SARTORIUS

Octet® CFR Software V12.X and Software Validation Package

Confident 21 CFR Part 11 Compliance

Octet® CFR Software Version 12.X

Recent enhancements to our Octet® CFR Software version 12.X and the Sartorius FB Server Monitor Module, along with software validation package enable all Octet® instruments to be integrated seamlessly into GxP regulated environments.

Primary Data Integrity

The integrity of raw data is a primary design consideration of Octet® CFR Software. All data acquired using Octet® Acquisition CFR Software is time stamped and traceable to the user who initiated data acquisition. Acquired data is digitally signed and any modification invalidates the data and prevents it from being opened in Octet® CFR Software. Both the method file containing experiment settings and the experiment files contains data and analysis settings are digitally signed to protect data integrity.

Controlled Access with Multiple User Levels

Octet® CFR Software controls the access of all features that can be used to create or modify users, and acquire, modify and analyze data, including exporting and saving results. The Administrator manages all users and sets user permissions based on their authorization level. Four user levels | groups – Administrator, Supervisor, Developer and Lab User – are available with default permissions. Each user or user group may be customized based on your company's requirements.

Beginning with Octet® Software version 12.1, the applications have been renamed. The Data Acquisition Software has been renamed Octet® BLI Discovery. The Data Analysis HT Software has been renamed Octet® Analysis Studio Software.

Enhanced Audit Trail

More actions are logged into the Audit Trail, including any modifications to an existing method file, preprocess settings changes such as reference sensors | wells and interstep corrections, and analysis settings changes such as curve fits. Octet® CFR Software automatically generates timestamped Audit Trails, recording transactions that create, delete, or modify electronic records. In each instance, the Audit Trail records the date and time of the transaction, the computer and project name, the user ID, and information on the action performed. Additional information such as old and new values for most acquisition parameters and analysis settings are also added to the Audit Trail. Octet® Analysis Studio Software also has an option to require users to enter comments or notes for each Audit Trail event. Once logged, the Audit Trail cannot be deleted. Audit trails can be filtered by experiment, user, machine, project or date for viewing and subsequently printed into a PDF document.

Electronic Signatures

Users can access and electronically sign the experiment data after completing analysis. When an experiment dataset is signed twice, it completely locks the dataset from further modification. Administrators can enable user permission to allow removal of signatures. These actions are also captured in the Audit Trail.

Full Control for Routine Assays and Speed up Analysis

Once method files and data analysis settings are set, they can be saved and reloaded to new datasets for routine assays. This feature enables locking the methods and analysis settings for regulated labs and significantly reduces analysis time.

Customized Reports

Once analysis is complete, customized reports can be created by combining various data elements such as graphs, text, data tables, company logo, images and experimental details. Reports can then be printed or saved as PDFs, and uploaded to an electronic notebook or stored in the database. Report templates can be locked and reloaded to create similar reports for additional datasets.

Figure 1: Octet® Analysis Studio CFR Software's new Security tab. User info, including username and privileges, are on the left panel. Audit Trail details are in the middle and the old vs. new values are on the right panel on the Security tab.

Software Validation Package

For researchers working in GLP or GMP laboratories, the Octet® Software Validation Package provides the most comprehensive documentation and tools available to validate the Sartorius FB Server Monitor and Octet® CFR Software features and functions.

Shorten Validation Time to Just Three Days

Ensuring the consistency, quality, and integrity of your experiments is of utmost importance, but it can also take several months to adequately certify and document experimental test procedures and data output. The Octet® Software Validation Package trims validation time to just three days using a fully-integrated electronic manual that mirrors the validation process in a regulated laboratory.

Authenticate Calculations with Third Party Software

Streamline confirmation of Octet® data acquisition and analysis features using a step-by-step instructions guide. When testing the Sartorius FB Server Monitor functions, the guide walks you through verifying multiple functions such as password expiry, inactivating user, automatic user logout, and new user creation. In addition, the guide covers how to verify basic pre-processing calculations and quantitation and kinetics curve fits using external software. Sample data sets are provided to shorten the time

necessary to authenticate and compare analysis algorithms using Octet® CFR Software to traditional programs including Microsoft® Excel® and GraphPad Prism.

System Requirements

- Windows 10, 32-bit or 64-bit
- Octet® CFR Software version 12.0 and above
- GraphPad Prism version 5.0.4 (optional)
- Microsoft Excel 2016 and above

Validation Package Contents

- Details on Octet® CFR Software features for implementation of FDA 21 CFR Part 11-compliance requirements
- Instructions for installation qualification of the Sartorius FB Server Monitor software and Octet® CFR Software
- Detailed operational qualification sections with:
  - Instructions and templates for testing routine calculations and important curve fits
  - Test files for result confirmation in .xlsx (Excel), .pzm (Graph Pad Prism), .efrd (Octet® analysis settings) and frd files (Octet® data)

OQ Test 1: 4PL Unweighted Fit
Purpose: To use previously acquired data to test the curve fit results for 4PL Unweighted.

Required Files: Located in the Quantitation Tests folder, in the Data and 4PL Unweighted folders.

Table 1: 4PL Unweighted Fit. Step-by-step instructions for verifying Octet® Software 4PL unweighted quantitation curve fit with Graphpad Prism fit in the Software Validation Package User Guide.

Step	Action	Expected Results	Yes	No
1	Launch Octet® Analysis Studio Software if it is not already running and log on as required. Make sure the Experiment Explorer window is displayed. If not, click **Explore** in the **Home** tab.	The Octet® Analysis Studio Software Home screen is displayed showing the Experiment Explorer window.	
2	In Experiment Explorer, browse to Data in the Quantitation Tests folder and double click to open.	Data traces are displayed.	
3	In the Home tab, click **Load** (Analysis Settings).	The Import Settings dialog displays asking if you want to overwrite settings.	
4	Click **OK** to dismiss the dialog and overwrite existing analysis settings.		N/A
5	Browse to the 4PL Unweighted folder, select **4PL Unweighted.efrd** and click **Open**.	A dialog appears indicating that analysis settings have been imported.	
6	Select the **Quantitation Analysis tab** and in the Export options at the top of the screen, click **Excel Export**.	The Report Selection dialog is displayed.	
7	Verify that Standard Curve Table is checked (other selections are optional).		N/A

Step	Action	Expected Results	Yes | No
8	In the **Save to** field, browse to the 4PL Unweighted folder and click **Open**. Click **Save**, then click **Export**.	Results are exported into a file entitled ExcelReport_[date-time].xls.	
9	Open **ExcelReport_[date-time].xls**, then in the Standard Curve worksheet, type **Ctrl+A** to select all.	Standard curve contents become selected.	
10	Copy the worksheet by typing **Ctrl+C**.	Results are copied onto the clipboard.	
11	Browse to the Quantitation Tests folder and open **4PL Unweighted Validation.xlsx**.		N/A
12	Select the **Analysis Studio Software** worksheet. Click on cell **A1** and type **Ctrl+V** to paste the contents of the clipboard.	The Analysis Studio Software results are pasted into the worksheet.	
13	Select the **Validation Worksheet** and inspect the OUTCOME results.	All results are Pass.	
14	Save 4PL Unweighted Validation.xlsx with a new name and close it.		N/A

Ordering Information

Part No.	Description
50-0296	Octet® CFR Software V12.X Validation Package
50-5093	Octet® CFR V12.X Software Module