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**Control Information**

- **Author:** BJ42  
- **Owner:** BJ42
- **Previous Number:** COMM-QA-065 Rev 02  
- **Change Number:** COMM-CCR-022
COMM-QA-065
MASTERCONTROL USER PROCEDURES – FORMS PROCESS

1 PURPOSE
1.1 This procedure provides the details for using and navigating the MasterControl Process module, also referred to as “Forms”.

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.

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 Computer to access MasterControl
   6.1.1 Windows XP and Internet Explorer (IE)
   6.1.2 Adobe Reader

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 routes. 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 Mouse over the **Start Task** menu in **My MasterControl** and click **Forms**.

8.2.3 Click the **Forms** tab. Templates to access a form are displayed in this tab (Forms).
8.2.4 The **Actions** column displays the following icons:

<table>
<thead>
<tr>
<th>ICONS ON START TASK PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Launch</td>
</tr>
<tr>
<td>Start a new task.</td>
</tr>
<tr>
<td>Preview Form</td>
</tr>
<tr>
<td>Allows you to view the form <strong>before</strong> launching the task.</td>
</tr>
<tr>
<td>Details</td>
</tr>
<tr>
<td>Allows you to view Route information about a particular task.</td>
</tr>
<tr>
<td>External Links</td>
</tr>
<tr>
<td>Allows the linking of an InfoCard to an external source.</td>
</tr>
<tr>
<td>Scheduled Task</td>
</tr>
<tr>
<td>Can be set for tasks that need to be initiated at regular intervals.</td>
</tr>
</tbody>
</table>

8.2.5 Click the **Launch** icon (✔) to start a new task.

8.2.6 The task will display in another window.

**NOTE:** Some fields may be pre-populated (example below).

![Image of CHANCE CONTROL REQUEST FRM1](image)

---

**CHANGE CONTROL REQUEST FRM1**

<table>
<thead>
<tr>
<th>SECTION</th>
<th>CHANGE CONTROL REQUEST #:QSU-CCR-070</th>
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<tbody>
<tr>
<td>Initiator: Betsy Jordan</td>
<td></td>
</tr>
<tr>
<td>Date of Request: 03-Apr-2013</td>
<td></td>
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**Instructions to Initiator:** Complete Sections 1 and II by checking applicable items and provide explanation where requested.

- **Document**
  - New Document Title:
  - Existing Document: [ ] Revise [ ] Archive
    - Existing Document Number:
    - Existing Document Title:
    - Final Revision Number:

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QSU, DUMC
Durham, NC

CONFIDENTIAL - Printed by: SYSADMIN on 08 Sep 2015 07:50:53 am
8.2.7 Complete the data entry on the Form.

8.2.8 Click the **SUBMIT** button at the end of the form.

**NOTE:** The **SUBMIT** button does not capture data. Actions are associated with it. If the **SUBMIT** button is not clicked after data entry, the data entered will not be saved.

8.2.9 The Sign Off Task window displays.

8.2.10 Select a **Status** for the step

8.2.10.1 **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 Route.

8.2.10.2 **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 Route until the data entry is completed and the **Data Complete** status is selected.

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

**NOTE:** Comments are optional.

8.2.12 Click Save. A **wink** will appear stating “the form was successfully submitted with the status Data Complete.”
8.3 Tracking a Task

8.3.1 Once a Task leaves your Pending Task List, you can track its progress through the Route by going to:

8.3.1.1 TRACKING in My MasterControl
8.3.1.2 Click Search in the toolbar
8.3.1.3 Select Search method (Simple, Basic, or Advanced).

8.4 Performing an Action on a Forms Task

8.4.1 Click the My Tasks menu item in My MasterControl.

8.4.1.1 The My Tasks Actions column may contain the following icons. The number of icons you see is dependent on your role in that particular task.

Tracking  
Data Entry  
Modify Step  
Dependencies

8.4.2 On Data Entry steps ( ينا)

8.4.2.1 Click the Data Entry icon (ينا). The form will open in a new window.

8.4.2.2 Enter data in the appropriate form fields.
8.4.2.3 When data entry is complete, click the **SUBMIT** button at the end of the form.

**NOTE:** If the **SUBMIT** button is **not clicked** after data entry, the data entered **will not be saved**.

8.4.2.4 The **Sign Off Task** window displays.

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

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

8.4.2.6.1 **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 Route.

8.4.2.6.2 **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.

8.4.2.7 Click **Save**. A **wink** will appear stating “the form was successfully saved with the status **Data Approval**.”
8.5 As the task moves through the steps of the Route, approvals () of the task are required. Different Sign-Off Statuses may be required.

8.5.1 On Approval Steps

8.5.1.1 Click the Sign Off icon (). The form will open in a new window, but previously completed fields will generally be disabled so you can view information entered by others, but not alter it.

8.5.1.2 When you are finished reviewing the data, click the [SUBMIT] button in the form.

8.5.1.3 The Sign Off window will display.

8.5.1.4 Select a Status (refer to Route Step Statuses, Section 8.5.3).

NOTE: The selection of Statuses will change depending on what step of the Route the task is on.

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

8.5.1.6 Click Save. A wink will appear with a message.

8.5.1.7 The task continues its route and is removed from your My Task page.

8.5.2 On Rejection Steps

8.5.2.1 Click the Sign Off icon (). The form will open in a new window, but previously completed fields will generally be disabled so you can view information entered by others, but not alter it.

8.5.2.2 When you are finished reviewing the data, click the [SUBMIT] button in the form.

8.5.2.3 The Sign Off window will display.

8.5.2.4 Click Data Rejection in the Status window.

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

8.5.2.6 Enter your esig password in the Electronic Signature field. Comments are required for Data Rejection.
8.5.2.7 Click Save. A **wink** will appear stating “the form was successfully submitted with the status **Data Rejection.**”

8.5.2.8 The task is removed from your **My Task** page and **RETURNS** to the Initiator (and the process starts over).

8.5.3 Route Step Statuses

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Data Approval</strong></td>
<td>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 route.</td>
</tr>
<tr>
<td><strong>Data Complete</strong></td>
<td>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 route.</td>
</tr>
<tr>
<td><strong>Work Inprocess</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Status</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Data Rejection</td>
<td>Signifies that the data entry performed on a previous step was not acceptable. The task is rejected and sent back to the Initiator.</td>
</tr>
<tr>
<td>Final Approval</td>
<td>Used when the entire process to that point has been approved.</td>
</tr>
<tr>
<td>Notify</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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| 03           | B. Jordan | • Equipment section – removed IE version numbers; v7 or 8 are not compatible. 
|              |        | • Reset page numbering sequence to Page 1 of x, instead of Page 1 of 1, Page 2 of 2, etc. |
**Signature Manifest**

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All dates and times are in Eastern Time.

### COMM-QA-065 MasterControl User Procedures - Forms Process

#### Author

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#### Medical Director

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#### Quality

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#### Document Release

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