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MasterControl User Procedures - HTML Forms

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COMM-QA-065
MASTERCONTROL USER PROCEDURES – HTML FORMS

1   PURPOSE

1.1   This procedure provides the details for using and navigating the MasterControl Process module, also referred to as "Forms," which are created in HTML format.

2   INTRODUCTION

2.1   MasterControl Process automates, streamlines, and effectively manages form-based processes to help ensure compliance with FDA regulations with electronic records.

3   SCOPE AND RESPONSIBILITIES

3.1   This procedure covers MasterControl Process on how a user can start a forms task, enter form data, review saved form data, approve or reject a form, and track a form in process.

3.2   It is the responsibility of all employees using MasterControl to follow and apply these procedures.

4   DEFINITIONS/ACRONYMS

4.1   21 CFR Part 11 – Electronic Records; Electronic Signatures

4.2   Template – A guide used for creating form(s) that contain fixed fields for data entry and electronic-form generation.

4.3   Forms task – An assigned piece of work to be completed within a certain time.

4.4   Esig – Abbreviation for electronic signature.

4.5   HTML – (Hypertext Markup Language) is the standard markup language for documents designed to be displayed in a web browser.

4.6   Workflow – A series of customized steps that define the path a form follows.

5   MATERIALS

5.1   NA

6   EQUIPMENT

6.1   Computer to access MasterControl

    6.1.1   MasterControl is validated on Firefox and Chrome

        6.1.1.1   Do not use Internet Explorer (IE) or Microsoft EDGE.

7   SAFETY

7.1   NA

8   PROCEDURE

8.1   A Forms Task

NOTE: When new forms need to be filled out and approved, they are sent on specific data entry workflows. The **Start Task** page is the point from which all Forms tasks are started.

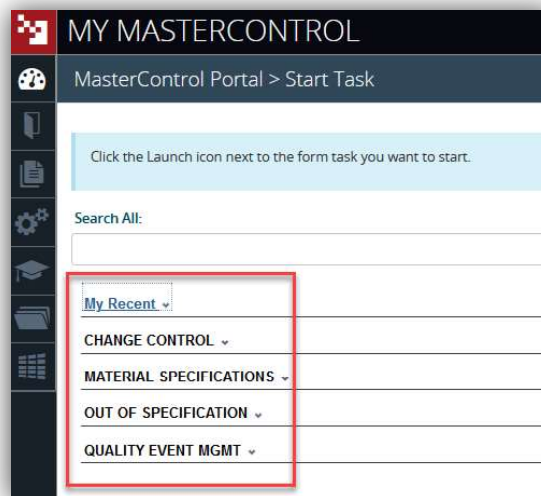8.2   Starting a Forms Task

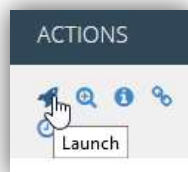8.2.1   Go to My MasterControl

8.2.2   Click on the **Start Task** tile.

8.2.3   From the drop-down menu, select **Forms**.

8.2.4   Click on a **Category** to display the form templates.

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8.2.5   Under the **Actions** column, click on the **ROCKET** to launch your selected form.

ACTIONS COLUMN ICONS

Launch		Starts a new task.
Preview Form		Allows you to view the form <u>before</u> launching the task.
Details		Allows you to view Workflow information about a particular task.
External Links		Allows the linking of an InfoCard to an external source.
Scheduled Task		Can be set for tasks that need to be initiated at regular intervals.

8.2.6   The window opens for the executed form.

8.2.7   Complete the data entry on the form.

NOTE: Some fields are auto-populated.

8.2.8   Click the **Save** or **Sign Off** button located at bottom-right.

8.2.8.1   Click **Save** allows you to continue working.

NOTE: Online forms are programmed to auto-save every 120 seconds.

8.2.8.2   Click **Sign Off** to access the Sign Off screen.

8.2.9   Select a **Status** for the step

     8.2.9.1   **Data Complete** – signifies all data entry for the current step has been completed, and the process is ready to move to the next step of the Workflow.

     8.2.9.2   **Work Inprocess** – used to place the process **on hold** for future data entry. Processes with the **Work Inprocess** status cannot move to the next step of the Workflow until the data entry is completed and the **Data Complete** status is selected.

         8.2.9.2.1   To re-enter the task after signing Work Inprocess, click on the Data Entry icon. ✏️

8.2.10   Enter your **esig** in the **Electronic Signature** field.

     NOTE: Comments are optional.

8.2.11   Click **Save**. A **wink** will appear stating "the form was successfully submitted.
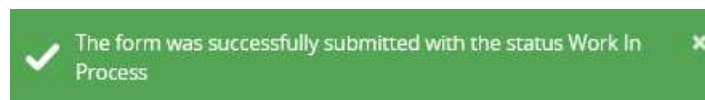
8.3   Tracking a Task

     8.3.1   Once a Task leaves your Pending Task List, you can track its progress through the Workflow.

         8.3.1.1   Locate the **TRACKING** tile.

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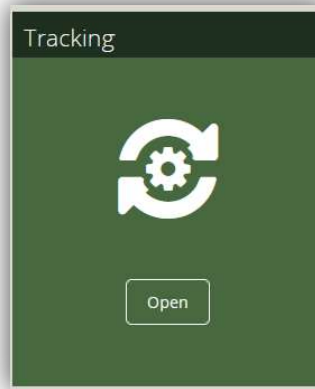
8.3.1.2 Click **Open**.

8.3.1.3 Select **Search method** (Simple, Basic, or Advanced).

8.4 Performing an **Action** on a Forms Task

8.4.1 Under the **Actions** column, the following icon appear.

8.4.2 Hover over each icon to indicate its use.

8.5 Data Entry

8.5.1 Click on the **Data Entry** icon (✏). The form will open in a new window.

8.5.1.1 Enter data in the appropriate form fields.

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8.5.1.2   Enter your **esig** password. Comments are optional, except for Data Rejection.

8.5.1.3   Select a **Status** for the step:

       8.5.1.3.1   **Data Approved** – used when the data entry that was performed on a previous step has been approved and allows the process to move to the next step in the Workflow.

       8.5.1.3.2   **Data Rejection** – signifies that the data entry performed on a previous step was not acceptable. When the status is added on the Sign Off, the form is rejected and sent back to the Initiator of the form.

8.5.1.4   Click **Save**. A **wink** will appear stating "the form was successfully saved with the status **Data Approval**."

8.6   As the task moves through the steps of the Workflow, approvals (👤) of the task are required. Different Sign-Off Statuses may be required.

    8.6.1   On Approval Steps

       8.6.1.1   Click the **Sign Off** icon (👤).

       8.6.1.2   When you are finished reviewing the data, click the Save or Sign Off button.

       8.6.1.3   The **Sign Off** window will display.

       8.6.1.4   Select a Status (refer to Workflow Step Statuses, Section 8.6.3).

             NOTE: The selection of Statuses will change *depending* on the step in the Workflow.

       8.6.1.5   Enter your **esig** password in the **Electronic Signature** field. Comments are optional for Approvals but required for Data Rejection.

       8.6.1.6   Click **Save**. A **wink** will appear with a message.

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8.6.1.7   The task continues its workflow and is removed from your **My Task** page.

8.6.2   On Rejection Steps

8.6.2.1   Click the **Sign Off** icon ( ). The form will open in a new window.
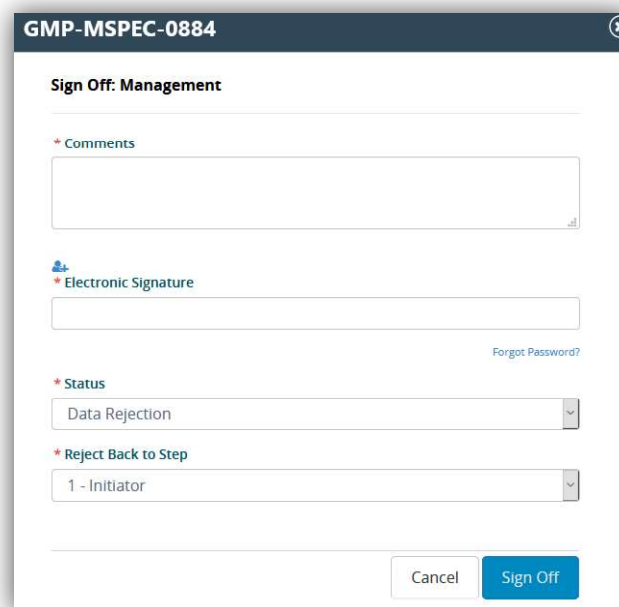
8.6.2.2   When you are finished reviewing the data, click the click the Save or Sign Off button.

8.6.2.3   The **Sign Off** window will display.

8.6.2.4   Click **Data Rejection** in the Status window.

8.6.2.5   Another Status window opens immediately (**Reject Back to Step**) and defaults to (step 1-Initiator).

8.6.2.6   Enter your **esig** password in the **Electronic Signature** field. Comments are required for Data Rejection.

8.6.2.7   Click **Sign Off**. A **wink** will appear stating "the form was successfully submitted with the status **Data Rejection**."
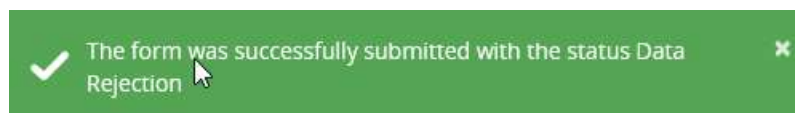
8.6.2.8   The task is removed from your **My Task** page and RETURNS to the Initiator (and the process starts over).

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8.6.3   Workflow Step Statuses

Status	Description
Data Approval	Used when the data entry that was performed on a previous step has been approved and allows the process to move on to the next step in the Workflow.
Data Complete	Signifies that all data entry for the current step has been completed, and that the process is ready to move on to the next step in the Workflow.
Work Inprocess	Used to place the process on hold for future data entry. Processes with the Work Inprocess status cannot move on to the next step until the data entry is completed and the Data Complete status is given. This status can be used in conjunction with any status.
Data Rejection	Signifies that the data entry performed on a previous step was not acceptable. The task is rejected and sent back to the Initiator.
Final Approval	Used when the entire process to that point has been approved.
Notify	Sends e-mail notifications to all users added in the step. These notifications can be sent to any user in the system, regardless of whether they have direct involvement with the process.

9   RELATED DOCUMENTS/FORMS

9.1   NA

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)
05	B. Jordan	• Updates made to reflect system upgrade to v2021.3 cloud-hosted MasterControl. • Some images updated to match those for v2021.3.

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