



## FDA CVM eSubmitter Data Book User Guide

[Home](#) » [FDA](#) » FDA CVM eSubmitter Data Book User Guide 

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## Contents

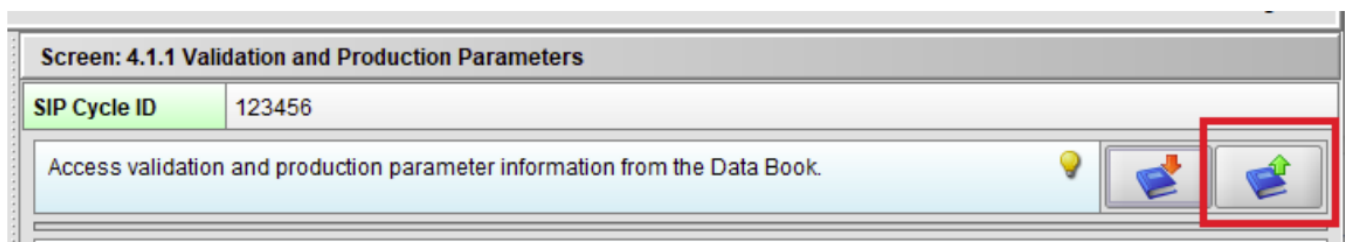
- 1 Introduction
- 2 Save to the Data Book
  - 2.1 Data Type Description
  - 2.2 Identifying Name
  - 2.3 Data Items List
- 3 Select from the Data Book
  - 3.1 Access Saved Data
  - 3.2 Data Type Description
  - 3.3 Search Criteria
  - 3.4 User Specified Data Name List
  - 3.5 Data Items for the Selected Data Name
- 4 Managing Data
  - 4.1 Edit (from the Data Book Selection Dialog)
  - 4.2 Delete (from the Data Book Selection Dialog)
  - 4.3 Rebuild Index (from the Preferences Dialog)
- 5 Documents / Resources
- 6 Related Posts

## Introduction

The value of the Data Book is to provide a means of storing information from within a section of a submission to be reused at a later time. Depending on the section, the information could be configured to be reused across sections within the same submission, within the same section of a later submission of the same type, or even reused across submissions of different types as long as the data is relevant within those scenarios. Reusing data makes building a submission more efficient, as well as ensuring data entry consistency.

## Save to the Data Book

After completing the data entry within a submission section that has the data book functionality enabled, click on the icon with the up arrow.



This will open the Data Book Save Dialog box which collects information from the current section of a submission and saves it to the Data Book for future reuse

Data Book Save Dialog

## Save to Data Book

Data Save for Data Type: **Sterilization-In-Place (SIP) - Validation and Production Parameters**

Enter an Identifying Name to Represent the Data

SIP Cycle ID: 123456

**Data Items to be Saved**

Data Item Name	Data Item Value
Cycle Time - Validation	27
Cycle Time - Production	32
Temperature Set Point - Validation	35
Temperature Set Point - Production	35
Number of Thermocouples - Validation	6
Number of Thermocouples - Production	6
Number of Biological Indicators - Validation	82

### Data Type Description

The Data Type represents a short description of the type of data being saved to the Data Book. It typically is representative of the current section of the submission. The Data Type is used to group related data concepts when stored within the Data Book, as well as to limit what can be selected when copying data from the Data Book into a section of a submission.

### Identifying Name

The identifying name is a recognizable name provided by the user to describe the data being stored. It is important to name the data clearly because the name is what will be presented when selecting to copy data from the Data Book into a submission.

In cases where the section is part of a relationship (i.e., the current section is specific to the selected item within the parent section) a default name will be provided based on content from the selected item in the parent section. The default name can be used as is or added to as needed.

Data names must be unique to be added to the data book. If there is a duplicate, a warning message will be displayed.

### Data Items List

List of the data items to be saved with their respective values. The list is presented so the data can be reviewed prior to being saved to the Data Book.

### Select from the Data Book


#### Access Saved Data

To retrieve data retained within the data book, click on the Select Data from Data Book button with the down arrow.

**Screen: 4.1.1 Validation and Production Parameters**

**SIP Cycle ID** 123456

Access validation and production parameter information from the Data Book.




This will open the Data Book Selection Dialog box. This dialog allows the user to select a data item from the Data Book and copy it into the current section of a submission.

**Data Book Selection Dialog**

**Select from Data Book**

Data Selection for Data Type: **Sterilization-In-Place (SIP) - Validation and Production Parameters**

**Search Criteria**  **Clear**

Enter Search Text

**User Specified Data Name List (2 found)**

User Specified Data Name
SIP Cycle ID: 1111
SIP Cycle ID: 33333

**Data Items for the Selected Data Name (7 found)**

Data Item Name	Data Item Value
Cycle Time - Validation	111
Cycle Time - Production	112
Temperature Set Point - Validation	121
Temperature Set Point - Production	122
Number of Thermocouples - Validation	131
Number of Thermocouples - Production	132
Number of Biological Indicators - Validation	141

**Edit...** **Delete** **Select** **Cancel**

## Data Type Description

The Data Type represents a short description of the type of data being saved to the Data Book. It typically is representative of the current section of the submission. The Data Type is used to group related data concepts when stored within the Data Book, as well as to limit what can be selected when copying data from the Data Book into a section of a submission.

## Search Criteria

Allows for up to five keywords to be entered to help narrow down the data names presented within the data names list. Useful within data types that contain many data items. Each keyword is separated by a space. The order of the keywords is not relevant to the search results. A Clear option is provided to clear the search text and initialize the list results.

## **User Specified Data Name List**

Represents the list of valid data names that can be copied from the Data Book into the current section of the submission. The list is automatically filtered on the specified data type listed at the top of the dialog. Further narrowing of the list contents can be performed by providing additional search criteria.

A data name can be selected by either double clicking with the mouse on the selected row or selecting the appropriate row and clicking the Select button. Once selected, the dialog is closed, and the data is copied from the Data Book into the submission.

## **Data Items for the Selected Data Name**

Represents a list of the data item details associated to the selected data name. Provides a means to review the individual data items to be copied into submissions prior to the actual selection.

## **Managing Data**

There are currently three capabilities to help manage the content within the Data Book.

### **Edit (from the Data Book Selection Dialog)**

Allows the Data Name of the selected item in the Data Name List to be updated. Any changes to the data name must ensure the data name remains unique within the list.

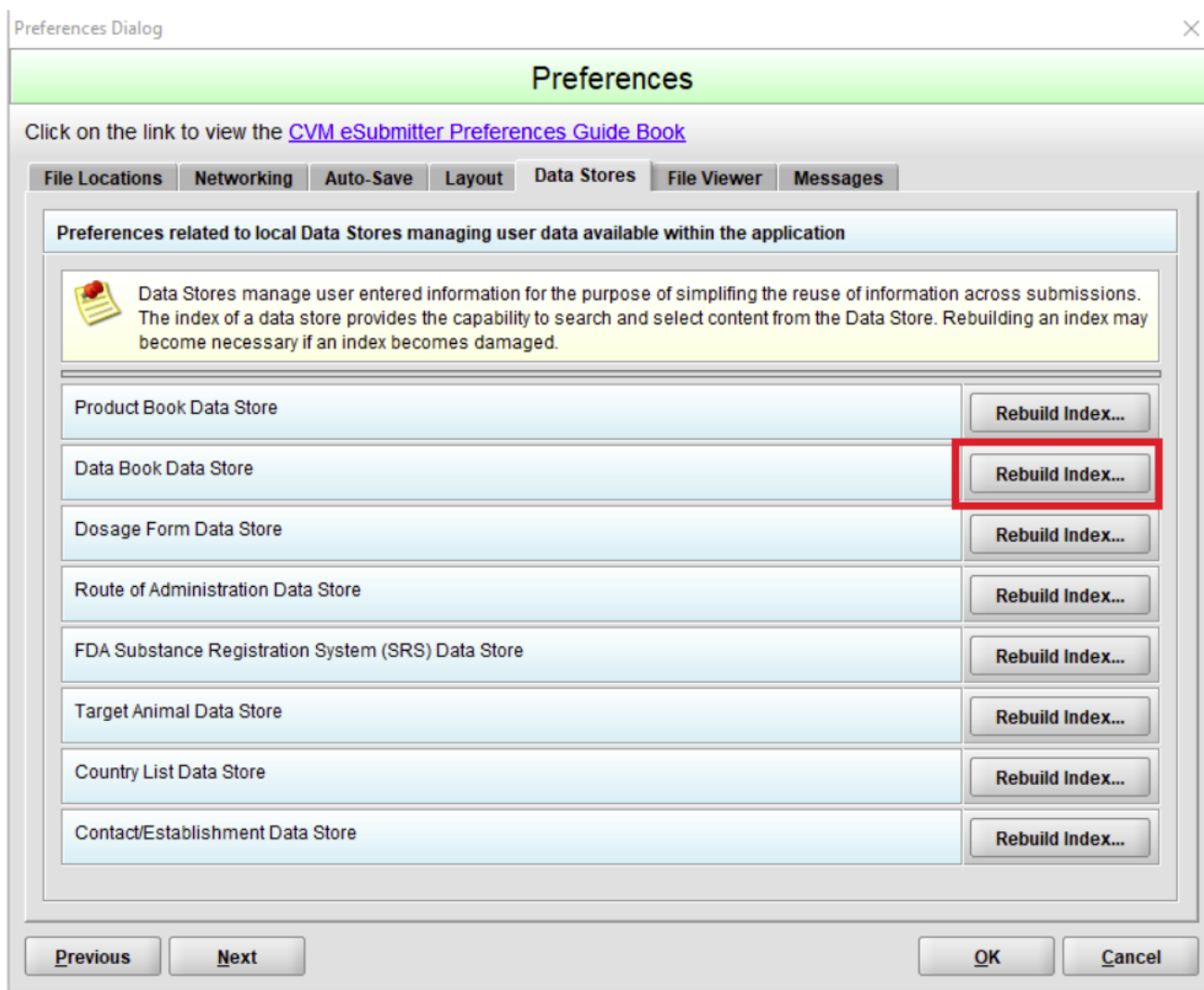
### **Delete (from the Data Book Selection Dialog)**

Allows the selected item in the Data Name List to be permanently removed from the list.


### **Rebuild Index (from the Preferences Dialog)**

The index of a data store provides the capability to search and select content from the data store. Rebuilding the index may become necessary if an index becomes damaged.

To rebuild the Data Book index, access the Preferences dialog by selecting the file menu and then selecting "Preferences". Once in the Preferences dialog window, select the "Data Stores" tab, then click the "Rebuild Index" button.



## Documents / Resources

	<p><a href="#">FDA CVM eSubmitter Data Book</a> [pdf] User Guide CVM eSubmitter Data Book, CVM eSubmitter, CVM, eSubmitter</p>
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