

# CVM eSubmitter

## Master File Quick Guide

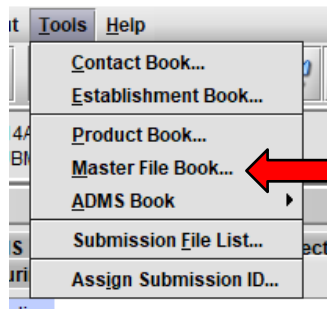
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### I. Introduction

The Master File Book is to provide a means of storing Master File information to be reused at a later time. Currently, this functionality is only implemented to support the Animal Drug and Manufacturing Supply Chain data book. Reusing this data makes building a supply chain information more efficient, as well as ensuring data entry consistency.

### II. Accessing the Master File Book

The Master File book can be accessed in two ways. Direct access to the book is available at anytime from the Tools option in the menu bar.



The master file book will also be accessible from within the Animal Drug and Manufacturing – Edit Supply Chain dialog window by clicking on the Select button in the Master File Reference section.

ADMS - Edit Supply Chain Dialog

### Animal Drug and Manufacturing - Edit Supply Chain

**File/Application Reference** Select... View...

I-112233; Test Drug

**Establishment Reference** Select... View...

ABC Company, DUNS: 111111111

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**Supply Chain Information**

Role Manufacturer

Entity Drug Substance

Qualifier Fermentation

Operational Status (CVM) [Not Yet Assigned By CVM]

Operational Status Pending

Approved Submission ID

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**Master File Reference**

Is there an associated master file?

☒ Yes  
☐ No

Master File Reference Select... View...

[No Master File Selected]

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**Substance Reference** Select...

PENICILLIN G PROCAINE (17R794ESYN)

The View Master File List Dialog will open.

View Master File List Dialog

### View Master File List

Click on the link to view the [CVM eSubmitter Master File Quick Guide](#) for additional information.

**Enter Search/Sort Criteria** Clear

MF File Type MF File Number MF Type Sort Order

File Type and Number

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**Master File List (4 found)** View...

MF File	MF Type	Ownership Status	LOA File Reference Included	Information Covered	Last Updated
D-055555	Type II	Yes	No		2021-12-15 T 14:21:57
V-001111	Type II	Yes	No		2021-12-15 T 14:21:24
V-002222	Type II	No	No		2021-12-15 T 14:21:43
V-003333	Type V	Yes	No		2021-12-15 T 14:22:17

Master File Comments (for internal sponsor use only)

New... Edit... Delete Close

## A. The Master File List

The Master File List displays all the master files matching the search criteria, or all master files available when no search criteria is provided. The list contains the MF File, MF Type, Ownership Status, LOA File Reference Status, Information Covered, and the date the information was last updated. The list title contains a count of the master files currently included within the list. In addition, internal sponsor comments are displayed for the selected master file.

The following options are available:

- View: Displays all details related to the selected master file.
- New: Allows for new master files to be added to the list.
- Edit: Allows for details on the selected master file to be updated.
- Delete: Allows for the selected master file to be permanently deleted from the list.

There are two modes for displaying the Master File List. The first is the View mode, which is used to manage the overall contents of the master file list. The View mode is available within the application Tools menu. The second is the Select mode, which is used to select a master file as a reference (e.g., to supply chain information). The Select mode is available from within the data screen where the reference is being initiated.

The default behavior of some operations are dependent on the mode used to open the Master File List. For example, in View mode using the Enter key on the keyboard or double-clicking with the mouse on the selected row initiates an Edit, while in Select mode the same operation initiates a Select.

## B. Search/Sort Criteria

The Search capability allows for searching across all master files contained within the Master File List. The fields available for searching include MF File Type (VMF/DMF), MF File Number, and MF Type (Type II/III/IV/V). The search locates all master files matching all criteria provided.

The screenshot shows a form titled "Enter Search/Sort Criteria". It has a light blue header bar with a yellow lightbulb icon and a "Clear" button. Below the header, there are four input fields: "MF File Type" (a dropdown menu), "MF File Number" (a text box), "MF Type" (a dropdown menu), and "Sort Order" (a dropdown menu). The "Sort Order" dropdown is currently set to "File Type and Number".

The MF File Type and MF Type searches retrieve all master files matching the selections made, while the MF File Number search is based on locating all master files that begin with the digits entered.

When no search criteria is provided, all master files are listed. A Clear option is provided to clear the search criteria and reset the master file list.

The Sort capability controls the ordering of master files within the list. The sort orders available include File Type and Number, Master File Type, and Ownership Status. The master file list will be reordered whenever a sort order is selected. The default sort order is File Type and Number. The sort order will reset to the default when the Clear option is selected.

### III. Entering Information into the Master File Book

#### A. Creating a New Entry

From the View Master File List Dialog, select New... to create a new entry. This will open the Add Master File Dialog.

The screenshot shows the 'Add Master File Dialog' window. The title bar reads 'Add Master File Dialog'. The main header is 'Add Master File'. The dialog is divided into several sections: 'Master File Reference' containing 'File Type' (a dropdown menu) and 'File Number' (a text input field); 'Master File Details' containing 'Master File Type' (a dropdown menu) and 'Information covered in the Master File' (a large text area); 'Do you own the Master File?' with radio buttons for 'Yes' and 'No'; 'Reference to file containing Letter of Authorization (LOA) providing Right of Reference' (a text input field with a lightbulb icon); and 'Master File Comments (for internal sponsor use only)' (a large text area with a lightbulb icon). At the bottom, there are three buttons: 'Add Another Master File', 'OK', and 'Cancel'.

Populate all of the required fields: MF File Type (VMF/DMF), MF File Number, and MF Type (Type II/III/IV/V). Provide a file reference (i.e., folder location and file name) to the Letter of Authorization (LOA) providing Right of Reference.

The comments field is for sponsor use only and is not included as part of any submission content. It is provided to aid sponsors in the overall management and identification of master file information by allowing the capture of additional information related to each master file.

When finished, select OK to close the dialog, or select Add Another Master File if you wish to create additional entries.

#### B. Edit Master File

From the View mode, selecting an entry in the Master File List and using the Enter key on the keyboard or double-clicking with the mouse on the selected row initiates an Edit. Additionally, you can edit information by highlighting an entry and then selecting the Edit button.