

**DUKE****DOCUMENT NUMBER:** COMM-QA-060**DOCUMENT TITLE:**

MasterControl User Procedures - Documents

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## **COMM-QA-060**

# **MASTERCONTROL USER PROCEDURES – DOCUMENTS**

### **1 PURPOSE**

- 1.1 This procedure provides the details for using and navigating MasterControl Documents.

### **2 INTRODUCTION**

- 2.1 The document management system, MasterControl, will provide the ability to create, route, and control all document control tasks.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 This procedure covers the operational (systematic) instructions on how to use MasterControl as a Creator/Revisor 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 Change Control Request (CCR) – A vehicle used in the process of approving and documenting changes to controlled documents, processes, equipment, operations, and design change(s) to ensure compliance with applicable regulatory requirements.
- 4.3 Collaboration – Collaboration is a MasterControl application that allows a user to work jointly with other users (a.k.a “collaborators”) on a document in an electronic route.
- 4.4 Creator/Revisor Users – Users that have the ability to view, create, edit, approve, and reject documents.
- 4.5 DCO – Document Control Operations
- 4.6 DUO – A service used for multi-factor authentication (MFA).
- 4.7 Esig – Abbreviation for electronic signature that is considered as a legally acceptable and functionally binding equivalent of a paper-based signature.
- 4.8 Fields – Space allocated for specific information or a certain piece of information.
- 4.9 HTML (Hypertext Markup Language) – A standard language used to create online eForms.
- 4.10 Hyperlink – An electronic link providing direct access from one distinctively marked place in a document to another in the same or a different document.

- 4.11 InfoCard – The InfoCard controls access to documents as well as the functions available to each user. InfoCards are the core of MC.
- 4.12 MasterControl (MC) Portal/Documents – A configurable off-the-shelf software system used for the automation and control of document approval, change control, distribution processes, and employee qualification (training).
- 4.13 MasterControl Portal – Provides the gateway and access to all major functions needed to set up and maintain the MasterControl applications.
- 4.14 MFA (Multi-factor Authentication) – This action provides an additional layer of security when logging in to a Duke system. A user is required to enter a password and also authenticate by using a second factor, typically an iPhone.
- 4.15 Native application – Referring to the original system or application used to create a document; e.g., Microsoft Word.
- 4.16 ODT – On-Demand Training via the MasterControl Customer website.
- 4.17 OIT – Duke Office of Information Technology.
- 4.18 Okta – An enterprise-grade, identity management service, built for the Cloud.
- 4.19 Packet – The vehicle that carries an object (a task) through an approval cycle.
- 4.20 Production Site – This is where the MasterControl licensed software is installed, and it is used as a repository of our controlled documents.
- 4.21 Route – A route is the *workflow* component of a task. A route is composed of a series of steps, which include a predefined sequence of users who must act upon the task contents.
- 4.22 Security Questions – Questions that are a common method of identity authentication.
- 4.23 SOP – Standard Operating Procedure
- 4.24 System Administrator – The person in the position responsible for the administration, configuration, and control of the MasterControl software.
- 4.25 Task – An assigned piece of work to be completed within a certain time.
- 4.26 Tiles and Hubs – MasterControl’s design of their user interface (UI).
- 4.27 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.
- 4.28 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are of three (3) common types: Draft, Release, Archive.

## **5 MATERIALS**

### **5.1 NA**

## **6 EQUIPMENT**

### **6.1 Computer to access MasterControl.**



## 7 SAFETY

### 7.1 NA

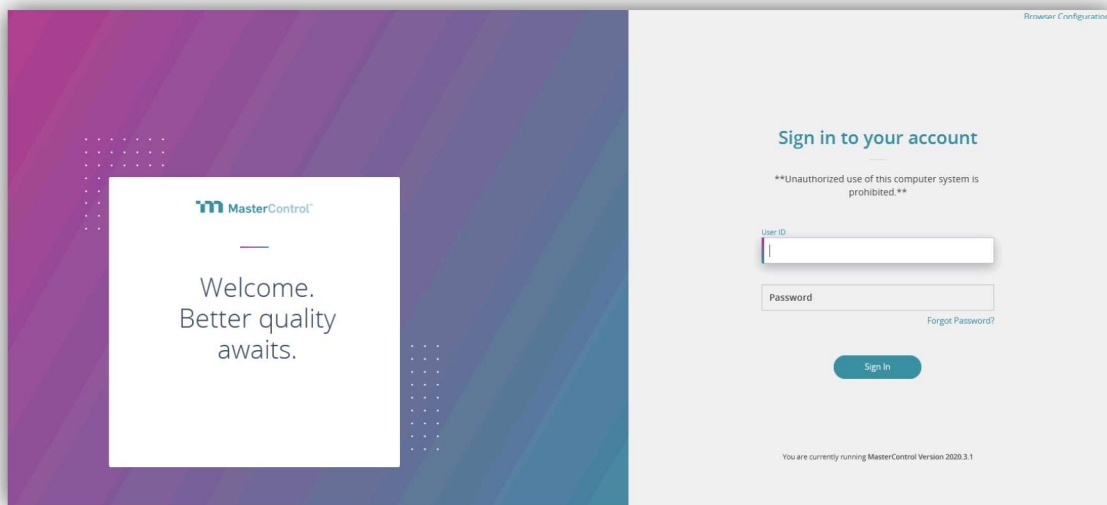
## 8 PROCEDURE

### 8.1 Components of MasterControl

**NOTE:** MasterControl is validated using Firefox and Chrome. Explorer (IE) or Microsoft EDGE are not to be used.

#### 8.1.1 User Interface (UI)

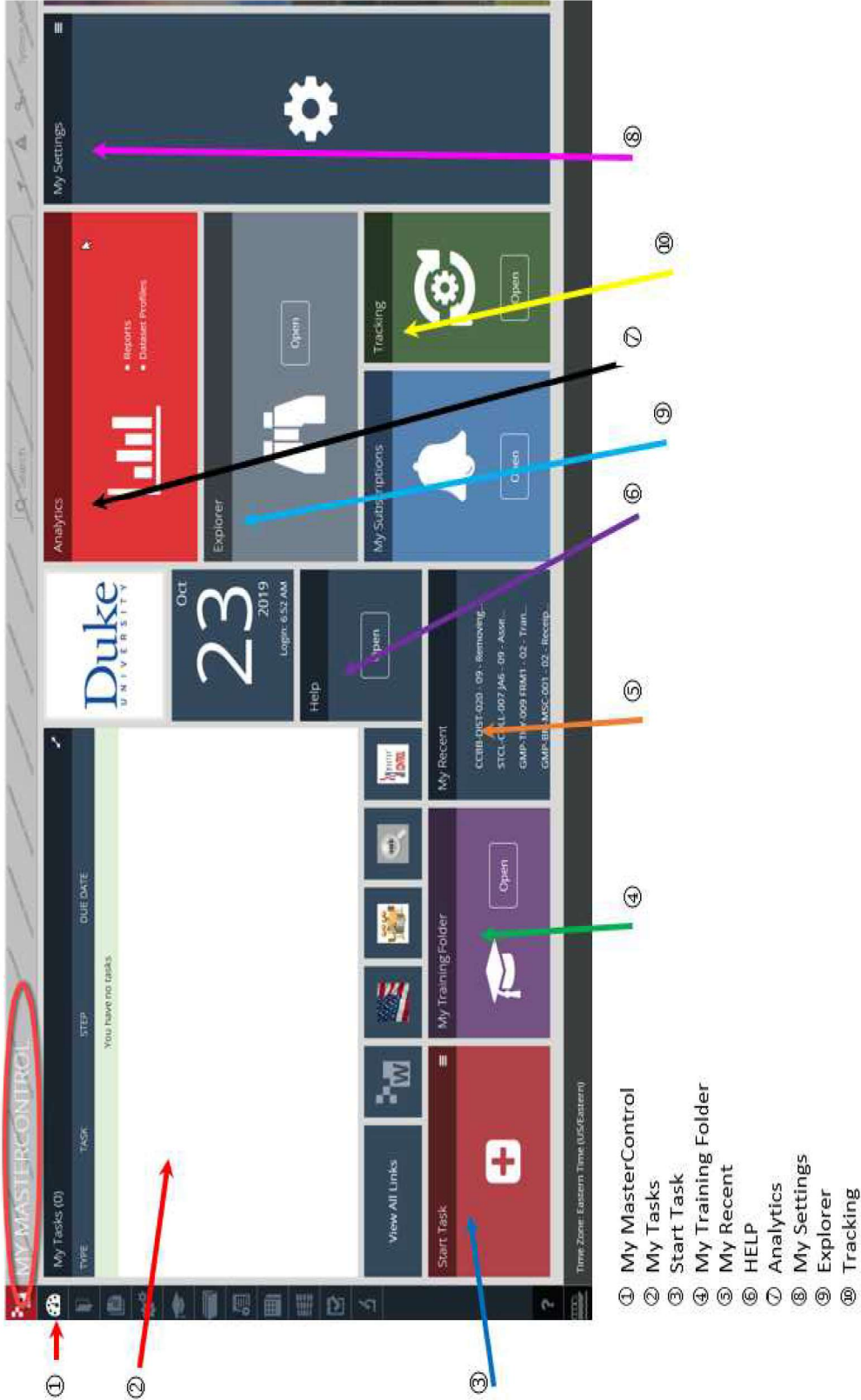
8.1.1.1 This upgraded version of MasterControl maintains the same Sign In screen as the previous version.





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.



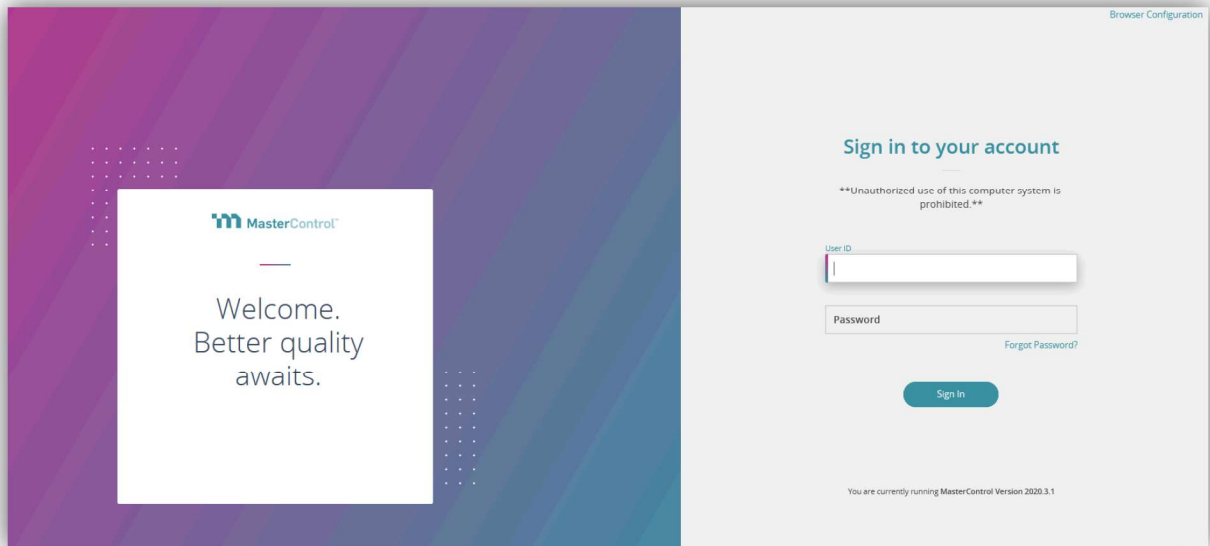
## 8.2 System Login to MasterControl Portal Home Page

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.

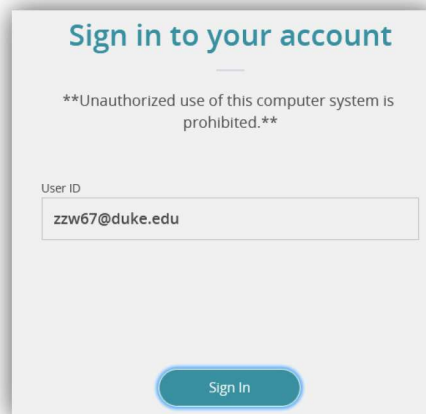
The MasterControl Login Screen displays.



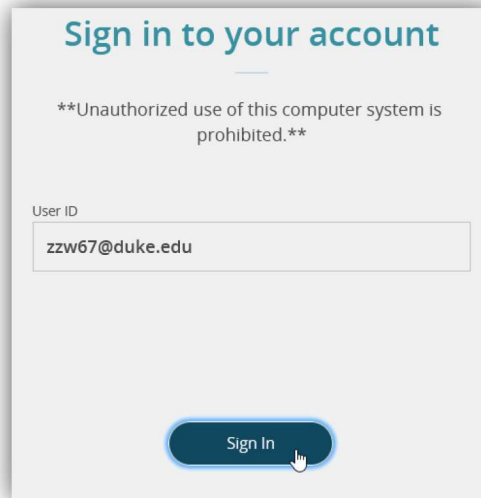
**NOTE:** A new user's MasterControl User account is **locked** preventing access to the Production site until completion of the ODT via the MasterControl Customer website. This coursework is outlined in the orientation email sent to new users from DCO. **Once this training has been completed, the user 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 user's Duke NetID followed by @duke.edu

**NOTE:** Example: [zzw67@duke.edu](mailto:zzw67@duke.edu)



- 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

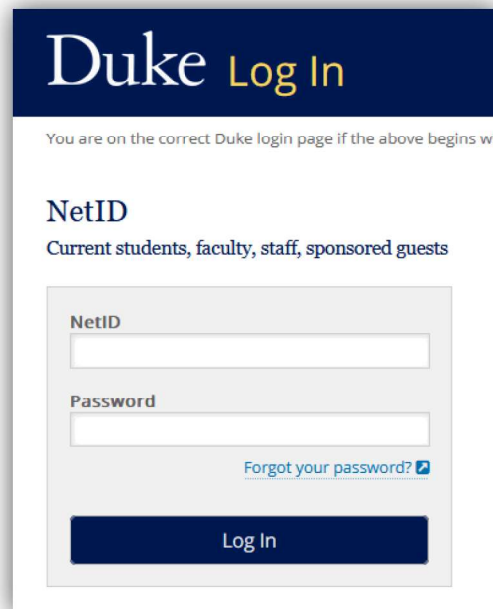
\*\*Unauthorized use of this computer system is prohibited.\*\*

User ID

zzw67@duke.edu

Sign In

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



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

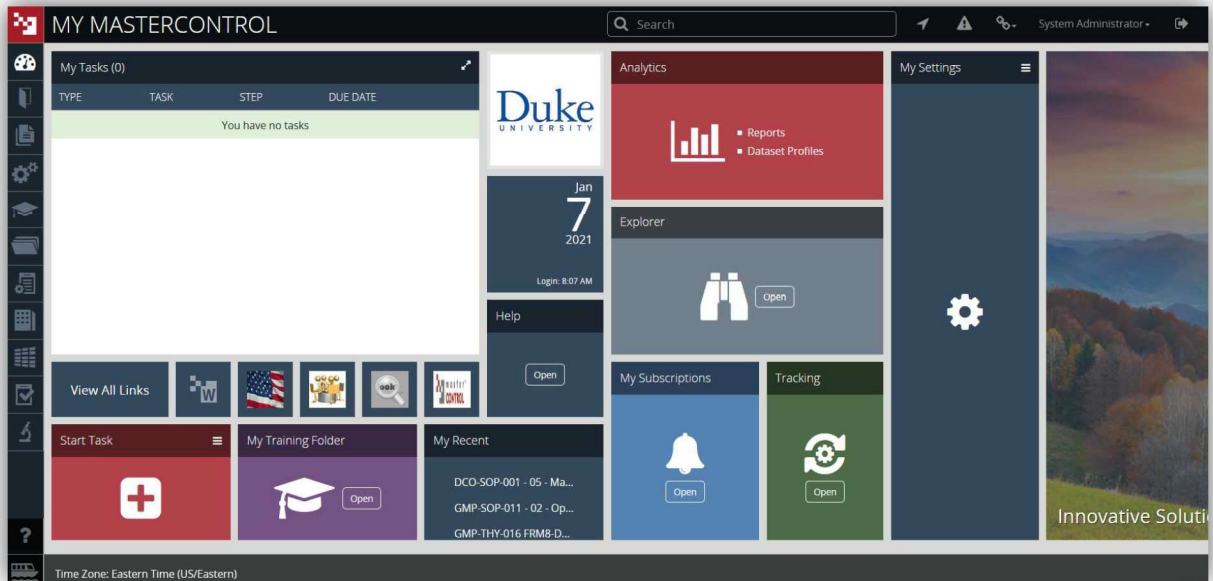
[Forgot your device?](#)

[Have a new device?](#)

**Log In**

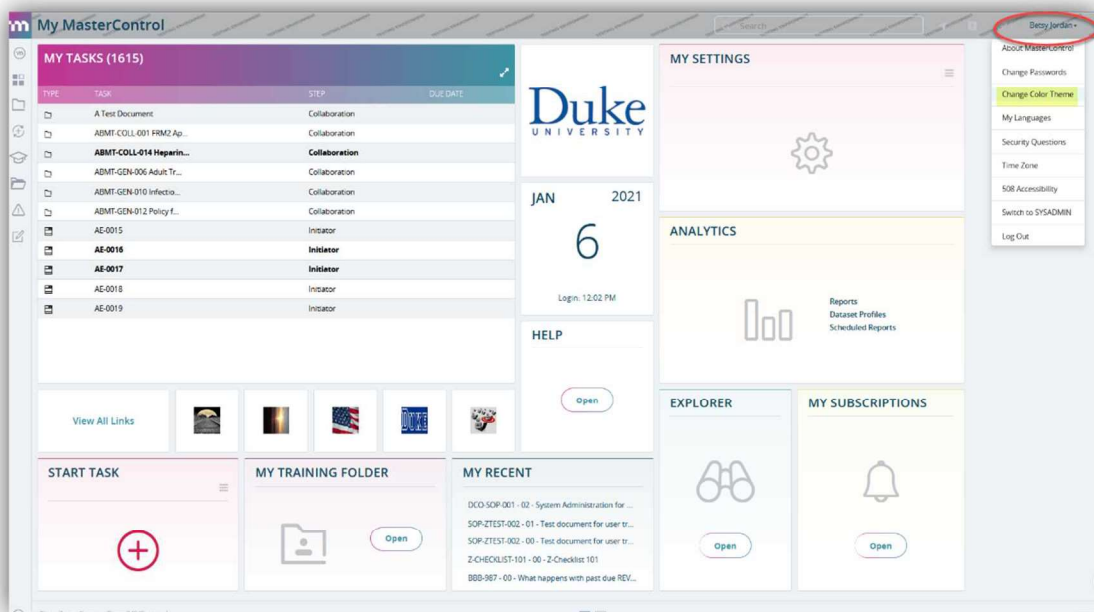
8.2.9 Click Log In.

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.

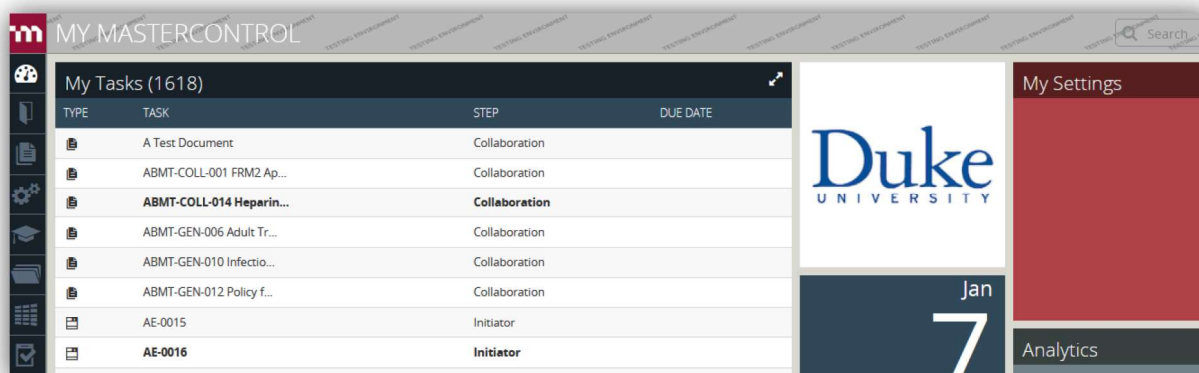


### 8.3.2 Color Theme changed.



## 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.

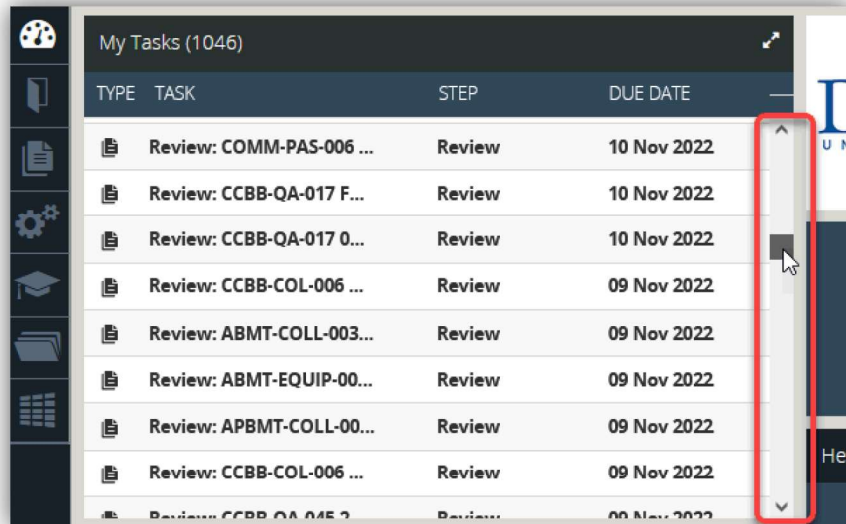


## 8.5 My Tasks

8.5.1 The **My Tasks** page (item #2, Section 8.1.2) is where the user will find all of the tasks which require their attention (document the user needs to complete, access the collaboration workspace, documents needing revision, or sign off on any task requiring approval). **My Tasks** provides easy access to all the user's pending tasks.

8.5.1.1 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.

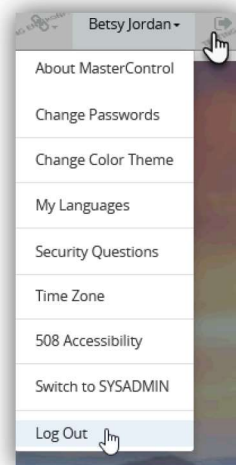




My Tasks (1046)			
TYPE	TASK	STEP	DUE DATE
Review	Review: COMM-PAS-006 ...	Review	10 Nov 2022
Review	Review: CCBB-QA-017 F...	Review	10 Nov 2022
Review	Review: CCBB-QA-017 O...	Review	10 Nov 2022
Review	Review: CCBB-COL-006 ...	Review	09 Nov 2022
Review	Review: ABMT-COLL-003...	Review	09 Nov 2022
Review	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

## 8.6 My Settings

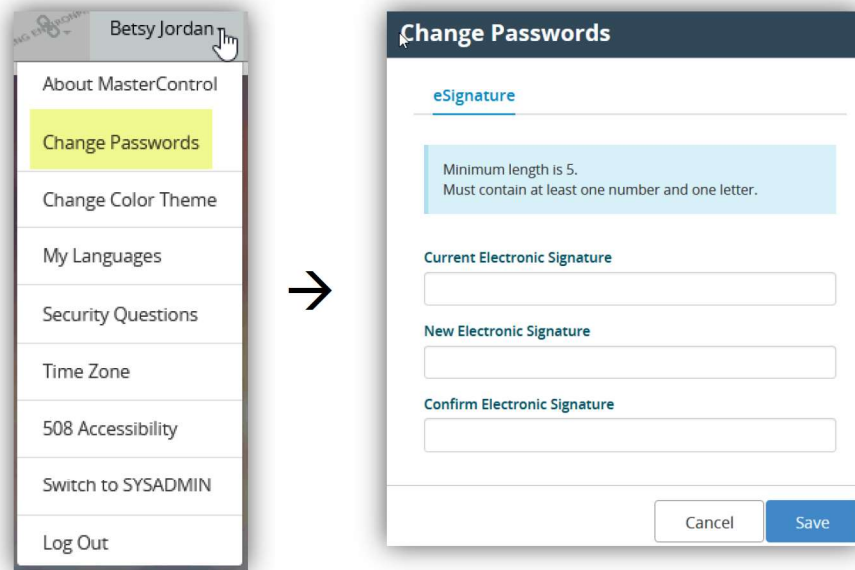
- 8.6.1 When you are logged in to MasterControl Portal, the main application header contains a number of items. Clicking on the **MasterControl** icon (item #1, Section 8.1.2) in the top-left will return the user to the MasterControl Portal Home Page from any other page.
- 8.6.2 The **Log Out** link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

## 8.7 Change Passwords

- 8.7.1 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
- 8.7.2 Click the User Name drop-down menu; select **Change Passwords**.



8.7.3 The Change Passwords screen will display.

8.7.4 Then the **eSignature** tab will display.

8.7.5 Satisfy the specific requirements for the esig password.

8.7.5.1 Minimum esig characters = 5

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

8.7.5.3 Expires after 90 days and must be reset.

8.7.5.4 Lockout occurs after five (5) attempts if the requirements for eSignature are not met.

**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.

8.7.6 Click **Save**.

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

8.7.8 Click **Save**.

8.8 Forgot Your Esig?

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

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



The screenshot shows a window titled "Electronic Signature Assistance" with a close button in the top right corner. The main heading is "Security Questions". Below it, there are two questions: "What was the color of your first car?" and "In what town was your first job?". Each question has a corresponding text input field. At the bottom of the window is a blue "Submit" button.

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

The screenshot shows a "Change Electronic Signature" screen. It features a light blue informational box stating: "You must change your Electronic Signature before continuing. Minimum length is 5 characters and will expire after 90 days. Must be alphanumeric." Below this, there are two required fields: "\* New Electronic Signature (Minimum Length 5)" and "\* Confirm Electronic Signature", both represented by masked input fields. At the bottom right, there are "Cancel" and "Submit" buttons. A mouse cursor is shown clicking the "Submit" button.

- 8.8.4 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.

## 8.9 Out of Office

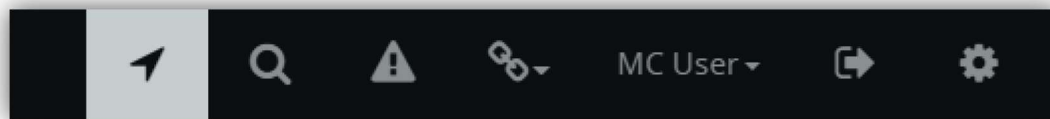
- 8.9.1 Users can set their own account status to **Out of Office**. When a user's out of office starts, the feature forwards selected approval, document, and forms tasks to a designated alternate.

8.9.1.1 Generally, Out of Office is used if a user is scheduled to be out for an extended period of time.

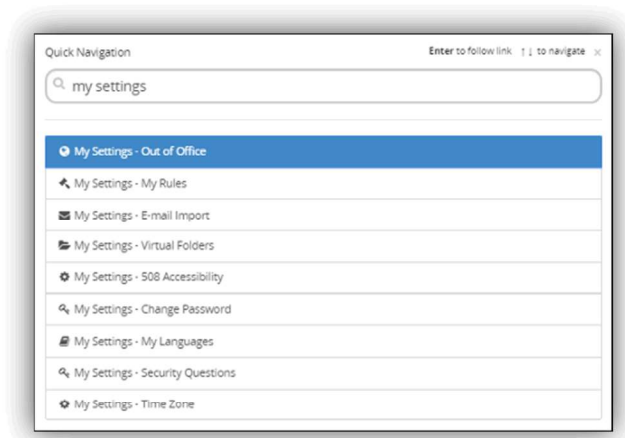
**NOTE:** Training tasks cannot be redirected.

8.9.1.2 In the My Settings tile (item #8, Section 8.1.2), check **Out of Office**.

8.9.1.3 OR click **Quick Navigation**.



- 8.9.1.4 Type **My Settings** to locate and select the **Out of Office** option.



- 8.9.1.5 Click the open selector to search for and select an alternate.

**NOTE:** Ensure to have the alternate's permission prior to setting the OOO.

- 8.9.1.6 Choose the **Start Date** and **End Date** by using the calendar selector for future occurrences or click the **Today's Date** option to set the user's Out of Office for the current day. The **End Date** is still required in the event of an open-ended absence.
- 8.9.1.7 Click a radio button to determine whether or not to include in-process tasks.
- 8.9.1.8 By default, all eligible tasks are directed to the Alternate. To select specific tasks, click **Selected Tasks** and move the tasks to **Selected Tasks**.

Redirect these incoming tasks to Alternate

☐ All Tasks  
☒ Selected Tasks

Available Tasks



- 2-Step Route
- ABMT - Collab+Appv
- ABMT - Collab+Appv (copy)
- ABMT Approval Route
- AE
- APBMT - Collab+Appv
- APBMT Approval Route
- Action Item

Selected Tasks

- GMP - Collab+Approval

Navigation buttons: > < >> <<

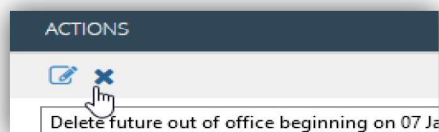
8.9.1.9 To modify or cancel a scheduled Out of Office event, click **Modify** or **Cancel** for the specific event.

Future Scheduled Out of Office			
ALTERNATE	START DATE	END DATE	ACTIONS
AHANSEN	26 Apr 2018 12:00 AM	27 Apr 2018 11:59 PM	 

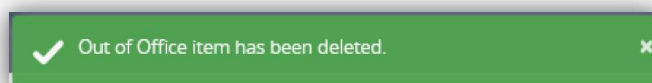
8.9.1.10 Click **Save**.

## 8.10 Ending Out of Office Status

- 8.10.1 When a user logs in to MasterControl for the first time **after** changing their status to Out of Office, the user is prompted to change their status to **In Office**.
- 8.10.2 When the reminder appears, click OK.
- 8.10.3 To end the Out of Office status and return to In Office, click the **X** under the **ACTIONS** column.



8.10.4 Click OK to delete the OOO setting.





## 8.11 My Links

8.11.1 **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.

8.11.1.1 For help on creating Links, users can visit the **Help** (item #6, Section 8.1.2) or contact DCO.

## 8.12 Start Task

8.12.1 When new eForms need to be filled out, the eForms are sent on specific **Data Entry Workflows** in HTML format from the Start Task tile (item #3, Section 8.1.2) on the Home Portal page.

## 8.13 Tracking

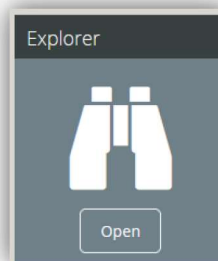
8.13.1 All tasks are tracked during the approval process and retained after they have completed their respective workflows. From the **My MasterControl Tracking** page, a user can search for a specific task, and then view the status or history details of the task, along with its file or form. Task details 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.

## 8.14 My Recent

8.14.1 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.

## 8.15 Explorer

8.15.1 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.



8.15.1.1 Select the Organizer to view by clicking.

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



## 8.16 My Training Folder

8.16.1 **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.

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

## 8.17 Analytics

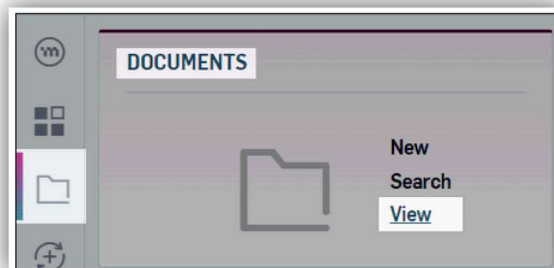
8.17.1 The **Analytics** menu (item #7, Section 8.1.2) allows a user to access reports to which a user has rights in MasterControl Analytics. From this menu item in the **My MasterControl** section, a user can view MasterControl Analytics reports for all installed applications. Each application in the menu also has a "Reports" menu item, which allows a user to access reports for that application.

## 8.18 Manage My Subscriptions

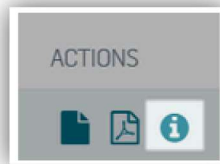
8.18.1 Track changes to any Document InfoCard by subscribing to those InfoCards. After subscribing to a Document InfoCard, users are notified any time a change takes place.

**NOTE:** A user must access their Subscriptions in MasterControl to view notifications about their subscribed InfoCards.

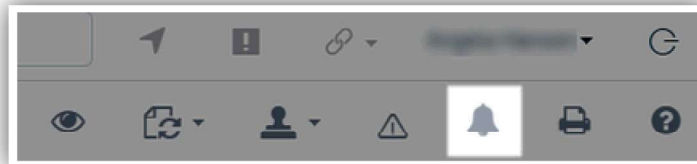
8.18.2 Click Documents > Document > View or search for the preferred InfoCard.



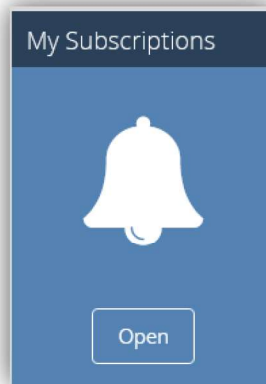
8.18.3 Click View InfoCard for the InfoCard to track.



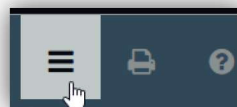
8.18.4 Click the Subscribe icon

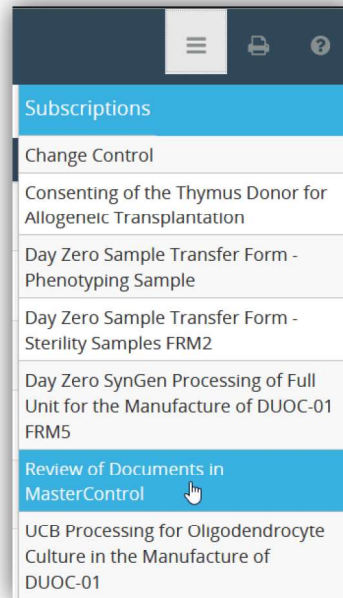


8.18.5 Click **My MasterControl** > **My Subscription** > **Open** to view the changes to the subscription.

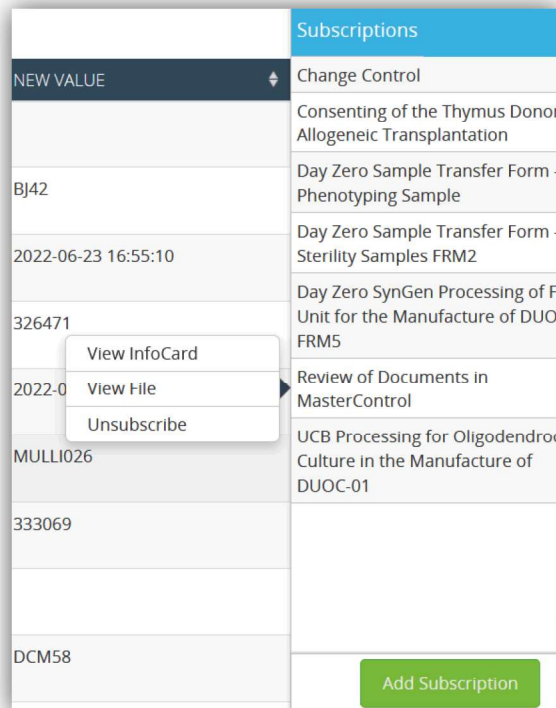


8.18.6 Click **EXPAND** to open the **Subscription sidebar**





8.18.7 Click a subscription name and select an option or click the **Add Subscription** button to search for InfoCard(s) to add to the **My Subscription List**.



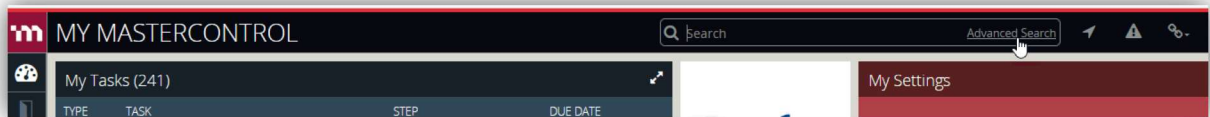
8.18.8 To **close** this window, navigating away from the **My Subscription**.



## 8.19 Search MasterControl

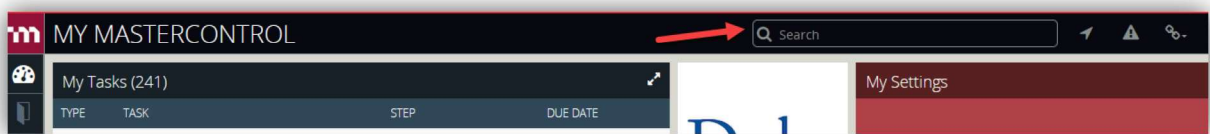
- 8.19.1 The Search function offers three search methods: Simple, Basic, and Advanced, which behave similarly in the Portal and Toolbar searches. Search results display only InfoCards that belong to vaults for which a user has rights.

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



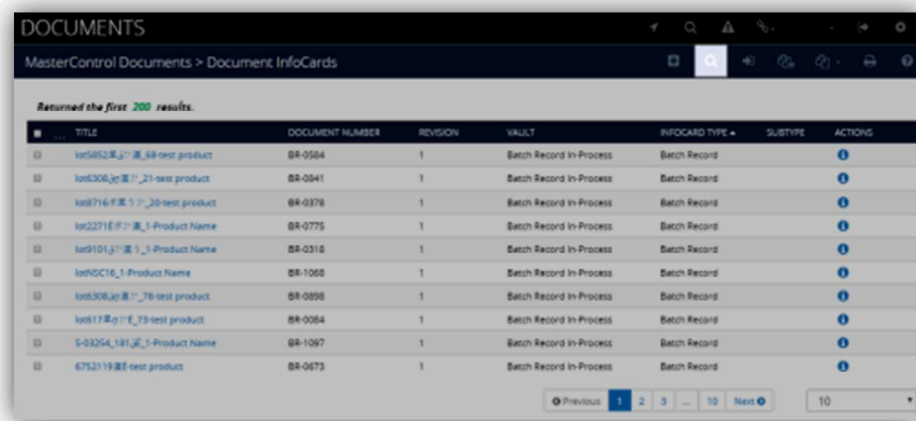
### 8.19.2 Portal Search

- 8.19.2.1 Locate the **Portal Search toolbar** at the top of the page from anywhere in the MasterControl interface. When a 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.



### 8.19.3 Toolbar Search

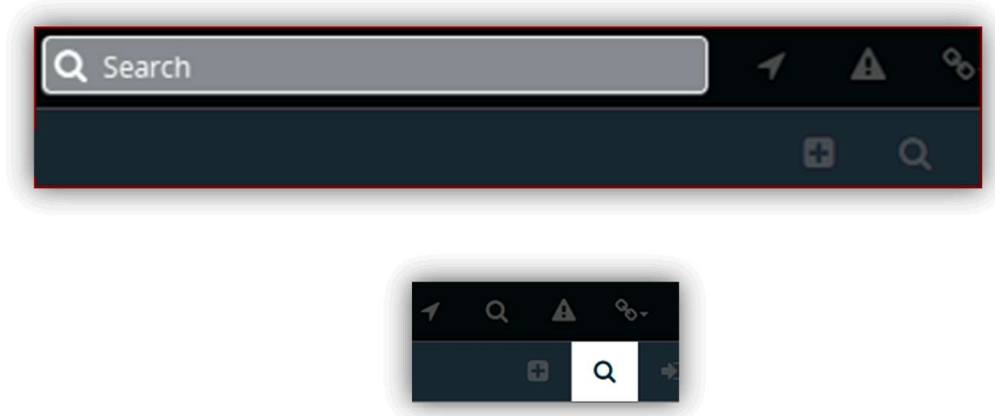
- 8.19.3.1 Locate the Toolbar Search from the InfoCard list page toolbar. The Toolbar Search returns only results from the InfoCard list page from which the user initiates the search. Results are displayed in a sortable InfoCard list. Click the checkbox for one or more of the InfoCards to perform actions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



## 8.19.4 Simple Search

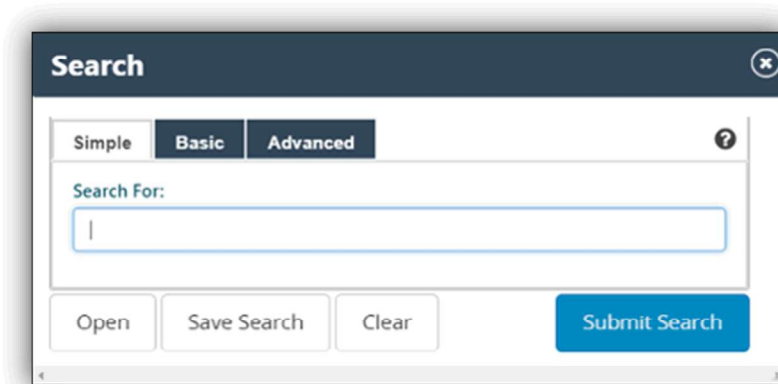
8.19.4.1 **Simple** Search displays a single field for the user to specify their search criterion. The system compares the values typed in the search field against all searchable fields.

8.19.4.2 Select either the Portal or the Toolbar Search option.



8.19.4.3 Click Simple.

8.19.4.4 In the Search for field, type the words for which they want to search.



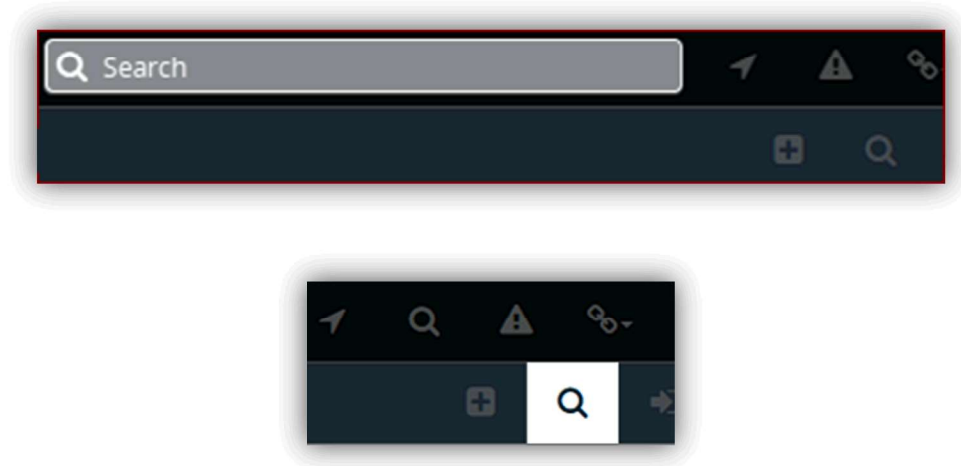
8.19.4.5 Click Submit Search and view the search results.

## 8.19.5 Basic Search

8.19.5.1 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 the user includes an underscore in their search, wrap the underscore in brackets ( [ \_ ] ) so that the search recognizes the character as itself.

#### 8.19.6 Select either the Portal or the Search option.



##### 8.19.6.1 Click Basic.

##### 8.19.6.1.1 In one or multiple fields, type the search criteria.

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

##### 8.19.6.1.2 Click **Submit** Search.

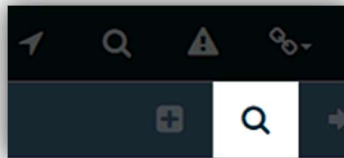
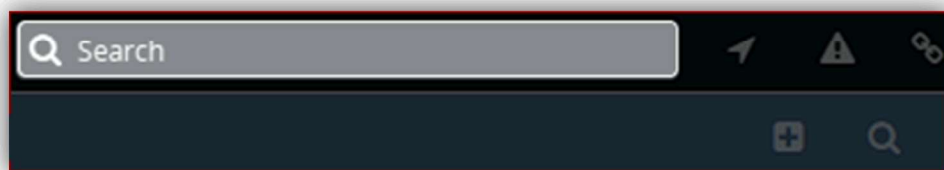
#### 8.19.7 Advanced Search

**8.19.7.1 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.

8.19.7.2 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.

8.19.7.3 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.

8.19.8 Select either the Portal or the Toolbar Search option.



8.19.8.1 Click Advanced.

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

Buttons: Open, Save Search, Clear, Submit Search, Calendar View

8.19.8.1.1 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.



## 8.19.8.1.2 Select an Operator from the drop-down list:

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

## 8.19.8.1.3 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.

## 8.19.8.1.4 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.

8.19.8.1.5 Click **Submit** Search.

## 8.19.9 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.

8.19.9.1 To perform a FTS, use the **Advanced** search method as described in Section 8.19.7.8.19.9.1.1 Select the **Full Text Search** option from the drop-down list and enter the desired values in the appropriate fields.

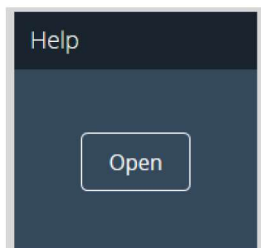
The screenshot shows the 'Search' window with the 'Advanced' tab selected. It displays a table with columns: FIELD, OPERATOR, VALUE, LOGIC, and action buttons (+ and -). The table contains three rows of search criteria:

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

At the bottom of the window, there are buttons for 'Open', 'Save Search', 'Clear', and 'Submit Search'. A red 'SAMPLE' watermark is overlaid on the bottom right of the interface.

## 8.20 MasterControl Icons

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



8.21 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

File Name

COMM-QA-042 Deviations and Investigations.docx

File Size

61.91 KB

☐ Include signature manifest on gateway export

Created

26 Jan 2022

Effective

14 Feb 2022

Moved to Phase

14 Feb 2022

Released

14 Feb 2022

Expires

Next Review

14 Feb 2024

Training

Enable all training

\*Information

Training

Controlled Copies

Attachments & Links

Custom Fields

History

Status

Versions

## 8.22 InfoCard Page Tabs

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

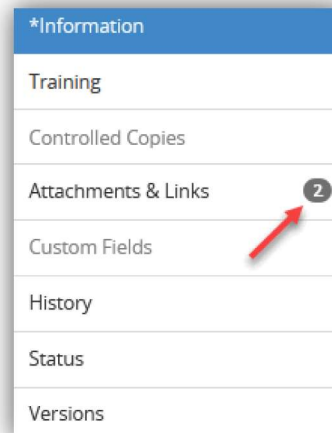
8.22.1.1 Information – includes general data about the InfoCard including Version, Main File, Date, and Standards

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

8.22.1.3 Controlled Copies – contains copy information such as Location

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

8.22.1.4.1 **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.



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

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

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

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



## 8.23 Creating and Revising Documents

**NOTE:** COMM-QA-057, *Procedure Development*, and COMM-QA-057 JA1, *Procedure Development SOP Template JA1*, define the steps required to develop/create a new procedure or document. A specific numbering scheme for the new document will be assigned by DCO when the document is entered into MC.

## 8.24 Creating New Document

### 8.24.1 Document Creator

- 8.24.1.1 Complete a Change Control Request (CCR) per procedures COMM-QA-019 FRM1 *Change Control Request (Effectiveness Check)*; or COMM-QA-019 FRM2 *Change Control Request (No Effectiveness Check)* for change controls for the CCBB or GMP programs)
- 8.24.1.2 For the ABMT, PBMT, and STCL programs, use COMM-PAS-004, *Change Control*.
- 8.24.1.3 Create the new document by following the COMM-QA-057 *Procedure Development* and COMM-QA-057 JA1 *Procedure Development SOP Template JA1*.
- 8.24.1.4 Email the new document with additional instructions, if needed, to DCO for entry into MasterControl.
- 8.24.1.5 Upon approval of the CCR, DCO will create a Document InfoCard for the new document and launch the document packet for collaboration, review, and/or approval in MC.

## 8.25 Revising Existing Document

### 8.25.1 Document Initiator

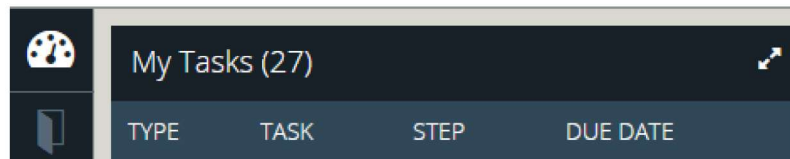
- 8.25.1.1 Complete a Change Control Request (CCR) per procedures COMM-QA-019 FRM1 *Change Control Request (Effectiveness Check)* or COMM-QA-019 FRM2 *Change Control Request (No Effectiveness Check)* for change controls for the CCBB or GMP programs).
- 8.25.1.2 For the ABMT, PBMT, and STCL programs, use COMM-PAS-004, *Change Control*.
- 8.25.1.3 Edit the document by following the COMM-QA-057 *Procedure Development* and COMM-QA-057 JA1 *Procedure Development SOP Template JA1*.
- 8.25.1.4 Upon approval of the CCR, DCO will follow the instructions of the CCR and enter the file (or attach a new one if provided by the Author) into the system. The file will be launched for collaboration, review and/or approval in MC.

## 8.26 Collaboration

- 8.26.1 MasterControl Collaboration is used to receive feedback on document content from more than one user, allow users to sign off on documents, view comments from other users, and add comments for others to see.
- 8.26.2 When a collaboration leader adds a user to a task, a link to the task displays in My Tasks and directs the user to the Collaboration Workspace to complete the task and perform other collaboration functions.
- 8.26.3 Inclusion in the collaboration process affords the collaborator the opportunity for input to the content of a document. The role of a collaborator is to review the assigned document and provide timely feedback to the author based on the collaborator's unique expertise or perspective. To avoid duplication of work and/or implementation of a flawed document, feedback from the collaborator must be received before collaboration on the document is ended by the author. Once collaboration has closed, further change(s) must be incorporated in the next revision of the document. When this happens, not only must previous efforts be duplicated, it can result in a significant delay in implementation of the change(s).
- 8.26.4 This section details the steps required to collaborate on a task. Specific instructions for additional functions for a **Collaboration Leader** are detailed in Section 8.35. **Collaborator** information is detailed in Section 8.34.2

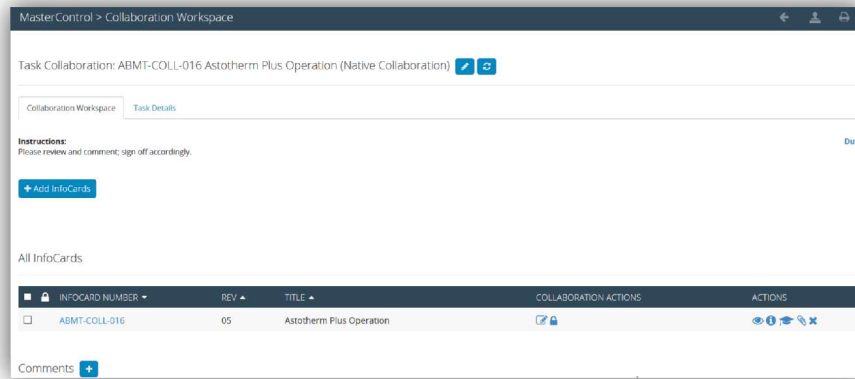
## 8.27 Collaboration Workspace

- 8.27.1 Click My MasterControl → My Tasks.



- 8.27.2 Click the Collaborate icon for the task the user wants to open the Collaboration Workspace.

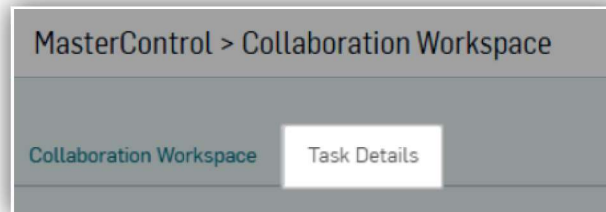




## 8.28 Manage Task Details

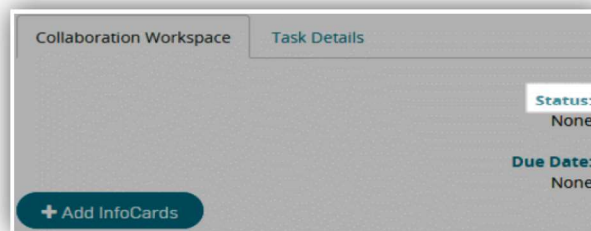
8.28.1 Manage the due date, instructions, task attachments from the Task Details tab.

8.28.1.1 In the Collaboration Workspace, click Task Details.



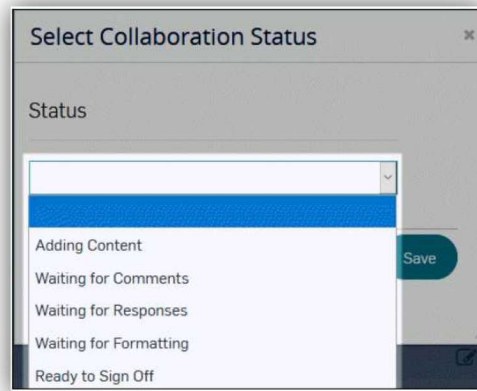
## 8.29 Set the Collaboration Status (optional)

8.29.1 Select an option to inform other collaborators of the collaboration current status.



8.29.2 In the Select Collaboration Status pop-up, click the drop-down and select an option.

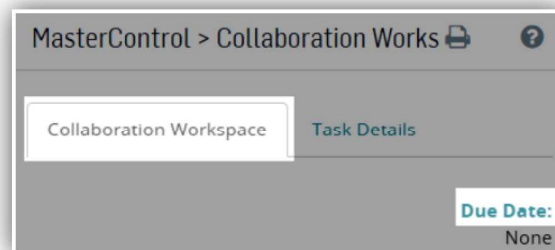




8.29.2.1 Click **SAVE**.

### 8.30 Set a Collaboration Due Date (*optional*)

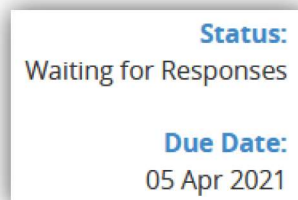
- 8.30.1 Set a due date for collaboration users during the process of a collaboration. When a collaboration task has a set due date, the date appears in the My Tasks page. This task displays in red on the day of the due date.
- 8.30.2 In the Collaboration Workspace, click Due Date.



- 8.30.3 In the Enter a Date field, click Calendar View and select a date or click Today's Date.



- 8.30.3.1 If options were selected, the Status and Due Date would appear like this:



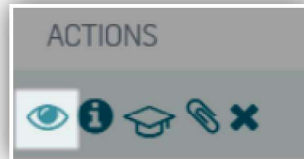


### 8.31 View and Edit a Collaboration

**NOTE:** Use the Collaboration Workspace to view or edit an InfoCard's main file. A user can also view previous redlines made to the main file.

When a user checks files out for redlining, MasterControl's Collaboration feature locks the InfoCard so other users cannot redline the same document until the file is either uploaded or unlocked. Collaboration Leaders can unlock any file, but other users can only unlock files they have locked.

8.31.1 In the Collaboration Workspace, click View File.



**NOTE:** When engaging this **View File** option, the file **CANNOT** be edited.

8.31.2 The **Comments** section allows users to exchange ideas and comment outside the context of a document. Collaborators can add comments, delete own comments, view other user's comments, and e-mail users.

8.31.3 Comments can either be added through the **Comments** section, or by entering them when signing off on a collaboration task. Comments made during sign-off are identified in the Comments section by a "**Sign-Off Comments**" subject.

8.31.4 To add a comment:

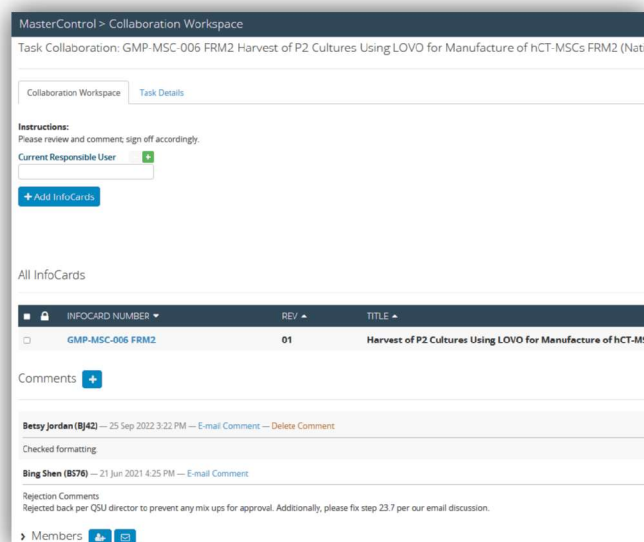
8.31.4.1 Tap **Add Comment** to expand the **Comments** field.

8.31.4.2 Type a message in the **Comments** field.

8.31.4.3 Click Add Comment.

8.31.4.4 If the user wants to delete a comment, click **Delete Comment** next to any comment they previously added.

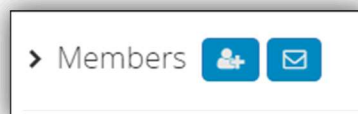
**NOTE:** A user can only delete *their own* comments; not comments from other users.



## 8.32 Manage Collaboration Members

**NOTE:** Manage collaboration members from the Members section of the Collaboration Workspace, even if the task already launched.

### 8.32.1 Click **Show** or **Hide** the Collaboration Members.

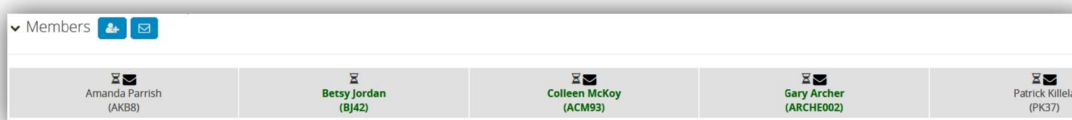


### 8.32.2 The Collaboration member names display in the following way:

Members		Member Name
Collaboration leader		Bold green text
Collaborators		Black text
Collaborators who have quit the collaboration		Gray text

Icons above the members' usernames indicate actions they took in the collaboration:

Icon	Description
Notified	The system has notified the user but the user has not entered the Collaboration Workspace.
In Process	The user opened the collaboration task.
Complete	The user completed the collaboration task.



- 8.32.3 You can e-mail any user in the collaboration by clicking the **E-mail** icon. Clicking the icon next to a user's name will e-mail that user. Clicking the icon at the top of the **Members** section will e-mail all the users in the list.




### 8.33 Modify Step

**NOTE:** All Collaboration Leaders are automatically granted the right to add or remove users from specific steps. This is called Modify Step. A Modify Step icon will display next to tasks in the user's Pending Task List to which they are the Collaboration Leader.

**NOTE:** During the course of a route, Collaboration Leaders may modify any step by adding or removing users.

**NOTE:** If the user or users they add to a step are **out of office**, they will receive an alert stating that the task will be assigned to their alternate.

- 8.33.1 Click the **Modify Step** icon (  ) located in the **ACTIONS** column of the **Pending Tasks** page or in the **MEMBERS** section of the Collaboration Workspace.

**NOTE:** A **Modify Step Error Message** displays when multiple users attempt to perform Modify Step changes concurrently – if a user's change *collides* with another user's changes via Modify Step, the user will receive a notification stating changes were not saved. If this happens, refresh the browser page then reattempt the changes.

- 8.33.2 To add a user(s), click the **GREEN + button**, type in user to add, click **GO**, and select correct user; then click **ADD**.

- 8.33.3 To remove a user, click on the user to be removed. Click on the **RED-button** to remove the user.



**Modify Step**

**Modify Step: A Test Document**

Use the controls to add and remove users to the selected step.  
**Note:** Adding a role will simply add all the users for that role when you save.

**Step**

Collaboration Undo Changes

**Users** Notification

**Leaders**

**Users**

- ☐ Amanda Parrish (AKB8)
- ☐ Betsy Jordan (BJ42)
- ☒ Erin Arbuckle (EPA9)
- ☐ Jennifer Frith (JLF29)

Remove selected items

**Modify Step**

Collaboration Undo Changes

**Users** Notification

**Leaders**

**Users**

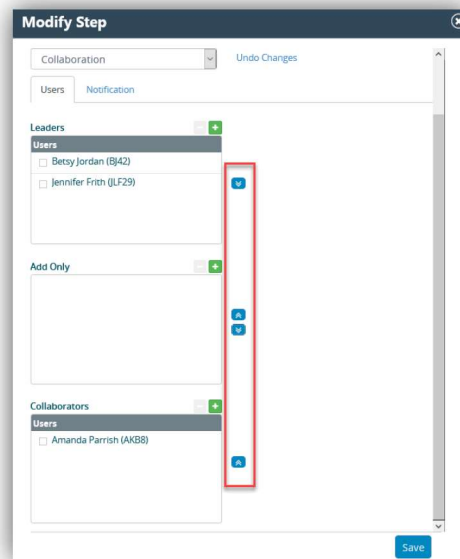
- ☐ Amanda Parrish (AKB8)
- ☐ Betsy Jordan (BJ42)
- ☐ Jennifer Frith (JLF29)

**Add Only**

**Collaborators**

**Save**

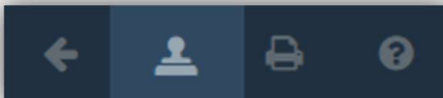
- 8.33.4 Click **SAVE**.
- 8.33.5 Use the **up and down arrows** to promote or demote a user to a different role; i.e., from the Collaboration Leader frame to Collaborators frame and vice versa.



#### 8.33.1 Click **Save**.

### 8.34 Signing Off on Collaboration

- 8.34.1 After the user completes their portion of the collaboration, choose one of the following sign-off options:
- 8.34.2 When their portion of the collaboration is complete (through adding redlines, comments, etc.), they are ready to sign off on the task. **COLLABORATORS** have two (2) options when signing off on a collaboration: **Complete** or **Complete and Quit**.
- 8.34.3 Selecting **Complete** allows the user to sign off on the collaboration. However, the user will receive notification each time a new redline has been uploaded, and the collaboration will reappear in the user's task list, allowing further input.
- 8.34.4 Selecting **Complete and Quit** allows the user to sign off on the collaboration. It also permanently removes the task from their task list (not to be seen again).
- 8.34.5 To sign off on a collaboration task, complete the following steps:
- 8.34.5.1 Upload the outstanding redline to the task.
- 8.34.5.2 Click the **Sign Off** button in the toolbar.



- 8.34.5.3 A user may elect to enter a comment in the **Comments** field, but it is not required.
- 8.34.5.4 Type the user's esig in the appropriate field.

8.34.5.5 Select either **Complete** or **Complete and Quit** from the **Status** field.

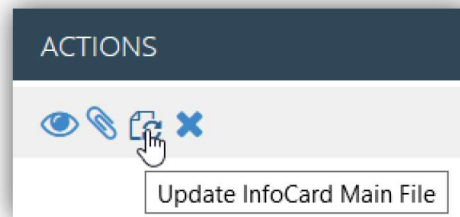
8.34.5.6 Click the **Save** button.

### 8.35 Collaboration Leader

**NOTE:** A **COLLABORATION LEADER** (usually the Author of the document) can perform additional tasks, e.g., modifying collaborators, replacing InfoCard main file with other files or the latest redline, ending or aborting collaboration. When collaborations are complete, the Collaboration Leader will want to ensure the most accurate file is included in the InfoCard. MC Collaboration gives the leaders the right to replace the main file of InfoCards in the tasks. Throughout a collaboration, leaders have the option to abort the collaboration step, ending the route and returning the task to an unlaunched state.

**NOTE:** Only **COLLABORATION LEADERS** can abort or end a collaboration, but they do not have the option to quit. All other collaboration members can only sign off with Complete or Complete and Quit. If there is more than one leader on a collaboration step, all users except the last leader to sign off have the Complete option. Leaders with this option can make additional changes and sign off. The collaboration task then resends for feedback. The last leader to sign off must select the **End Collaboration** option to end the step.

**NOTE:** The **COLLABORATION LEADER** **MUST** perform the “Update InfoCard Main File” before signing off.



#### 8.35.1 Replacing InfoCard Files

8.35.1.1 The Collaboration Leader is responsible for replacing the main InfoCard File (Update InfoCard Main File) before Ending Collaboration.

8.35.1.2 If this step is NOT completed, a message will appear when the user clicks the Sign Off icon.

**InfoCard Main Files Not Updated**

One or more InfoCard main files have not been updated with the changes made in the collaboration.

Click Discard to proceed without updating the InfoCard main files when the collaboration is ended. Depending on your company's Workflow settings, some changes may be lost.

Click Replace to update the InfoCard main files when the collaboration is ended.

Cancel

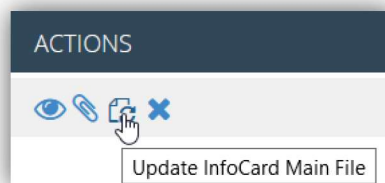
Discard

Replace



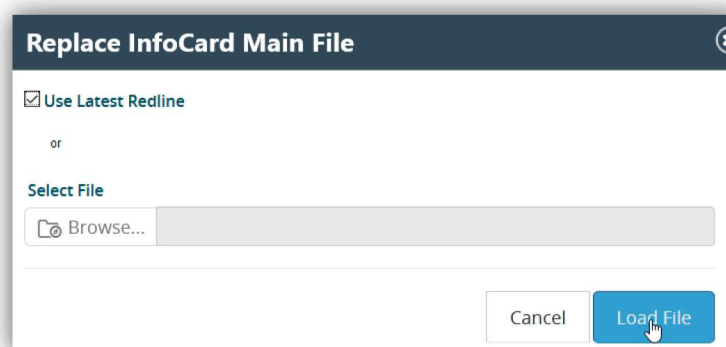
Warning: If you select End Collaboration and changes have been uploaded to the collaboration but not yet applied to the main files of the associated InfoCards, the system prompts you to choose whether to replace the InfoCard main files with the latest changes or to discard the changes. If you continue without replacing the main files, and the Shred redlines upon workflow completion option is selected for the step, the latest changes are lost.

## 8.35.2 Click Update InfoCard Main File Icon



8.35.3 Select **Use Latest Redline** to use the latest redline of an InfoCard file. To add a different file, either type the path and the filename in the **Select File** field or click **Browse** and locate the file.

## 8.35.4 Click Load File



**NOTE:** If this **Replace File** operation is not completed, the user *will lose the redline files*, which would require the user to restart the Collaboration process.



### 8.36 End/Abort Collaborations

- 8.36.1 **End Collaboration** status sends the document on an Approval Route.

**NOTE:** Once Collaboration has ended, no additional changes can be made unless another user **REJECTS** the task back to the Collaboration step.

- 8.36.2 **Aborting Collaboration** status ends the Route and returns the task to an unlaunched state.

### 8.37 Print Collaboration Information

- 8.37.1 Print the information displayed on the Collaboration Workspace tab or Task Details tab

- 8.37.2 In the Collaboration Workspace, click Print.



### 8.38 Rejecting a Document

- 8.38.1 If any user on a route rejects a task, that task is archived and a new task is started in its place with the same document.

- 8.38.2 A collaboration step is added so the reason the task was rejected can be examined and fixed.

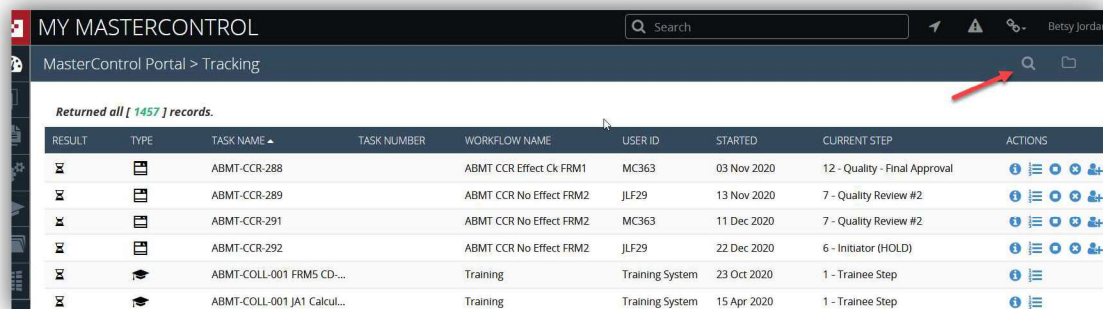
- 8.38.3 The author, owner, originator, and rejecter of the packet task are included in the collaboration.

- 8.38.4 After completion of the collaboration step, the packet task can be sent on its original route again. If it is sent on the route, the rights of all users in the collaboration remain the same as they were before the packet task was rejected.

- 8.38.5 All changes made to the route via Modify Step will be intact.

### 8.39 Tracking Collaboration Tasks

**NOTE:** All tasks are tracked during the approval process and retained after they have completed their respective routes. Task details show the user's tasks and all the steps that a task has completed, steps yet to be completed (in-process ⌘), and comments made by users along the route. All in-process tasks show up in **Tracking** (item #10, Section 8.1.2).



Returned all [ 1457 ] records.

RESULT	TYPE	TASK NAME	TASK NUMBER	WORKFLOW NAME	USER ID	STARTED	CURRENT STEP	ACTIONS
		ABMT-CCR-288		ABMT CCR Effect Ck FRM1	MC363	03 Nov 2020	12 - Quality - Final Approval	
		ABMT-CCR-289		ABMT CCR No Effect FRM2	JLF29	13 Nov 2020	7 - Quality Review #2	
		ABMT-CCR-291		ABMT CCR No Effect FRM2	MC363	11 Dec 2020	7 - Quality Review #2	
		ABMT-CCR-292		ABMT CCR No Effect FRM2	JLF29	22 Dec 2020	6 - Initiator (HOLD)	
		ABMT-COLL-001 FRM5 CD...		Training	Training System	23 Oct 2020	1 - Trainee Step	
		ABMT-COLL-001 JA1 Calcul...		Training	Training System	15 Apr 2020	1 - Trainee Step	

## 8.40 PDF Files

- 8.40.1 PDF files are in a distributable format to allow electronic information to be transferred between several types of computers.
- 8.40.2 MasterControl generates PDF files to “sandwich” the actual document between a cover page and a signature manifest page.
  - 8.40.2.1 The **Cover Page** maintains the metadata of the document; e.g., document number, revision number, document title, vault location, etc.
  - 8.40.2.2 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-057 Procedure Development
- 9.2 COMM-QA-057 JA1 Procedure Development SOP Template JA1
- 9.3 COMM-QA-019 Change Control Request (Effectiveness Check) FRM1
- 9.4 COMM-QA-019 Change Control Request (No Effectiveness Check) FRM2
- 9.5 COMM-PAS-004 Change Control
- 9.6 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)
10	B. Jordan	<ul style="list-style-type: none"> <li>• Added definitions for ODT, Production Site, and Security Questions in DEFINITIONS/ACRONYMS section.</li> <li>• 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.</li> <li>• Updates made to reflect system upgrade to v2022.3 cloud-hosted.</li> <li>• Information/enhancements added in Section 8: <ul style="list-style-type: none"> <li>▪ 8.1.1.1 – Scroll Bar</li> <li>▪ 8.4 – Forgot Your Esig?</li> <li>▪ 8.14 – My Subscriptions</li> <li>▪ 8.18.1.4.1 – Attachments &amp; Links Indicator</li> <li>▪ 8.27.4.4 – Deleting Comments in Collaboration Workspace</li> <li>▪ 8.29.1 – Modify Step Error Message</li> </ul> </li> </ul>

**Signature Manifest****Document Number:** COMM-QA-060**Revision:** 10**Title:** MasterControl User Procedures - Documents**Effective Date:** 03 Oct 2022

All dates and times are in Eastern Time.

**COMM-QA-060 MasterControl User Procedures - Documents****Author**

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		28 Sep 2022, 07:01:49 AM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		28 Sep 2022, 08:43:21 AM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Beth Elder (EYE3)		29 Sep 2022, 11:01:14 AM	Approved

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