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MasterControl User Procedures - Training

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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 (MC), 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 – An action e.g. to trigger (or launch) a Training Task.

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 Computer access to MasterControl
6.2 MasterControl is validated on Firefox and Chrome.

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 My MasterControl → My Training Folder → Open to open the My Training list page.

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 under the Actions column.

8.2 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 All training tasks are sent on a two-step route by default. These steps include:

8.2.1.1 Step One: Trainee Completion and Sign Off – The training task is sent to the trainee, who completes the training task and signs off.

8.2.1.2 Step Two: Verifier Sign off – The training task is sent to the training verifier (supervisor), who signs off after certifying that the training was completed.

8.2.2 Completing a Training Task

8.2.2.1 To complete your training, login to MasterControl.

8.2.2.2 Click My MasterControl and from the My Tasks window, click the name of the task you want to complete.

8.2.2.3 The Training Task page opens.

8.2.2.4 Click Introduction and read the introductory material.

NOTE: Be sure to read the training instructions as instructions can change from course to course.
8.2.2.5 Click **Materials** and view the materials associated with the Course.

8.2.2.6 If there is an **Exam** associated with the training task, click **Exam**. Complete the exam until you get a PASS score (see section 8.2.3).

8.2.2.7 Click **Sign Off**.

8.2.2.8 Click **Overview** to view the overview information.

8.2.2.9 In the **Comments** field, type any comments you want to add.

8.2.2.10 In the **Electronic Signature** field, type your esig.

8.2.2.11 Click **Save**.

8.2.3 Completing an Exam

8.2.3.1 Select a training task to which an Exam has been attached from My Tasks.

8.2.3.2 Follow the progression for training tasks.
8.2.3.3 In the Exams section, select the exam name to begin taking the exam.

NOTE: You will fail the exam if you do not complete it in the allotted time or navigate away from a closed-book exam before you have completed it.

Select an answer to a question and then select the Submit Answer button. Continue until you have completed the exam.

8.2.3.4 If, at any point, you need to save the progress of your exam and finish the rest later, click to CLOSE the window. A prompt will appear asking if you want to save your progress. Select Yes. Your exam progress is now saved, and will continue at the spot you left off the next time you access it.

NOTE: Saving exam progress only works for Open Book exams.

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.

8.2.3.4.1 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.

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

8.2.3.6 If you fail, you must retake the exam. See Section 8.3

8.2.3.7 Click the Sign Off button.

8.2.3.8 Enter your esig.

8.2.3.9 The Status automatically defaults to “Course Completed.”

NOTE: Comments are optional.

8.2.3.10 Click Save.

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 exam will be removed from the Training Task list.

8.3.2 In order to retake the exam after failing to pass it three times, 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 retake the exam and complete the training assignment.

8.4 Manager – Launching Retraining

**NOTE:** Supervisors can manually launch retraining for tasks on which trainees need to be retrained. This may occur when a course has changed and trainees need to be retrained, or when the supervisor feels the trainee could use a refresher.

8.4.1 Login to MasterControl.

8.4.2 Click Training → Training Folders → Open to open the Trainee list page.

8.4.3 Click the **Details** for the trainee in which you want to initiate retraining.

8.4.4 Click **Retrain** icon to start/trigger the training.

8.4.5 Click OK to confirm.

**NOTE:** Clicking **OK** 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 MasterControl – My Tasks.

![My MasterControl - My Tasks](image)

8.5.2 From the Task list, click the name of the task you want to verify.

8.5.3 In the Additional Files section, click on an attached document.

![Additional Files](image)

8.5.4 Click Sign Off to open the Sign Off window.

8.5.5 Type any necessary information in the fields.

**NOTE:** If you approve the task, MasterControl completes the Workflow for the task. If you reject the task, MasterControl completes the Workflow for the task, and sends a new training task to the user.
8.5.6  Click Sign Off

8.6  Group Verify

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

8.6.1  From the list of trainees, in the Actions column, click Details for the trainee information you want to edit.
8.6.2 From the My Training list, in the Actions column, click Sign Off for the task you wish to make exempt for this trainee.

8.6.3 In the Approve Task page, type your comments.

8.6.4 In the Electronic Signature field, type your esig.

8.6.5 Click Sign Off. This completes the training task.

8.6.6 Enter your esig in the Electronic Signature field.

8.6.7 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.

8.6.7.1 Select Approved or Rejected in the Status drop-down list.

8.6.8 Click Approve.

9 RELATED DOCUMENTS/ FORMS

9.1 NA

10 REFERENCES

10.1 MasterControl System Administration Manual

10.2 FDA 21 CFR Part 11

11 REVISION HISTORY

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<th>Description of Change(s)</th>
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<td>05</td>
<td>B. Jordan</td>
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COMM-QA-062 MasterControl User Procedures - Training

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