

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

MasterControl User Procedures - Documents for View-Only Users

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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 DCO – Document Control Operations.
- 4.3 DUO – A service used for multi-factor authentication (MFA).
- 4.4 Esig – Abbreviation for electronic signature that is considered as a legally acceptable and functionally binding equivalent of a paper-based signature.
- 4.5 InfoCard – InfoCards are the core of MC. InfoCards store document information and associated links in one location.
- 4.6 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.
- 4.7 ODT – On-Demand Training via the MasterControl Customer website.
- 4.8 OIT – Duke Office of Information Technology.
- 4.9 Okta – An enterprise-grade, identity management service, built for the Cloud.
- 4.10 PDF – Portable Document Format.
- 4.11 Production Site – This is where the MasterControl licensed software is installed, and it is used as a repository of our controlled documents.
- 4.12 Route – A route is the *workflow* component of a task composed of a series of steps, generally three or more, 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.

- 4.13 Security Questions – Questions that are a common method of identity authentication.
- 4.14 SOP – Standard Operating Procedure
- 4.15 Systems Administrator – The person or position responsible for the administration, configuration, and control of the MasterControl software.
- 4.16 Task – An assigned piece of work to be completed within a certain time period.
- 4.17 Tiles and Hubs – MasterControl’s redesign of their user interface (UI).
- 4.18 Trainee – A user who has the responsibility of completing training tasks in MC. A trainee is responsible for completing training requirements and keeping their Training Folder up to date.
- 4.19 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are usually of three (3) common types: Draft, Release, Archive.
- 4.20 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

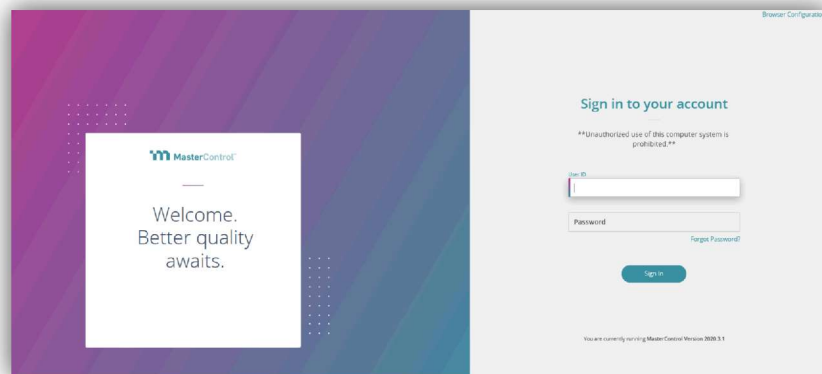
- 6.1 Computer to access MasterControl
- 6.2 MasterControl is validated on Firefox and Chrome

7 SAFETY

- 7.1 NA

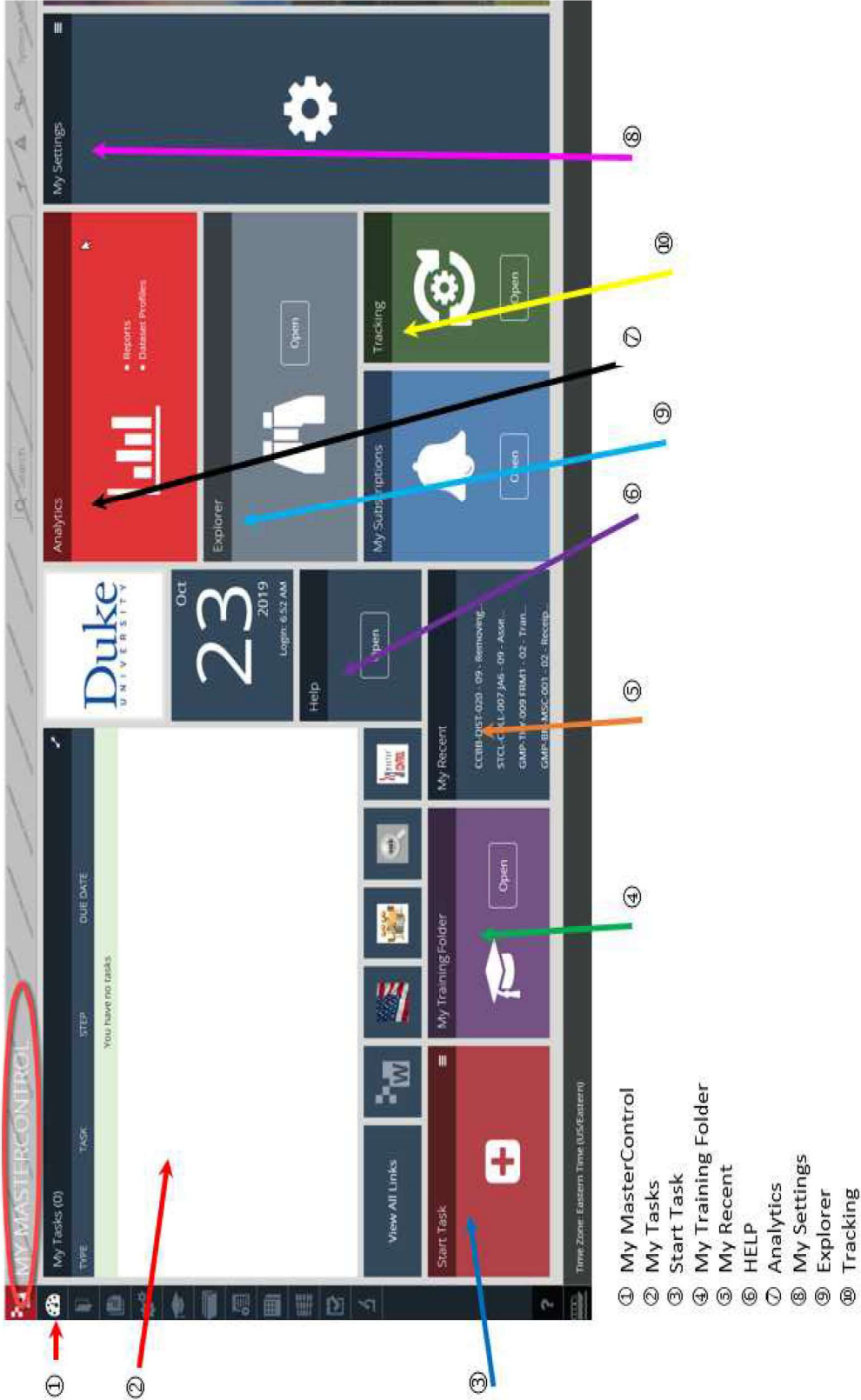
8 PROCEDURE

- 8.1 Components of MasterControl
 - 8.1.1 User Interface (UI)
 - 8.1.1.1 This upgraded version of MasterControl maintains the same Sign In screen as the previous version.



8.1.2 Hubs and Tiles

As a result of MasterControl's all-inclusive approach to user experience (UX), users do not have to jump to a different module to perform related tasks. The 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.



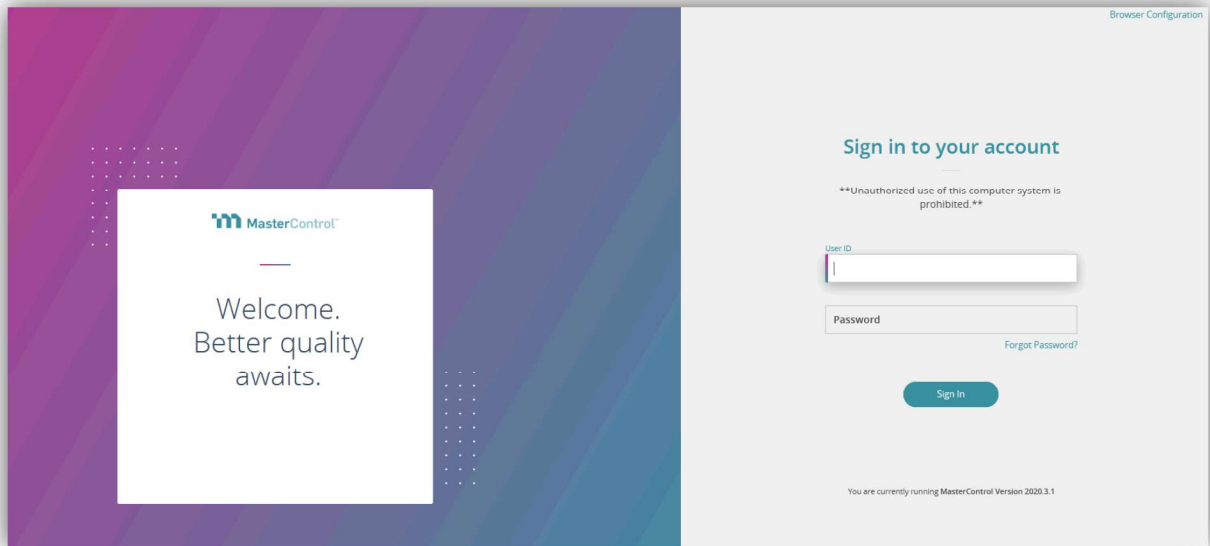
8.2 System Login to MasterControl Portal Home Page

8.2.1 Click on the browser (Firefox or Chrome or Chrome Incognito).

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

NOTE: Bookmark this URL site for easy access.

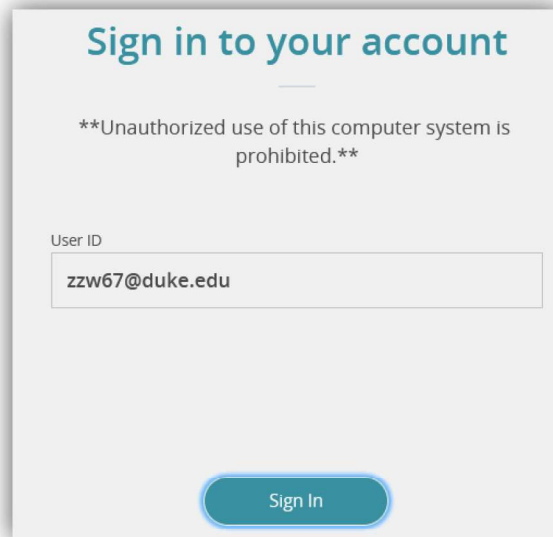
The MasterControl Login Screen displays.



NOTE: A new user's MasterControl User account is **locked** preventing access to the Production site until completion of the ODT via the MasterControl Customer website. This coursework is outlined in the orientation email sent to new users from DCO. **Once this training has been completed, the user is to reply to that email informing DCO that the ODT training has been completed.** Once DCO has received this confirmation from the user, their MasterControl User account will be unlocked allowing the new user access to the Production site.

8.2.3 In the **User ID** field, enter the user's Duke NetID followed by @duke.edu

NOTE: Example: zzw67@duke.edu



Sign in to your account

Unauthorized use of this computer system is prohibited.

User ID

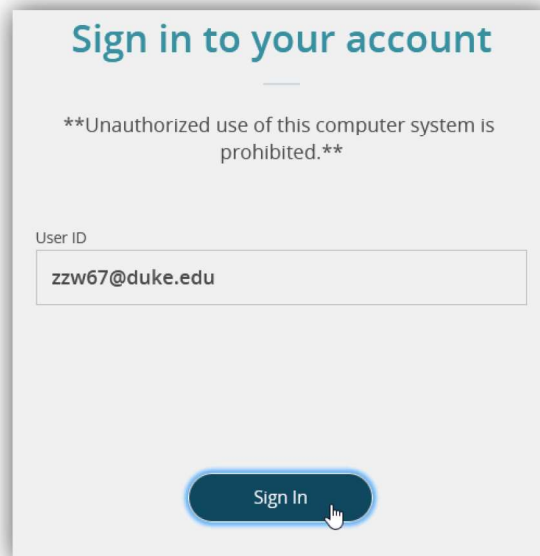
zzw67@duke.edu

Sign In

8.2.4 Click **ENTER** or click the **TAB** key.

8.2.5 The **PASSWORD** field is removed.

8.2.6 Click the **Sign In** button.



Sign in to your account

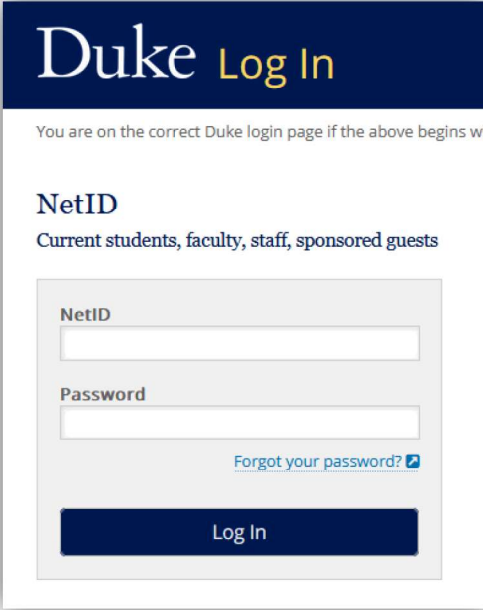
Unauthorized use of this computer system is prohibited.

User ID

zzw67@duke.edu

Sign In

8.2.7 Clicking the Sign In button directs the user to the **Duke Log In** screen.

The image shows the Duke Log In page. At the top, there is a dark blue header with the text "Duke Log In" in white and yellow. Below the header, a line of text reads: "You are on the correct Duke login page if the above begins with". The main content area is white and contains the "NetID" section. Under "NetID", it says "Current students, faculty, staff, sponsored guests". There are two input fields: "NetID" and "Password". Below the "Password" field is a link that says "Forgot your password?" with a small icon. At the bottom of the form is a dark blue button labeled "Log In".

Duke Log In

You are on the correct Duke login page if the above begins with

NetID

Current students, faculty, staff, sponsored guests

NetID

Password

[Forgot your password?](#)

Log In

- 8.2.8 Enter the user's Duke **NetID** credentials, along with a **Duo** authentication 6-digit number for the user's **MFA**.

Example:

Duke Log In

You are on the correct Duke login page if the above begins with Duke

NetID
Current students, faculty, staff, sponsored guests

NetID
BJ42

Password
••••••••

[Forgot your password?](#)

Multi-factor Authentication

- ☐ Use Duo Push (Duke iPhone)
- ☐ Use Duo Push (personal phone)
- ☐ Call phone (My Phone)
- ☐ Call phone (Duke iPhone)
- ☐ Call phone (personal phone)
- ☐ Send SMS codes (My Phone)
- ☐ Send SMS codes (Duke iPhone)
- ☐ Send SMS codes (personal phone)

Or, enter pass code/YubiKey@:

141844 [What are pass codes?](#)

☒ Remember device for 72 hours

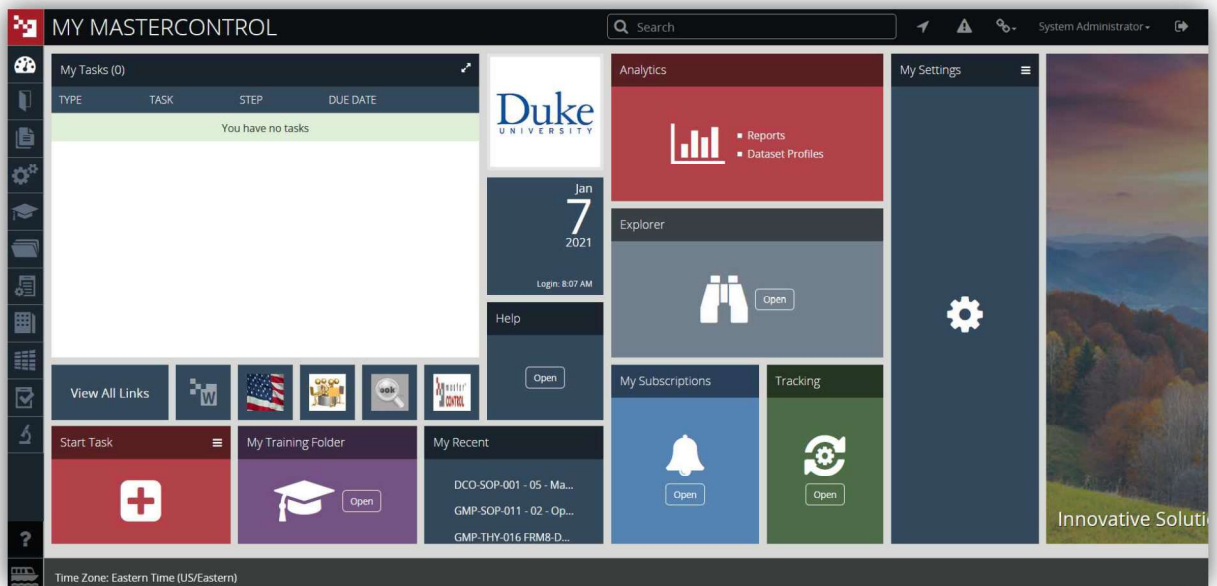
[Forgot your device?](#)

[Have a new device?](#)

Log In

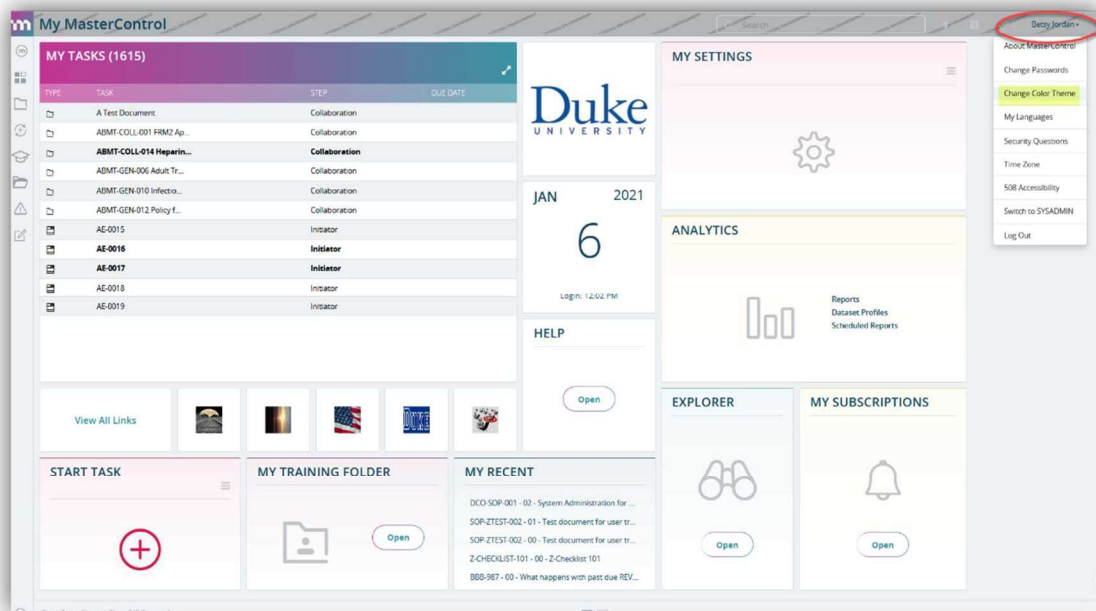
8.2.9 Click Log In.

8.2.10 The user's MasterControl home portal page displays.

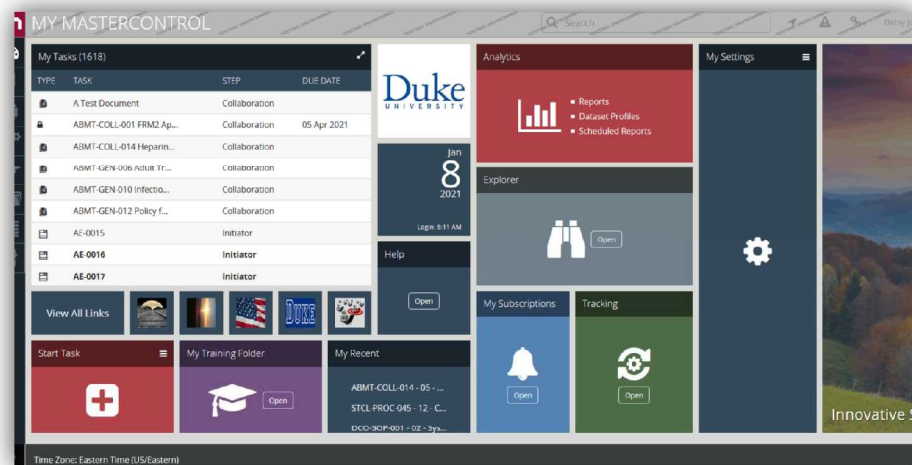


8.3 Change Color Theme

8.3.1 To change the **color theme** of the interface, click the drop-down menu next to the Username in the upper right corner; then select the color scheme preference.

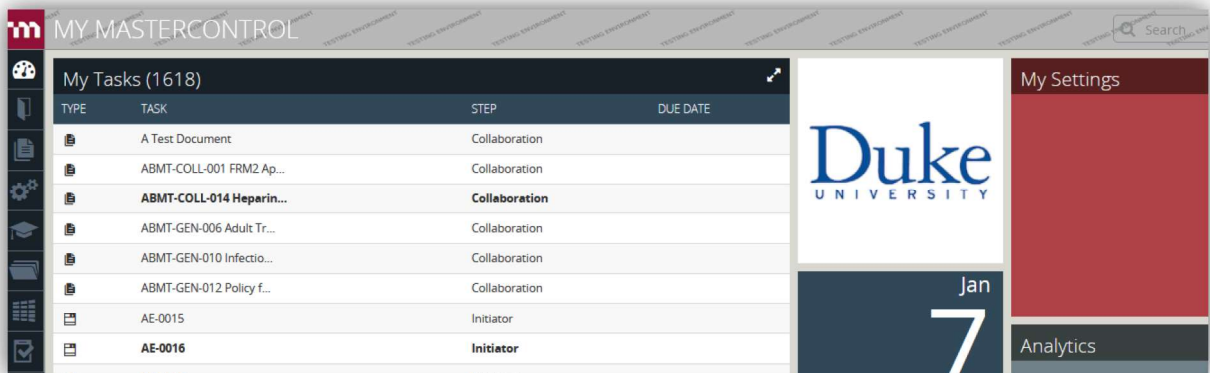


8.3.2 Color Theme changed.



8.4 My MasterControl

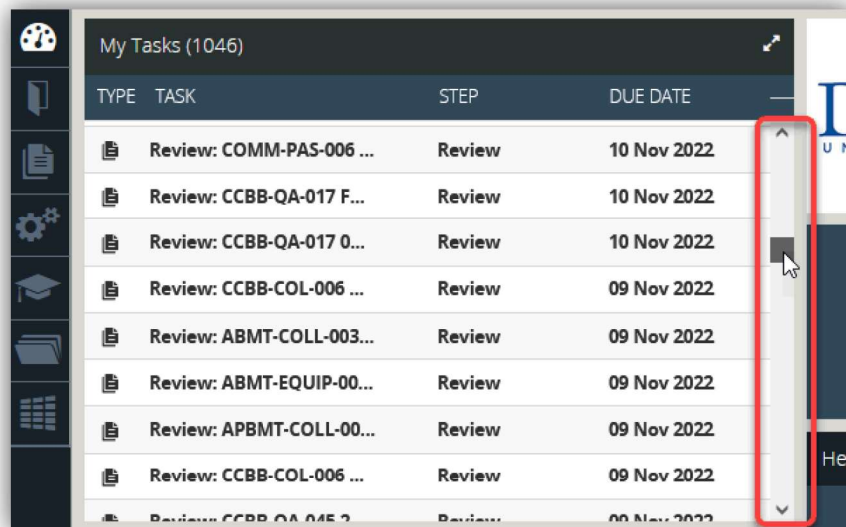
8.4.1 **My MasterControl** (item #1, Section 8.1.2) provides ready access to commonly accessed areas of the system.



8.1 My Tasks

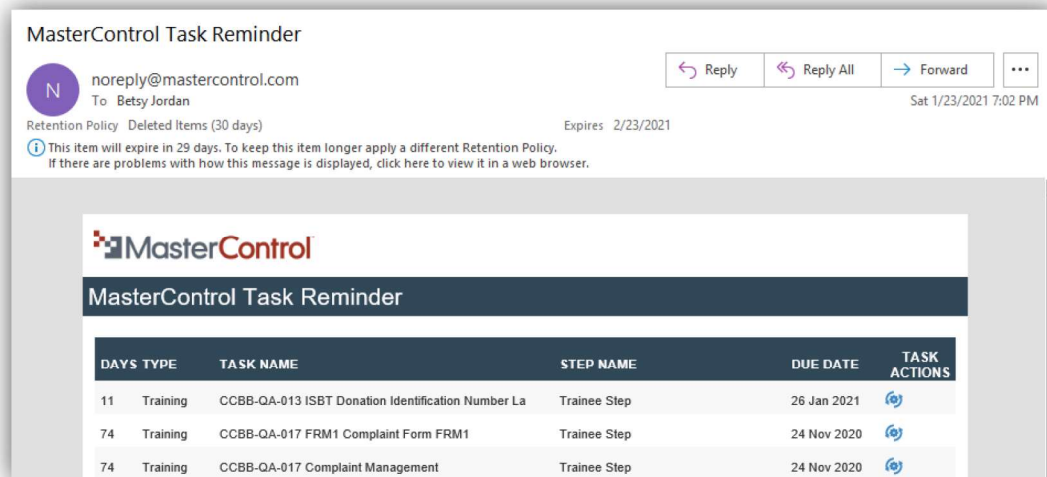
8.1.1 The My Tasks page (item #2, Section 8.1.2) is where the user will find all of the tasks which require their attention. It is here that the user will open the documents for the training tasks they need to complete and sign off on tasks requiring their approval.

8.1.2 A **Scroll Bar** is provided to easily review current tasks in a user's My Task tile. The **Scroll Bar** appears when a user has more than 11 tasks and will display up to 100 tasks by scrolling.



| TYPE | TASK | STEP | DUE DATE |
|--------|--------------------------|--------|-------------|
| Review | Review: COMM-PAS-006 ... | Review | 10 Nov 2022 |
| Review | Review: CCBB-QA-017 F... | Review | 10 Nov 2022 |
| Review | Review: CCBB-QA-017 O... | Review | 10 Nov 2022 |
| Review | Review: CCBB-COL-006 ... | Review | 09 Nov 2022 |
| Review | Review: ABMT-COLL-003... | Review | 09 Nov 2022 |
| Review | Review: ABMT-EQUIP-00... | Review | 09 Nov 2022 |
| Review | Review: APBMT-COLL-00... | Review | 09 Nov 2022 |
| Review | Review: CCBB-COL-006 ... | Review | 09 Nov 2022 |
| Review | Review: CCBB-QA-045 ... | Review | 09 Nov 2022 |

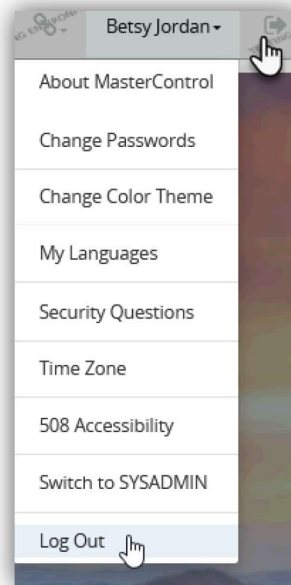
- 8.1.3 Any task waiting for completion will appear in **My Tasks**. Trainees are responsible for completing their own training.
- 8.1.4 **My Tasks** also identifies the type of task, how long it has been waiting, and a shortcut to tracking which shows the route or process status.
- 8.1.5 A Training Task is illustrated as (📎). Refer to *COMM-QA-062 MasterControl User Procedures – Training* for details on performing a Training Task.
- 8.1.6 Trainees will receive an email notification that a **task requires their attention in MasterControl**.



- 8.1.7 Trainees should click on the link in their email to access MasterControl. They will be prompted to login; **OR** click on **My Tasks** in **My MasterControl**.

8.2 My Settings

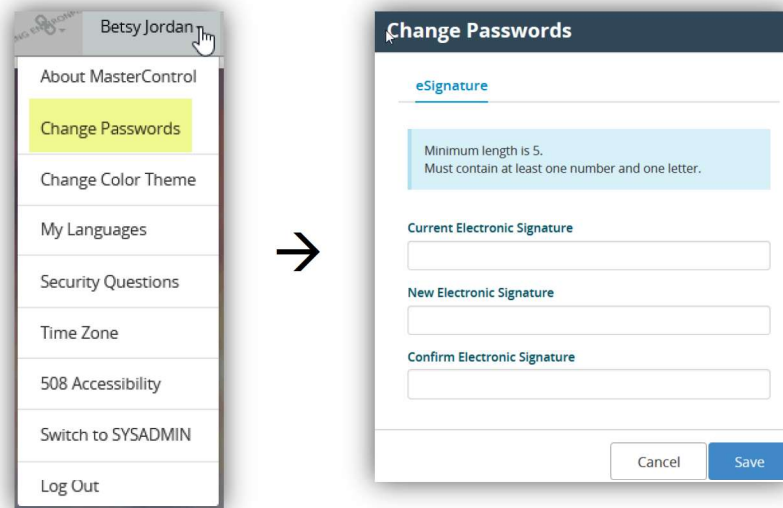
- 8.2.1 When a user is logged in to MasterControl Portal, the main application header contains a number of items. Clicking on the **MasterControl** icon (item #1, Section 8.1.2) in the top-left of the header will return the user to the MasterControl Portal Home Page from any other page.
- 8.2.2 The **Log Out** link located in the top-right of the header will log the user out of MasterControl Portal.



NOTE: The user should be sure to click on **Log Out**.

8.3 Changing Passwords

- 8.3.1 A user should change their esig password if the system prompts them to do so, if they want to update it, or if they forget their current esig password.
- 8.3.2 Click the User Name drop-down menu; select **Change Passwords**.



8.3.3 In The Change Passwords screen will display.

8.3.4 The **eSignature** tab will display.

8.3.5 Satisfy the specific requirements for the esig password.

8.3.5.1 Minimum esig characters = 5

8.3.5.2 Forced alphanumeric; i.e., at least one (1) number and at least one (1) letter.

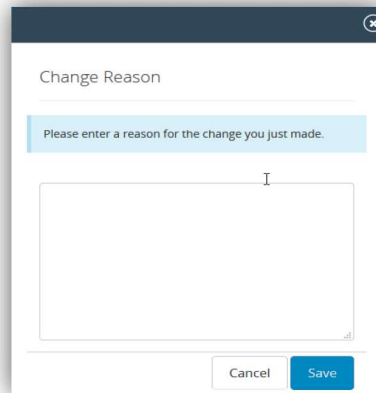
8.3.5.3 Expires after 90 days and must be reset.

8.3.5.4 Lockout occurs after five (5) attempts.

NOTE: Duke OIT implemented a password policy that eliminates the need to change NetID passwords unless a password has been compromised. This updated password policy removes password expiration. Duke users and sponsored Duke guests will no longer be required to regularly update login passwords associated with their Duke NetID.

8.3.6 Click **Save**.

8.3.7 The **Change Reason** window will display for the user to include a brief reason for the change; i.e., updated their esig.



8.3.8 Click **Save**.

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. Users 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, users can visit the **Help** (item #6, Section 8.1.2) or contact DCO.

8.5 Forgot Your Esig?

8.5.1 Reset a forgotten electronic password by clicking on the [Forgot your electronic signature?](#) link on the Sign Off screen.

Sign Off: Review

Comments

* Electronic Signature

[Forgot your electronic signature?](#)

* Status

Back Cancel Sign Off

8.5.2 Answer the **Security Questions** and click Submit.

Electronic Signature Assistance

Security Questions

What was the color of your first car?

In what town was your first job?

Submit

8.5.3 After the user submits the security answers, the **Change Electronic Signature** screen opens and a new Electronic Signature can be entered.

Change Electronic Signature

You must change your Electronic Signature before continuing. Minimum length is 5 characters and will expire after 90 days. Must be alphanumeric.

* New Electronic Signature (Minimum Length 5)

.....

* Confirm Electronic Signature

.....

Cancel Submit

- 8.5.4 Clicking **Submit** will redirect the user back to their Pending Task List. The user will locate the task and then be able to sign off.

8.6 Tracking

- 8.6.1 All tasks are tracked during the approval process and retained after they have completed their respective workflows. From the **My MasterControl Tracking** page, a user 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.

8.7 My Recent

- 8.7.1 The **My Recent** menu (item #5, Section 8.1.2) allows quick retrieval of any of the last 15 InfoCards with which the user has 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.

8.8 Explorer

- 8.8.1 Use **Explorer** (item #9, Section 8.1.2) to view Organizers as a list or in a tile view, or sort and filter Organizers for an improved search experience. The **Explorer** page provides visual access to organized InfoCards in an HTML view. The user can view the contents of an organizer in this view but cannot edit them. There is an **Explorer** tile located on MY MASTERCONTROL, PORTAL, and DOCUMENTS modules.

8.8.1.1 Select the Organizer to view by clicking.

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



8.9 My Training Folder

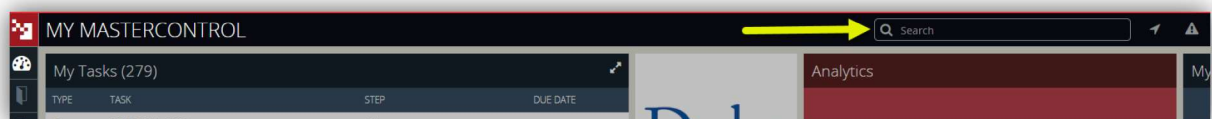
8.9.1 **My Training Folder** (item #4, Section 8.1.2) is a listing of every training task that has ever crossed the user's path. Anything the user wants to know about their training record can be found here, from task statuses, past and future due dates, completion dates, when retraining will be required, and who verified the training.

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

8.10 Search MasterControl

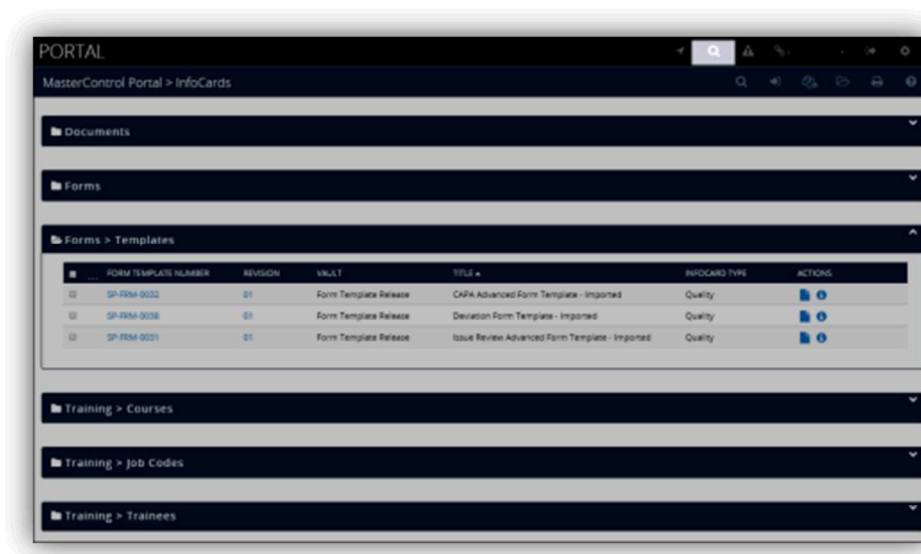
8.10.1 The Search function offers three search methods: Simple, Basic, and Advanced, which behave similarly in the Portal and Toolbar searches. Search results display only InfoCards that belong to vaults for which the user has rights.

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



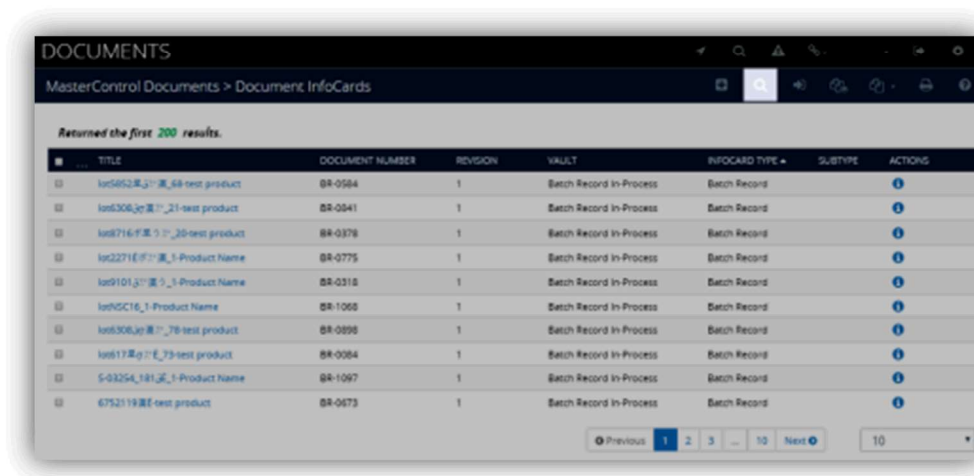
8.10.2 Portal Search

8.10.2.1 Locate the **Portal Search toolbar** at the top of the page from anywhere in the MasterControl interface. When the user searches 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.



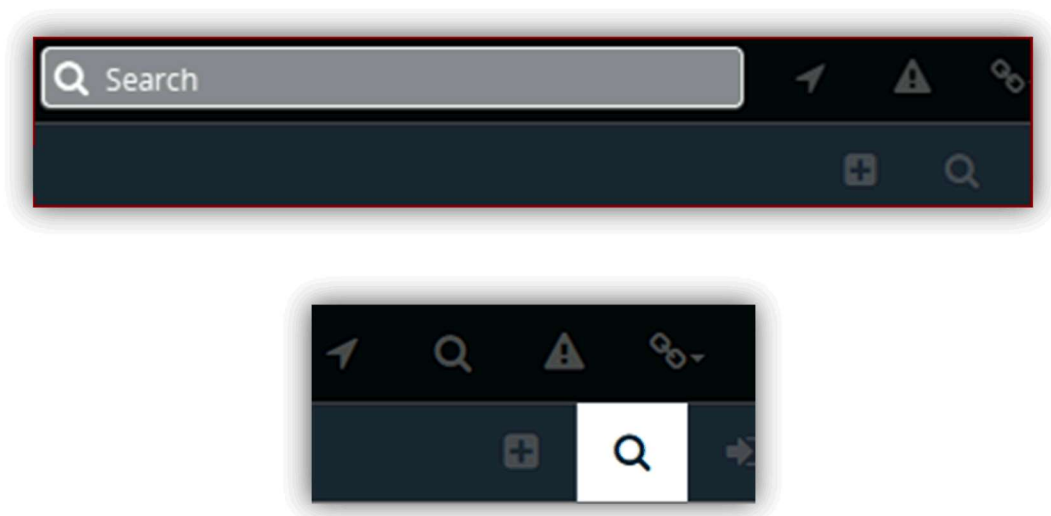
8.10.3 Toolbar Search

- 8.10.3.1 Locate the Toolbar Search from the InfoCard list page toolbar. The Toolbar Search returns only results from the InfoCard list page from which the user initiates 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.



8.10.4 Simple Search

- 8.10.4.1 **Simple** Search displays a single field for the user to specify their search criterion. The system compares the values typed in the search field against all searchable fields.
- 8.10.4.2 Select either the Portal or the Toolbar Search option.



8.10.4.3 Click Simple.

8.10.4.4 In the Search For field the user types the words for which they want to search.

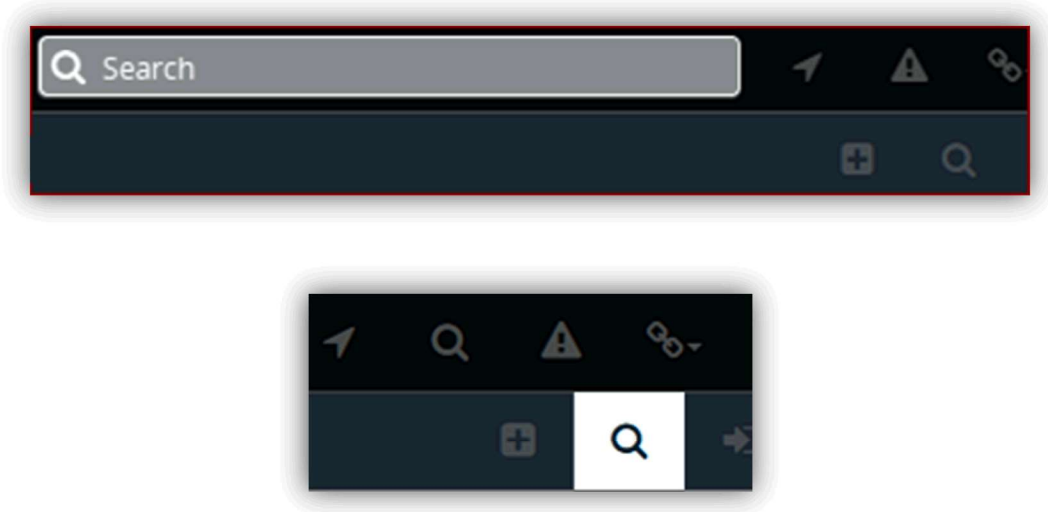
8.10.4.5 Click Submit Search and view the search results.

8.10.5 Basic Search

8.10.5.1 Use Basic Search's Query by Example feature to tailor a search and compare the values typed in the search fields against all searchable fields. An asterisk (*) can be used 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 an underscore is included in the search, wrap the underscore in brackets ([_]) so that the search recognizes the character as itself.

8.10.6 Select either the Portal or the Search option.



8.10.6.1 Click Basic.

8.10.6.1.1 In one or multiple fields, type the search criteria.

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

8.10.6.1.2 Click **Submit Search**.

8.10.7 Advanced Search

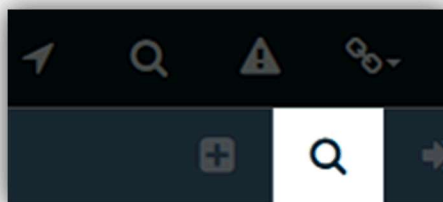
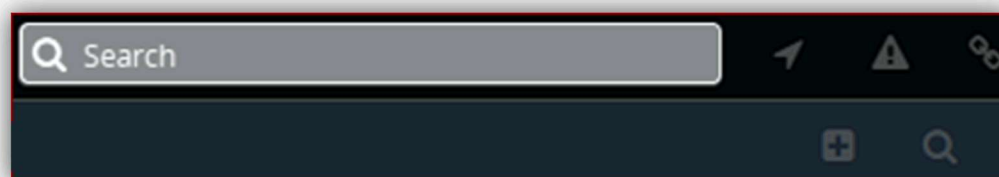
8.10.7.1 **Advanced Search** is used to narrow search results to specific values in particular fields. The user can also select a field, an

operator, and a field value for the search, as well as add more search fields.

8.10.7.2 When adding additional fields, if the user wants results to include information typed in all of the specified fields, the "and" logic should be used. If the user wants the results to include information typed in either one field or the other(s), but not all, the "or" logic should be used.

8.10.7.3 When populating the Value field, an underscore (_) can be used as a single-character wildcard for any character, including letters and numbers. If the search is for a term which includes an underscore, the underscore should be wrapped in brackets ([_]) so the search recognizes the character as itself.

8.10.8 Select either the Portal or the Toolbar Search option.



8.10.8.1 Click Advanced.

| FIELD | OPERATOR | VALUE | LOGIC | |
|-----------------|-------------|-------------|-------|-----|
| Author | Equals | wood0081 | And | + - |
| InfoCard Number | Contains | ccbb-col | And | + - |
| Effective Date | On or After | 30 Dec 2019 | | + - |

Open Save Search Clear Submit Search

- 8.10.8.1.1 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.

- 8.10.8.1.2 Select an Operator from the drop-down list:

- Contains
- Does Not Contain
- Ends With
- Equals
- Starts With
- Is Null
- Is Not Null

- 8.10.8.1.3 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.

- 8.10.8.1.4 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.

- 8.10.8.1.5 Click **Submit** Search.

8.10.9 Full Text Search (FTS)

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

NOTE: It does not recognize headers or footers.

- 8.10.9.1 To perform a FTS, use the **Advanced** search method as described in Section 8.10.7.

- 8.10.9.1.1 Select the **Full Text Search** option from the drop-down list and enter the desired values in the appropriate fields.

| FIELD | OPERATOR | VALUE | LOGIC | |
|------------------|-------------|-----------------|-------|-----|
| Full Text Search | Contains | sodium chloride | And | + - |
| Vault | Starts With | stcl- | And | + - |
| Vault | Ends With | rel | | + - |

Open Save Search Clear Submit Search

SAMPLE

8.11 MasterControl Icons

- 8.11.1 Hovering or pausing over an icon reveals the name/function of that particular option.
- 8.11.2 An Icon Directory can be found in the **HELP** (item #6, Section 8.1.2) tile of any module.

8.12 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** displayed on a Document InfoCard.

MasterControl Documents > View Document InfoCard

Document Number

COMM-QA-042

Revision

17

Version

1

Title

Deviations and Investigations

Notes

Lifecycle

COMM-QA

Vault

COMM-QA-rel

Document InfoCard Type

COMM-QA

Subtype

None

Status: Release

*Information

Training

Controlled Copies

Attachments & Links

Custom Fields

History

Status

Versions

Main File

File Name

COMM-QA-042 Deviations and Investigations.docx

File Size

61.91 KB

☐ Include signature manifest on gateway export

Date Information

Created

26 Jan 2022

Released

14 Feb 2022

Effective

14 Feb 2022

Expires

Moved to Phase

14 Feb 2022

Next Review

14 Feb 2024

Training

Enable all training

8.13 InfoCard Page Tabs

8.13.1 InfoCard information is stored in tabs within each InfoCard page. An InfoCard may contain any or all of the following tabs (depending on application).

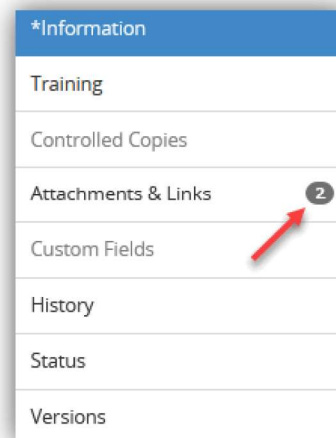
8.13.1.1 Information – includes general data about the InfoCard including Version, Main File, Date, and Standards

8.13.1.2 Training – displays a list of all training tasks to which the Document InfoCard has been linked.

8.13.1.3 Controlled Copies – contains copy information such as Location

8.13.1.4 Attachments & Links – contains information about the attached document(s) and other applicable links.

8.13.1.4.1 **Attachments & Links Indicator** is a number indicator display on the **Tab** indicating the number of attachments and/or links associated with a particular Document InfoCard. This indicator updates upon saving.



8.13.1.5 Custom Fields – includes information about the InfoCard's Custom fields.

8.13.1.6 History – contains information about the history of the InfoCard including Vault, Review Date, Release Date, Effective Date, Expiration Date, and Actions.

8.13.1.7 Status – displays the InfoCard's status information, including Locked, Workflow.

8.13.1.8 Versions – contains information about the previous versions of the InfoCard.

8.14 PDF Files

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

8.14.2 MasterControl generates PDF files to “*sandwich*” the actual document between a cover page and a signature manifest page.

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

8.14.2.2 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 Online Help

10.2 FDA 21 CFR Part 11

11 REVISION HISTORY

| Revision No. | Author | Description of Change(s) |
|--------------|-----------|---|
| 09 | B. Jordan | <ul style="list-style-type: none"> Added definitions for ODT, Production Site, and Security Questions in DEFINITIONS/ACRONYMS section. To address DEV-1394, added a NOTE to the “System Login to MasterControl Portal Home Page” section to inform new users that their MasterControl User account would be locked until the completion of their ODT coursework. Updates made to reflect system upgrade to v2022.3 cloud-hosted. Information/enhancements added in Section 8: <ul style="list-style-type: none"> 8.1.2 – Scroll Bar 8.4 – Forgot Your Esig? 8.12.1.4. – Attachments & Links Indicator |

Signature Manifest**Document Number:** COMM-QA-061**Revision:** 09**Title:** MasterControl User Procedures - Documents for View-Only Users**Effective Date:** 03 Oct 2022

All dates and times are in Eastern Time.

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

| Name/Signature | Title | Date | Meaning/Reason |
|---------------------|-------|--------------------------|----------------|
| Betsy Jordan (BJ42) | | 28 Sep 2022, 07:02:45 AM | Approved |

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| Joanne Kurtzberg (KURTZ001) | | 28 Sep 2022, 08:43:30 AM | Approved |

Quality

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|-------------------|-------|--------------------------|----------------|
| Beth Elder (EYE3) | | 29 Sep 2022, 11:31:18 AM | Approved |

Document Release

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| Sandra Mulligan (MULLI026) | | 29 Sep 2022, 11:36:14 AM | Approved |