.5 Click the Submit Search button.

8.17.1.6 Results will display.

8.17.1.7 To clear the search fields, click the Clear button.

8.17.2 Basic Search

**NOTE:** The Basic search allows you to search on the same data fields used to create a new InfoCard. These are context sensitive to the list page from which the search was started. You may use an asterisk (*) as a wildcard character; in addition, a trailing wildcard will be added to the end of each value entered.

8.17.2.1 Click an InfoCard list from the main navigation menu. For example, in the DOCUMENTS Module, click on Documents to display Document InfoCards to which you have access.

8.17.2.2 Click the Search button in the toolbar.

8.17.2.3 Select the Basic tab.

8.17.2.4 Enter search data in any field. Adding an asterisk to the search data creates a wildcard search.

8.17.2.5 Click the Submit Search button.

8.17.2.6 Results will display.

8.17.2.7 To clear the search fields, click the Clear button.

8.17.3 Advanced Search

**NOTE:** The Advanced Search allows you to select a field, select an operator, and then enter a value to be searched in that field.

8.17.3.1 Click an InfoCard list from the main navigation menu. For example, in the DOCUMENTS Module, click on
Documents to display Document InfoCards to which you have access.

8.17.3.2 Click the Search button in the toolbar.
8.17.3.3 Select the Advanced tab.
8.17.3.4 Select Field option from the drop-down list.
8.17.3.5 Select Operator option from the drop-down list.
8.17.3.6 Enter search data in the Value field. Adding an asterisk (*) to the search data creates a wildcard search.
8.17.3.7 To create another row, click the New icon.
8.17.3.8 Click the Submit Search button.
8.17.3.9 To clear the search fields, click the Clear button.

8.17.4 Full Text Search (FTS)

This option conducts a search for text in the main file attached to the InfoCard.

8.17.4.1 To perform a FTS, use the Advanced search method as described in Section 8.17.3.

8.17.4.1.1 Select the Full Text Search option from the drop-down list.

8.18 Icons

<table>
<thead>
<tr>
<th></th>
<th>Tracking</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="emoji" alt="" /> Details</td>
<td><img src="emoji" alt="" /> Tracking</td>
</tr>
<tr>
<td><img src="emoji" alt="" /> Document Task</td>
<td><img src="emoji" alt="" /> Training Required</td>
</tr>
<tr>
<td>❌ In-process</td>
<td><img src="emoji" alt="" /> Training Task</td>
</tr>
<tr>
<td>📋 Locked InfoCard</td>
<td><img src="emoji" alt="" /> View Document</td>
</tr>
<tr>
<td>✨ Revision</td>
<td><img src="emoji" alt="" /> View InfoCard</td>
</tr>
<tr>
<td>📋 Sign Off</td>
<td><img src="emoji" alt="" /> View PDF</td>
</tr>
</tbody>
</table>

8.19 Document InfoCard

NOTE: InfoCards are the core of MC. The InfoCard controls access to documents as well as the functions available to each user. This section describes the tabs you will see on a Document InfoCard.

8.19.1 If data is contained in a tab, the tab text appears black.
8.19.2 If no data is contained in a tab, the tab text is gray.
8.19.3 If the Information tab is red, the InfoCard is not approved.
8.19.4 If the Information tab is green, the InfoCard is approved.
8.20 Information Tab

8.20.1 The Information tab identifies the InfoCard and provides general InfoCard information.

8.21 Training Tab

8.21.1 The Training tab displays a list of all in-process and completed training tasks to which the Document InfoCard has been linked.

8.22 Controlled Copies Tab

8.22.1 The Controlled Copies tab has a sortable list of all controlled copies associated with the InfoCard and tracks the distribution location on the InfoCard.

8.23 Attachments & Links Tab

8.23.1 This Attachments & Links tab is used to maintain a list of all attached files; i.e., a listing, an image or picture, or PDF file.

8.24 Custom Fields Tab

8.24.1 The SysAdmin defines all the Custom Fields that are displayed on this tab.

8.25 History Tab

8.25.1 The History tab is used to view a record of InfoCard approvals.
8.26 Status Tab

8.26.1 The **Status** tab allows you to view the current status of the selected InfoCard.

8.27 Versions Tab

8.27.1 A new version appears each time a new Main File is uploaded to the InfoCard. You can view all previous versions main files from the **Versions** tab.

8.28 My Tasks

8.28.1 Any task waiting for completion will appear in **My Tasks**. Trainees are responsible for completing their own training.

8.28.2 **My Tasks** also identifies the type of task, how long it has been waiting, and a shortcut to tracking which shows the route or process status.

8.28.3 A Training Task is illustrated as ( ). Refer to *MasterControl User Procedures – Training* for details on performing a Training Task.

8.28.4 You will receive an email notification that a task requires your attention in **MasterControl**.

8.28.5 Click on the link in your email to access **MasterControl**. You will be prompted to login; **OR** click on **My Tasks** in **My MasterControl**.

8.29 PDF Files

8.29.1 PDF files are in a distribution format to allow electronic information to be transferred between various types of computers.

8.29.2 MasterControl generates PDF files to “sandwich” the actual document between a cover page and a signature manifest page.
8.29.2.1 The cover page maintains the metadata of the document; e.g., document number, revision number, document title, etc.

8.29.2.2 The Signature Manifest page is populated and published on all PDF documents as the last page. Signature Manifest is a FDA 21 CFR Part 11 requirement that allows users to see who has had any action on the document, such as approval, review, rejection, etc.

9 RELATED DOCUMENTS/FORMS
9.1 MasterControl User Procedures – Training, COMM-QA-062

10 REFERENCES
10.1 MasterControl System Administration Manual
10.2 FDA 21 CFR Part 11

11 REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
</tr>
</thead>
</table>
| 05           | B. Jordan | • Added definitions for 21 CFR Part 11, and SOP (Section 4).
|              |           | • Removed the word “If” from the Change Password illustration.
|              |           | • Removed the statement: “Note: If your Login password is not synchronized...” All passwords are synchronized.
|              |           | • Added illustration to Portal Search section. |
# Signature Manifest

**Document Number:** COMM-QA-061  
**Title:** MasterControl User Procedures - Documents for View-Only Users  
**Revision:** 05

All dates and times are in Eastern Time.

## COMM-QA-061 MasterControl User Procedures - Documents for View-Only Users

### Author

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betsy Jordan (BJ42)</td>
<td></td>
<td>21 Aug 2015, 09:13:25 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

### Medical Director

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joanne Kurtzberg (KURTZ001)</td>
<td></td>
<td>24 Aug 2015, 09:50:57 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

### Quality

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Carpenter (JPC27)</td>
<td></td>
<td>28 Aug 2015, 01:08:50 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

### Document Release

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandy Mulligan (MULLI026)</td>
<td></td>
<td>08 Sep 2015, 08:32:25 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>