**DOCUMENT NUMBER:** COMM-QA-061

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

**DOCUMENT NOTES:**

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<td><strong>Author:</strong> BJ42</td>
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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 Tiles and Hubs – MasterControl’s redesign of their user interface (UI).
4.13 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are usually of three (3) common types: Draft, Release, Archive.
4.14 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
  6.2 MasterControl is validated on Firefox and Chrome

7 SAFETY
  7.1 NA

8 PROCEDURE
  8.1 Components of MasterControl
8.1.1 Hubs and Tiles

As a result of MasterControl's all-inclusive approach to user experience (UX), users now do not have to jump to a different module to perform related tasks. The new **Hubs** replace the landing pages formally associated with each MasterControl module. The **Hubs** contain **tiles** with critical information and tasks, which allow users to easily navigate between pages or perform additional tasks. This creates a truly connected workflow that aligns more directly to how users perform their jobs.
8.2 System Login to MasterControl Portal Home Page

8.2.1 Click on your browser.

8.2.2 Type in the following URL address: https://duke.mastercontrol.com/duke

The **Login Screen** displays.

8.2.3 In the **User ID** field, enter your Duke NetID.

8.2.4 In the **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 incorrectly, you will see a red drop-down message indicating Invalid Login information.
8.2.5 Click the **Sign In** button.

8.2.6 Reset a Forgotten Password

8.2.6.1 Click on the **Forgot Password** button.
8.2.6.2 In the User ID and Email Address fields, type your User ID and email associated with your user account and click CONTINUE to get a temporary password.

8.2.6.3 In the ANSWER field, type the answer to the security question and click SUBMIT ANSWER.

8.2.6.4 From your Outlook inbox, open the email that contains your temporary password.

NOTE: If you do not see the email, check your junk mail.

8.2.6.5 Return to the login page, and in the appropriate fields, type your User ID and temporary password.

8.2.6.6 When prompted, type and confirm a new password.

8.2.6.7 Click Sign In.

8.3 My MasterControl

8.3.1 My MasterControl provides ready access to commonly accessed areas of the system.
8.1 My Tasks

8.1.1 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.

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

8.1.3 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.

8.1.4 A Training Task is illustrated as ( ). Refer to COMM-QA-062 MasterControl User Procedures – Training for details on performing a Training Task.

8.1.5 You will receive an email notification that a task requires your attention in MasterControl.
8.1.6 Click on the link in your email to access MasterControl. You will be prompted to login; OR click on My Tasks in My MasterControl.

8.2 My Settings

8.2.1 When you are logged in to MasterControl Portal, the main application header contains a number of items to facilitate use of the system. Clicking on the MasterControl icon in the top-left of the header will return to the MasterControl Portal Home Page from any other page.

8.2.2 The Log Out link located in the top-right of the header will log you out of MasterControl Portal.

8.3 Changing Esig Password

8.3.1 Change your esig password if the system prompts you to do so, if you want to update it, or if you forget your current esig password.

8.3.2 Click the User Name drop-down menu; select Change Passwords.
8.3.3 In the **Current Esig Password** field, type your current password.

8.3.4 In the **New Esig Password** field, type a new password.

8.3.5 In the **Confirm Esig Password** field, type the new password again to verify it.

8.3.6 Click **Save**.

8.3.7 The **Change Reason** window will display for you to include a brief reason for the change.

8.3.8 Click **Save**.

![Change Reason](image)

**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.

8.4 **My Links**

8.4.1 **My Links** is a links section that provides quick access to different landing pages or actions within the MasterControl system. You can access, create and manage private links that all users can add to their home pages; however, users may only access those links for which they have corresponding rights.

8.4.2 For help on creating Links, you can visit the **Help** or contact your System Administrator.

8.5 **Tracking**

8.5.1 All tasks are tracked during the approval process and retained after they have completed their respective Workflows. From the **My MasterControl Tracking** page, you can search for a specific task, and then view the status or history details of the task, along with its file or form. Task details show all the steps that a task has completed, steps yet to be completed (if in-process), and comments made by users along the Workflow.
8.6 My Recent

8.6.1 The **My Recent** menu item allows quick retrieval of any of the last 15 InfoCards with which you have worked with or viewed. Mouse over the menu and select the desired InfoCard. The system will navigate directly to it. The most recent InfoCard appears at the top of the list.

8.7 Explorer

8.7.1 Use **Explorer** to view your Organizers as a list or in a tile view, or sort and filter your Organizers for an improved search experience. The **Explorer** 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.

8.7.1.1 Select the Organizer to view by clicking.

8.7.1.2 A list of documents contained in the subfolder populates. Click the document to view.
8.8 My Training Folder

8.8.1 **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.

8.8.2 Refer to **COMM-QA-062 MasterControl User Procedures – Training**, for detailed MC Training information.

8.9 Search MasterControl

8.9.1 The Search function offers three search methods: Simple, Basic, and Advanced, which behave similarly in the Portal and Toolbar searches. Search results display only InfoCards that belong to vaults for which you have rights.

**NOTE:** Search fields in MasterControl have a 50-character limit.

8.9.2 Portal Search

8.9.2.1 Locate the Portal Search toolbar at the top of the page from anywhere in the MasterControl interface. When you search using Portal Search, MasterControl scans the entire portal for defined values and displays results in folders according to module for easier navigation of application-wide searches.
8.9.3 Toolbar Search

8.9.3.1 Locate the Toolbar Search from the InfoCard list page toolbar. The Toolbar Search returns only results from the InfoCard list page from which you initiate the search. Results are displayed in a sortable InfoCard list. Click the checkbox for one or more of the InfoCards to perform actions such as check-in, view, and create or view copies.

8.9.4 Simple Search

8.9.4.1 Simple Search displays a single field for you to specify your search criterion. The system compares the values you type in the search field against all searchable fields.
8.9.4.2 Select either the Portal or the Toolbar Search option.

8.9.4.3 Click Simple.

8.9.4.4 In the Search for field, type the words for which you want to search.

8.9.4.5 Click Submit Search and view the search results.

8.9.5 Basic Search

8.9.5.1 Use Basic Search's Query by Example feature to tailor your search and compare the values you type in the search fields against all searchable fields. You can use an asterisk (*) as a wildcard before a search term to look for results that contain the term or include an underscore (_) as a single-character wildcard for any character that contains letters and numbers.

**NOTE:** If you include an underscore in your search, wrap the underscore in brackets ([_]) so that the search recognizes the character as itself.
8.9.6 Select either the Portal or the Search option.

8.9.6.1 Click Basic.

8.9.6.1.1 In one or multiple fields, type your search criteria.

**NOTE:** To remove all field entries, click **Clear**.

8.9.6.1.2 Click **Submit Search**.

8.9.7 Advanced Search

8.9.7.1 Use Advanced Search to narrow search results to specific values in particular fields. You can also select a field, an operator, and a field value for the search, as well as add more search fields.
8.9.7.2 When adding additional fields, if you want results to include information you type in both specified fields, use the "and" logic. If you want the results to include information you type in either one field or the other, but not both, use the "or" logic.

8.9.7.3 When populating the Value field, you can use an underscore (_ ) as a single-character wildcard for any character, including letters and numbers. If you search for a term that includes an underscore, wrap the underscore in brackets ([ _ ] ) so the search recognizes the character as itself.

8.9.8 Select either the Portal or the Toolbar Search option.

8.9.8.1 Click Advanced.

8.9.8.1.1 Click the Field drop-down and select a field from which to search.

NOTE: The Advanced Search field options for each InfoCard list may vary based upon the fields MasterControl has built into each feature.
8.9.8.1.2 Select an Operator from the drop-down list:
  o Contains
  o Does Not Contain
  o Ends With
  o Equals
  o Starts With
  o Is Null
  o Is Not Null

8.9.8.1.3 Type the search value. For date fields, click Calendar View to choose a specific date, or click Today's Date to set the value to the current day.

8.9.8.1.4 To add an additional search field, click New Row, indicated by a plus sign, and select the and/or logic from the drop-down.

**NOTE:** To delete a search field, click Delete Row.

8.9.8.1.5 Click **Submit** Search.

8.9.9 Full Text Search (FTS)

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

It does not recognize headers or footers.

8.9.9.1 To perform a FTS, use the **Advanced** search method as described in Section 8.9.7.

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

8.10 MasterControl Icons

8.10.1 Hovering or pausing over an icon reveals the name/function of that particular option.

8.10.2 An Icon Directory can be found in the HELP tile of any module.
8.11 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. Formerly, these were tabs located across the top of the InfoCard.
8.12 PDF Files

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

8.12.2 MasterControl generates PDF files to "sandwich" the actual document between a cover page and a signature manifest page.

8.12.2.1 The Cover Page maintains the metadata of the document; e.g., document number, revision number, document title, etc.

8.12.2.2 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 COMM-QA-062 MasterControl User Procedures – Training

10 REFERENCES

10.1 MasterControl System Administration Manual

10.2 FDA 21 CFR Part 11

11 REVISION HISTORY

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<td>B. Jordan</td>
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# Signature Manifest

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All dates and times are in Eastern Time.

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

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