CVM eSubmitter

Data Book Quick Guide

I.	Introduction	1
II.	Save to the Data Book	1
Α.	Data Type Description	2
В.	Identifying Name	2
C.	Data Items List	2
III.	Select from the Data Book	2
Α.	Access Saved Data	
В.	Data Type Description	3
C.	Search Criteria	
D.	User Specified Data Name List	3
Ε.	Data Items for the Selected Data Name	
IV.	Managing Data	4
Α.	Edit (from the Data Book Selection Dialog)	4
В.	Delete (from the Data Book Selection Dialog)	4
C.	Rebuild Index (from the Preferences Dialog)	4

I. 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.

II. 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.

Screen: 4.1.1 Val	idation and Production Parameters		
SIP Cycle ID	123456		
Access validation	n and production parameter information from the Data Book.	V	



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.

	Save to Da	ata Book			
Data Save for Data Type: Sterilization-In-I	Place (SIP) - Validation	and Product	ion 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				
	35				
Temperature Set Point - Validation	30				
	35				
Temperature Set Point - Validation Temperature Set Point - Production Number of Thermocouples - Validation					
Temperature Set Point - Production	35				
Temperature Set Point - Production Number of Thermocouples - Validation	35 6				

A. 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.

B. 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.

C. 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.

III. Select from the Data Book

A. Access Saved Data

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

eSubmitter Submission Software	ADMINISTRATION	FDA U.S. FOOD & DRUG administration
Screen: 4.1.1 V	alidation and Production Parameters	
SIP Cycle ID	123456	
Access validati	on and production parameter information from the Data Book.	نے

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.

	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		
IP Cycle ID: 33333 Data Items for the Selected Data Name (7 found)		
IP Cycle ID: 33333 Data Items for the Selected Data Name (7 found) Data Item Name	Data Item Value	
NP Cycle ID: 33333 Data Items for the Selected Data Name (7 found) Data Item Name Cycle Time - Validation	111	
IP Cycle ID: 33333 Data Items for the Selected Data Name (7 found) Data Item Name Sycle Time - Validation Sycle Time - Production		
Data Items for the Selected Data Name (7 found) Data Item Name Cycle Time - Validation Cycle Time - Production emperature Set Point - Validation	111 112	
BIP Cycle ID: 33333 Data Items for the Selected Data Name (7 found) Data Item Name Cycle Time - Validation Cycle Time - Production Temperature Sel Point - Validation Temperature Sel Point - Production	111 112 121	
SIP Cycle ID: 33333 Data Items for the Selected Data Name (7 found) Data Item Name Cycle Time - Validation Cycle Time - Production Temperature Set Point - Production Number of Thermocouptes - Validation	111 112 121 122	
SIP Cycle ID: 33333 Data Items for the Selected Data Name (7 found)	111 112 121 122 131	

B. 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.

C. 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.

D. 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.

E. 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.

IV. Managing Data

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

A. 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.

B. Delete (from the Data Book Selection Dialog)

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

C. 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.

Preferences	
on the link to view the <u>CVM eSubmitter Preferences Guide Book</u>	
Locations Networking Auto-Save Layout Data Stores File Viewer Messages	
eferences related to local Data Stores managing user data available within the application	
Data Stores manage user entered information for the purpose of simplifing the reuse of infor The index of a data store provides the capability to search and select content from the Data S become necessary if an index becomes damaged.	
Product Book Data Store	Rebuild Index
Data Book Data Store	Rebuild Index
Dosage Form Data Store	Rebuild Index
Route of Administration Data Store	Rebuild Index
FDA Substance Registration System (SRS) Data Store	Rebuild Index
Target Animal Data Store	Rebuild Index
Country List Data Store	Rebuild Index
Contact/Establishment Data Store	Rebuild Index