**DOCUMENT NUMBER:** COMM-QA-062

**DOCUMENT TITLE:**
MasterControl User Procedures - Training

**DOCUMENT NOTES:**

---

**Document Information**

<table>
<thead>
<tr>
<th>Revision: 04</th>
<th>Vault: COMM-QA-rel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status: Release</td>
<td>Document Type: COMM-QA</td>
</tr>
</tbody>
</table>

**Date Information**

<table>
<thead>
<tr>
<th>Creation Date: 31 Jul 2015</th>
<th>Release Date: 18 Sep 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date: 18 Sep 2015</td>
<td>Expiration Date:</td>
</tr>
</tbody>
</table>

**Control Information**

<table>
<thead>
<tr>
<th>Author: BJ42</th>
<th>Owner: BJ42</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Number: COMM-QA-062 Rev 03</td>
<td>Change Number: COMM-CCR-021</td>
</tr>
</tbody>
</table>

CONFIDENTIAL - Printed by: SH259 on 18 Sep 2015 07:41:23 am
COMM-QA-062
MASTERCONTROL USER PROCEDURES – TRAINING

1 PURPOSE
1.1 This procedure provides the details for using and navigating the MasterControl Training application.

2 INTRODUCTION
2.1 The document management system, MasterControl, will help meet regulatory requirements by automating employee training and documentation.

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

4 DEFINITIONS/ACRONYMS
4.1 MasterControl Training – a software product from MC, which provides the functions to automate training, documentation, and issuance of training tasks.
4.2 InfoCard – InfoCards are the core of MC. The InfoCard controls access to documents as well as the functions available to each use.
4.3 Esig – Abbreviation for electronic signature.
4.4 Task – An assigned piece of work to be completed within a certain time.
4.5 Trainee – A user responsible for completing training requirements and keeping their Training Folder up-to-date.
4.6 Trigger – A term used that initiates an action e.g. to trigger a Training Task.

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 Computer access to MasterControl

7 SAFETY
7.1 NA

8 PROCEDURE
8.1 My Training Folder
NOTE: My Training Folder is a location where you can quickly view the status of your training records. You can view Training task statuses, when they are due, when they were completed, and when retraining will be required.

8.1.1 To access My Training Folder, click on My Training Folder in My MasterControl.

8.1.2 The My Training screen opens and displays your Training Records.

8.1.3 Your Training Record could reflect the following symbols in the Status column:

- In-Process
- Approved
- Retrain
- Rejected
- Aborted

8.1.4 To view the link of any of your courses, click on the Details icon (骷髅骨) under the Actions column.

8.2 Processing Training Tasks

NOTE: When a new or revised procedure or document is approved, MasterControl will automatically send training tasks to those Trainees who require it. Trainees can then view the training course, review any attached files or InfoCards, complete the training, and sign off on the task(s).

8.2.1 Completing a Training Task

8.2.1.1 To complete your training, login to MasterControl.

8.2.1.2 Click on My Tasks (#) in My MasterControl.
8.2.1.3 The **My Tasks** screen displays. Any training task waiting for completion ("Pending Tasks") will appear in the **My Tasks**.

![My Tasks Screen](image)

8.2.1.4 Click the **Training** icon (_within the Actions column next to the task you want to complete._

![Training Icon](image)
8.2.1.5 The Training Task window displays.

NOTE: In the top section of the Training Task, there will be three or four icons, depending on whether there is an exam or not, to guide you through the Task. In the example above, there are four icons (Introduction, Materials, Exam, and Overview).

8.2.1.6 The Introduction icon is displayed on the screen.

NOTE: Be sure to read the training instructions as instructions can change from course to course.

8.2.1.7 To move forward, click the green arrow (○) to the right of the icon to move to the next step.

8.2.1.8 The Materials window displays. There may be multiple course materials for you to open and read.
8.2.1.9  Click the View PDF icon ( unfolds ) to open the document.

8.2.1.10 The document opens in another window.

8.2.1.11 Read the material carefully; close the document.

8.2.1.12 When you finish with all course materials, click the green arrow ( ) to the right of Materials to move to the next step.
8.2.1.13 The Exam window displays.

8.2.1.14 When you are ready to take the exam, click the Begin Exam icon (○) under the Actions column. You must answer each question.

⚠️ If you begin an Exam and then navigate away from the Exam without answering all of the questions, the system considers this a FAIL, and you will be required to restart the exam.

NOTE: If a Trainee fails to pass an exam after the two retake attempts permitted, the action button (●) that launches the exam will be removed from the Training Task page. See Section 8.3 (Retake Exam) on what the Trainee will be required to do in order to retake the exam.
8.2.1.15 The first question displays in another window.

8.2.1.15.1 The number of exam questions can vary, as can the types of question. The available question types are: Multiple Choice, True/False, Matching, Numeric, and Sequencing.

8.2.1.16 You must answer each question; click the Submit Answer button on each question.

8.2.1.17 If you fail, you must retake the exam.

8.2.1.17.1 On the results window, MasterControl reveals your score.
8.2.1.18 Click the Close button.

8.2.1.19 The Exam screen will refresh and display your Results.

8.2.1.20 To retake the exam, click on the Retake Exam icon (.coordinates) under the Actions column.

8.2.1.20.1 You can retake the exam immediately after fail, or at a later time.

8.2.1.21 To test your comprehension, the questions will be shuffled and will not be in the same order you saw them the first time.

8.2.1.22 If you score at or higher than the passing score and you pass the exam, the next step is to sign off the training task.

8.2.1.23 Click Close.
8.2.1.24 The Training Task screen will refresh and display your Results.

8.2.1.25 When you finish with the Exam (pass), click the green arrow (○) to the right of Exam to move to the next step.

8.2.1.26 The Overview screen reveals training results, retraining requirements, and may include additional files for you to view and/or print.

8.2.1.27 Click the Sign Off button in the toolbar. The Sign Off Task window displays.
8.2.1.28 Enter your esig.
8.2.1.29 The Status automatically defaults to “Course Completed.”
   NOTE: Comments are optional.
8.2.1.30 Click Save.
8.2.1.31 The Pending Tasks page displays. A green “wink” appears confirming “sign off successful.”
8.3 Retake Exam

8.3.1 If a Trainee fails to pass an exam and reaches the number of attempts permitted to retake the exam (2), the action button (Sandwich) that launches the exam will be removed from the Training Task page.

8.3.2 In order to retake the exam, the Trainee must sign off on the task. This action redirects the task to the Trainee’s supervisor/manager.

8.3.3 The supervisor/manager will sign off the task as rejected. This action redirects the task back to the Trainee, so the Trainee can complete the training assignment and retake the exam.

8.4 Manager – Launching Retraining

NOTE: If a Manager determines that an employee needs to be retrained on a procedure, the Manager may launch a retraining task for the employee. A Manager will only be able to launch retraining tasks on those Training Folders for which they are the Supervisor.

8.4.1 Log in to MasterControl.

8.4.2 Click the Training Folders menu item from the MasterControl Training section of the main navigation menu. A list of Trainees for whom you are the supervisor displays.

8.4.3 Click the Details icon (Sandwich) under the Actions column next to a user in the list. The user's Training Folder appears.

NOTE: You can search for specific tasks using the Search button in the toolbar. You can also view which tasks are complete, who verified the tasks, etc.

8.4.4 Click the Retrain icon (Sandwich) next to the task you wish to start/trigger.

8.4.5 Click the Yes button in the confirmation message to resend the task to the Trainee.

8.4.6 Clicking Yes will relaunch (trigger) the Course to the Trainee.
8.5 Course Verification – Verifiers

**NOTE:** Once a Trainee completes a training task, the task is sent to the designated Course Verifier, who will certify that the Trainee completed the training satisfactorily. Once the Verifier signs off on the task, the training task completes its route and the task is considered complete.

8.5.1 To verify a completed training task, click the My Tasks menu item.

8.5.2 The training task will display in the Task List with the User ID of the Trainee that completed the task in parentheses after the task name.

8.5.3 Click the Training icon (⻆) next to the task you want to verify.

8.5.4 Click the Sign Off button in the toolbar.

8.5.5 Enter your esig in the Approve Task screen. Comments are optional, but are required when Rejected status is selected.

8.5.5.1 Select the Approved or Rejected status and click the Save button.

8.5.5.1.1 If approved, the task completes its Route and training is finished.

8.5.5.1.2 If rejected, the current task completes its Route and a new training task based on the course is sent to the Trainee.

8.6 Group Verify

**NOTE:** Group Verify is used to verify multiple training tasks simultaneously.

8.6.1 In My Tasks, click Group Verify (⒌ Group Verify) button in the toolbar.

8.6.2 Click the check box next to the name(s) of the Trainee(s) you wish to verify for each course listed. Click Select All to select all Trainees for all courses.
8.6.3 Click Submit.
8.6.4 Enter your esig in the Electronic Signature field.
8.6.5 Enter a date in the Effective Date field; click the Today's Date icon (📅). It is highly recommended that training tasks be signed off and made effective immediately.
     8.6.5.1 Select Approved or Rejected in the Status drop-down list.
8.6.6 Click Approve.

9 RELATED DOCUMENTS/ FORMS
9.1 NA

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

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
</tr>
</thead>
</table>
| 04           | B. Jordan | • Course Verification section: added bolded text to the following statement to define when a training task is considered complete. “Once the Verifier signs off on the task, the training task completes its route and the task is considered complete.”  
• Added definition for “trigger.”  
• Section 8: NOTE added to explain what happens if a trainee fails to pass an exam.  
• Added new section detailing “Retake Exam.” |
## Signature Manifest

**Document Number:** COMM-QA-062  
**Title:** MasterControl User Procedures - Training  
**Revision:** 04

All dates and times are in Eastern Time.

---

### COMM-QA-062 MasterControl User Procedures - Training

---

#### Author

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betsy Jordan (BJ42)</td>
<td></td>
<td>21 Aug 2015, 09:13:53 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

#### Medical Director

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joanne Kurtzberg</td>
<td></td>
<td>24 Aug 2015, 09:51:11 AM</td>
<td>Approved</td>
</tr>
<tr>
<td>(KURTZ0101)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Quality

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Carpenter</td>
<td></td>
<td>28 Aug 2015, 01:08:00 PM</td>
<td>Approved</td>
</tr>
<tr>
<td>(JPC27)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Document Release

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandy Mulligan</td>
<td></td>
<td>08 Sep 2015, 08:36:11 PM</td>
<td>Approved</td>
</tr>
<tr>
<td>(MULLi026)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>