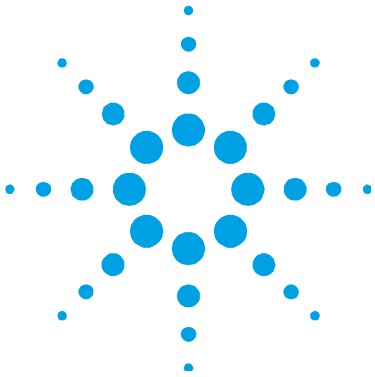

Agilent UV-Visible ChemStation

OpenLAB ECM Compliance Pack

Concept Guide

Notices

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1. Introduction

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This chapter introduces the following topics:

- OpenLAB ECM
- The integration of UV-Visible ChemStation with OpenLAB ECM
- The requirements of 21 CFR Part 11.

What is OpenLAB ECM?

The Agilent Enterprise Content Manager (ECM) is a web-based electronic library that allows you to safely archive and catalog any electronic file. ECM allows you to store and index analytical raw data, reports, and all other types of documents. The stored files can be shared with other users.

You can store any electronic file type, such as Microsoft Office documents, Adobe PDF documents, images, and molecular drawings, as well as raw data and reports generated by UV-Visible ChemStation.

ECM allows you to easily collect, organize, search, and review all of your data. It automatically extracts searchable metadata from files, and provides powerful search capabilities. In addition, ECM provides embedded viewers for many file types.

The ECM interface is opened via Microsoft Internet Explorer, also referred to as the ECM Web Client.

Add-On Solution for UV-Visible ChemStation: OpenLAB ECM Compliance Pack

Starting with revision B.04.01, Agilent UV-Visible ChemStation provides an interface to the Agilent Enterprise Content Manager (ECM), which enables you to store analytical data and reports in a secure location. From UV-Visible ChemStation, you can log in to OpenLAB ECM and store methods, data files and reports. UV-Visible ChemStation data stored in OpenLAB ECM can later be downloaded back to UV-Visible ChemStation for review at any time.

Since revision B.05.01, UV-Visible ChemStation with the OpenLAB ECM Compliance Pack Add-On offers the following features for compliance with 21 CFR Part 11 and similar regulations for electronic records and electronic signatures:

- Mandatory login/connection to OpenLAB ECM
- Configurable session locking
- Configurable UV-Visible ChemStation user roles and privileges
- Full data traceability through a UV-Visible ChemStation audit trail
- Full data versioning though the OpenLAB ECM database

The OpenLAB ECM Compliance Pack Add-On requires the following components:

- OpenLAB ECM Server

- OpenLAB ECM Web Client installed on the UV-Visible ChemStation computer
- UV-Visible ChemStation with the OpenLAB ECM Compliance Pack installed on the UV-Visible ChemStation computer
- A connection between the UV-Visible ChemStation computer and the OpenLAB ECM Server

The main workflows for the transfer of raw data and methods are listed below. These workflows indicate the system activities in relation to the work processes.

Overview of data-related workflows

Workflow 1: Data acquisition and manual transfer to OpenLAB ECM

1. Analytical data is acquired using UV-Visible ChemStation.
2. You are prompted to save the file to the OpenLAB ECM database. The file must be saved before any other function can be performed in the UV-Visible ChemStation software.
3. A new OpenLAB ECM data set is created in the defined location as a UV-Visible ChemStation results file. The data set includes method, data and results, as a *.SSIZIP along with the application audit trail.

Workflow 2: Data acquisition using UV-Visible ChemStation Automation and automatic transfer to OpenLAB ECM

1. An automation method is generated by a user with the appropriate privileges and uploaded to OpenLAB ECM. The **ECM > Configure** menu is used to define where the file is to be saved.
2. A user with the appropriate privileges runs the method generating new data.
3. A new Results file comprising the method, data and associated audit trail is automatically uploaded to OpenLAB ECM to the configured location defined in the method file. In addition, the user is prompted to save the file before any other function can be performed in the UV-Visible ChemStation software.
4. A new version of the data is created.

Workflow 3: Data acquisition using an existing UV-Visible ChemStation results file

1. An existing UV-Visible ChemStation results file is loaded from the OpenLAB ECM database. It contains method, data and audit trail information.
2. The user makes changes to this results file by collecting more data, changing the method or analyzing the existing data.
3. The new results file is saved using the **File > Save Results** command (or saved with the same file name).
4. A second version of the same results file is created.

For more details, and for additional workflows, refer to *Data-related workflows* on page 27.

Overview of workflows for methods

Workflow 1: Uploading a new method

1. A new method is created by a user with the appropriate privileges.
2. The method is uploaded to OpenLAB ECM using the path selected by the user.
3. Version 1 of the method is automatically created in ECM.

Workflow 2: Saving a changed method

1. An existing method is loaded from OpenLAB ECM.
2. The method is edited by a user with the appropriate privileges and the changed method is saved to OpenLAB ECM.
3. A new version of the method is automatically created in OpenLAB ECM.

For more details, and for additional workflows, refer to *Workflows for Methods* on page 29.

Data Storage in OpenLAB ECM

OpenLAB ECM provides a four-level data storage model consisting of Locations, Cabinets, Drawers and Folders. The Location, Cabinet, Drawer and Folder names together comprise the path name (called either LCDF path or Remote Data Path) of the storage location. Data is stored at Folder level only.

The LCDF structure can be created using the ECM Web Client. You can also create additional Locations, Cabinets, Drawers, and Folders using the ChemStation Remote Data Path and you can set predefined tokens for the Drawers and Folders in ChemStation.

In the OpenLAB ECM tree view, paths are denoted as follows:

- Locations are denoted by a house icon
- Cabinets are denoted by the file cabinet icon
- Drawers are denoted by the drawer icon
- Folders are denoted by the folder icon.

The entire content structure appears in the Content book.

CFR Part 11 Compliance

21 CFR Part 11 Compliance

Effective August 20, 1997, the U.S. Food and Drug Administration (FDA) released and published a new rule to enable pharmaceutical companies to approve their results with electronic signatures and to transfer paper-trail documentation into electronic records. This rule is known as 21 Code of Federal Regulations Part 11 (referred to as 21 CFR Part 11) and applies to all industry segments regulated by the FDA.

21 CFR Part 11 includes the US Federal guidelines for storing and protecting electronic records and applying electronic signatures. The intent of these guidelines is to ensure that electronic records subject to these guidelines are reliable, authentic, and maintained with high integrity.

UV-Visible ChemStation B.05.01 with the OpenLAB ECM Compliance Pack Add-On provides the necessary controls for managing system access, audit trail functions, versioning of UV-Visible ChemStation data, and electronic signature functions. Agilent OpenLAB ECM provides secure record keeping and data archival functionality. Agilent OpenLAB ECM is proven and has been deployed at many leading life sciences companies to satisfy compliance mandates for 21 CFR Part 11.

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This chapter describes the installation and configuration of the UV-Visible ChemStation OpenLAB ECM Compliance Pack Add-On.

Compatibility

The UV-Visible ChemStation OpenLAB ECM Compliance Pack Add-On for UV-Visible ChemStation version B.05.01 or greater, is only compatible and supported with OpenLAB ECM version 3.4.1.

The UV-Visible ChemStation OpenLAB ECM Compliance Pack Add-On is not supported in combination with the UV-Visible ChemStation Security Pack.

Installation and Configuration Tasks on the Server

You must execute the database script for UV-Visible ChemStation on the OpenLAB ECM Server to implement UV-Visible ChemStation related users, roles and privileges. In addition, after installing the program, you must take care of several settings.

Updating roles in existing OpenLAB ECM Accounts

When updating the OpenLAB ECM Database, certain specific UV-Visible ChemStation roles and privileges are created. If you create a new OpenLAB ECM account, these roles and their privileges are automatically available in that new account. However, if you want to use UV-Visible ChemStation with an existing OpenLAB ECM account, you must first update the roles in that specific account. The new UV-Visible ChemStation roles and their privileges will be available only after updating the roles for the existing account.

To make the new roles and privileges available in an ECM Account

WARNING All system roles will be reset to default when performing **Reset Role**. If you made manual changes to a system role, these changes will be lost and any other manually created roles will be deleted.

1. Open a browser window and connect to the ECM Web Server.
2. Log in to the ECM Account for which you want to update the roles.
3. Select the **Administration** tab.
4. Click **Account Administration**.
5. Double-click **Users / Groups / Roles**.

   The Account Administration dialog opens.
6. Select the **Roles** tab.
7. Click **Reset Roles**.

The default UV-Visible ChemStation roles and the related UV-Visible ChemStation privileges are now available in the current account and can be assigned to users.

Configuring users, roles and privileges

About users, roles, and privileges

In OpenLAB ECM, you can either create specific OpenLAB ECM users or operate with the Windows users. Each user can be member of a specific group. The available groups depend on the OpenLAB ECM configuration.

You must assign a specific OpenLAB ECM role to each group. You can also assign roles to single users, however, for the sake of clarity we recommend that you assign roles only on the group level.

The roles are equipped with numerous specific privileges, which define what the users are allowed to view or do in OpenLAB ECM and in UV-Visible ChemStation.

NOTE Once you create a new OpenLAB ECM user, group, or role, you cannot delete it. You can only deactivate the unused item.

Default roles and privileges

There are a number of default roles and privileges in OpenLAB ECM that are created during the installation of OpenLAB ECM and UV-Visible ChemStation OpenLAB ECM Compliance Pack. The following table shows an overview of these roles and privileges.

Name	Description
•Starting with "UV:"	Default UV-Visible ChemStation roles and privileges related to UV-Visible ChemStation. Can be restored by the Reset Roles function. For details of the UV-Visible ChemStation privileges, see the *Appendix* on page 43.
•Starting with ":"	Default ECM role. Can be restored by the Reset Roles function.
•Starting with "Content:"	Privilege related to ECM
•Starting with "System:"	Privilege related to ECM

In addition, you can create your own roles in OpenLAB ECM, or grant further privileges to the default roles. For detailed information, refer to the *ECM Administrator's Guide*.

Assigning roles

Users do not need any specific role in order to log in to OpenLAB ECM. However, in order for users to see a particular Location, Cabinet, Drawer, or Folder in the user interface, they must have the **:Reader** role as a minimum requirement. As a result, domain users with no global roles might not be able to view anything in the content unless they were granted the appropriate privileges.

You should grant the users of the UV-Visible ChemStation Compliance Pack the **:Contributor** role. This can be done at the global level for the entire ECM Account, or individually for specific folders (see *Roles and folders* on page 38). The **:Contributor** role allows the user to view and add content to ECM. The **:Contributor** role should be enhanced with the **Content: Add Folder** privilege. This allows ChemStation ECM users to add folders to the LCDF hierarchy.

NOTE If the role does not include the **Add Folder** privilege, the users cannot add a new Remote Data Path (LCDF) in ChemStation.

Installation Tasks on the ChemStation Computer

UV-Visible ChemStation OpenLAB ECM Compliance Pack (G5182AA) is an Add-On that can be installed at the same time as the UV-Visible ChemStation. If UV-Visible ChemStation is already installed on the client PC, it must be upgraded (G1102AA) to the latest version for access to the OpenLAB ECM database.

The OpenLAB ECM Compliance Pack can be installed at the same time as the UV-Visible ChemStation software by entering a valid license number at the start of the installation process. Do not install the OpenLAB ECM Compliance Pack Add-On if no ECM server is available as this will cause an application error.

In addition to the OpenLAB ECM roles, users of UV-Visible ChemStation must be assigned at least one of the UV-Visible ChemStation roles or another, customized role with UV-Visible ChemStation privileges. You find a complete list of all UV-Visible ChemStation roles and all relevant privileges in the *Appendix* (page 43). The privileges are set in the OpenLAB ECM server Administration tab and define which functions you can use in UV-Visible ChemStation. Before running UV-Visible ChemStation, ensure that a user has been configured with login credentials and the appropriate UV:Roles and UV:Privileges. For more information, see *Users/Groups/Roles* on page 38.

Finally, ensure that instruments have been configured using the UV-Vis Configuration Editor. More information is in the *Agilent 8453 UV-Visible Spectroscopy System Installation Guide*.

Preparing the ECM Web Client

To prepare the ECM Web Client

1. Ensure that an up-to-date version of the ECM Web Client is installed on the UV-Visible ChemStation computer.
2. On the UV-Visible ChemStation computer: open a browser window and connect to the ECM Web Server.
3. Log in to ECM.

All relevant hotfixes are automatically installed. You may be asked to restart the UV-Visible ChemStation computer during the installation.

Uninstallation

To uninstall Agilent UV-Visible ChemStation, refer to the *Agilent 8453 UV-Visible Spectroscopy System Installation Guide*. To remove the UV privileges and roles from the ECM Server, contact your local Agilent representative.

3. Basic Concepts of UV-Visible ChemStation Open Lab ECM Compliance Pack

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This chapter describes how to log in to OpenLAB ECM in UV-Visible ChemStation, and explains the ECM-related user interface items and the main settings.

User Permissions

Log In/Log Out

To prevent unauthorized access to OpenLAB ECM or unauthorized use of UV-Visible ChemStation, OpenLAB ECM requires authentication with a user name and password. In addition, each user must have user privileges defining the accessible content.

The user administration is set up and managed on the ECM Server. For more details about ECM login and user setup refer to the *ECM User/Administrator's Guide*.

For UV-Visible ChemStation, the login is mandatory and you must log in during the UV-Visible ChemStation startup.

If you are already logged in to the UV-Visible ChemStation online session, and start the UV-Visible ChemStation offline session, you will need to re-enter a user name and password to login.

If you are not connected to OpenLAB ECM, or the network connection is temporarily lost, you will be unable to access the UV-Visible ChemStation application. If connection is lost during a UV-Visible ChemStation session, you can continue until the file (results or method) will need to be saved. See *Troubleshooting Saving and Retrieving Files to OpenLAB ECM* on page 29.

The login is dependent on the instrument session; only one user can be logged in to one instance of UV-Visible ChemStation at any one time. If another user wants to log in, the first user must log out.

User credentials

The **Login** dialog is displayed when UV-Visible ChemStation is launched. It requires you to enter a set of valid authorization details in order to log in. The login information is ECM Server-specific and will be provided by the ECM administrator.

You must enter the following login details:

- **Server URL:** the URL of the ECM Server.
- **Account:** you can store content to the locations assigned in the specific account; one ECM Server may have several accounts.

- **Username:** the user name defined in the ECM Account, or your NT domain user name (depending on the user configuration in ECM)
- **Password**: the password provided by your administrator, which can be changed on request (for ECM 'built-in' users), or the password of your NT domain account, if you are logging in using your NT domain user name.
- **Log on to:** the domain administrating the ECM users.

OpenLAB ECM User in UV-Visible ChemStation

As long as a user is logged on, the UV-Visible ChemStation user name is given by the OpenLAB ECM logon and cannot be overwritten. This user name will appear in OpenLAB ECM system activity audit trails and UV-Visible ChemStation audit trails.

Session lock

If you leave the UV-Visible ChemStation computer for a certain period of time, you can lock the application so that no other user can access the program. This is a safety feature to ensure that there is no unauthorized access.

When you activate the session lock, you or another user must first provide a valid login before continuing to work with UV-Visible ChemStation.

There are the following options to activate the session lock:

- Privately (**ECM > Lock Session > privately**): Only the user who activated the session lock, or a user with the UV: Break Session Lock privilege, can log in.
- Non privately (**ECM > Lock Session > non privately**): Any valid ECM user can log in. This is useful, for example, if there is a shift change, and the leaving personnel secures UV-Visible ChemStation until the personnel of the new shift starts work.
- Time based: Depending on the ECM Account configuration, UV-Visible ChemStation is automatically locked after a given period of time without any user interaction (see *Inactivity Timeout* under *Administration in ECM* on page 37). If there is no activity in an OpenLAB ECM Web Client, the Web Client is also locked after the given period of time. UV-Visible ChemStation and the OpenLAB ECM Web Client are locked independently from each other.

- Time base: UV-Visible ChemStation can be configured to lock automatically after a set amount of time within the ECM File menu. The number of minutes before the Session Lock is activated is set via **ECM > Configure**. This configuration is not saved until UV-Visible ChemStation is closed and you select the **Save Configuration** checkbox which appears before the application shuts down. The time based lock is broken by either a mouse click or by hitting a key on the keyboard.
- The time based session lock can be configured to lock the UV-Visible ChemStation session either privately or non-privately (see *Log In/Log Out* on page 20).

OpenLAB ECM User Interface in UV-Visible ChemStation

Overview of new interface elements

With the installation of OpenLAB ECM Compliance Pack with UV-Visible ChemStation, the following new menus and menu items become available:

Menu	New Elements	Description
File	View Signature Logbook	Display the Signature Logbook
	Add Signature	Add a signature to the current result file within the UV-Visible ChemStation application (for a user with appropriate privileges)
	Save Method	Set the location to which the method will be saved in OpenLAB ECM.
	Save Result	Set the location to which the result will be saved in OpenLAB ECM.
View	Audit Trail	See *Audit Trails and Logbooks* on page 34
ECM	Configure	See *The ECM menu* on page 23
	Change User	
	Lock Session	

The ECM menu

The **ECM** menu includes the following commands:

Command	Description
Configure	The configure menu allows for two key settings: • Default path and location for saving method and result files to the OpenLAB ECM. • Time based application lock
Change User...	Logs out the current user and opens the OpenLAB ECM login dialog. UV-Visible ChemStation cannot be accessed until a user with the appropriate privileges has logged in.
Lock Session	The UV-Visible ChemStation session can be locked either: • Privately • Non-privately (see *Log In/Log Out* on page 20)

Automatic Data Transfer Settings

There are no options to configure how data is transferred from UV-Visible ChemStation to the OpenLAB ECM database. Data transfer will be completely automatic, and the user will be prompted to save a results file before any further functions in the UV-Visible ChemStation application can be accessed. See *Troubleshooting Saving and Retrieving Files to OpenLAB ECM* on page 29 for more details.

Compressed ChemStation File Formats and Legacy Data

When UV-Visible ChemStation result files are uploaded to OpenLAB ECM, they are automatically packaged into an SSIZIP file. These files include the method, data and audit trail. Files that are not packaged as *.SSIZIP will not contain an audit trail. All files that contain data must be saved as *.SSIZIP.

The table below indicates which file types exist as compressed files.

UV-Visible ChemStation	Non-ECM file type	Packaging format
Methods	*.m	No packaging
Samples/Auxiliary	*.sd	Must be saved as part of Results file
Standards	*.std	Must be saved as part of Results file
Sample table (Advanced mode)	*.st	No packaging
Automation (Advanced mode)	*.a	No packaging
Standard mode results	*.sr	*.sr.SSIZIP
Advanced mode results	*.ar	*.ar.SSIZIP
Thermal Denaturation mode results	*.td	*.td.SSIZIP
Kinetics mode results	*.kd	*.kd.SSIZIP
Dissolution mode results	*.dr	*.dr.SSIZIP
Verification and Diagnostics mode Self Test results	*.sft	*.sft.SSIZIP
Verification and Diagnostics mode Diagnostics results	*.dgr	*.dgr.SSIZIP
Verification and Diagnostics mode MCT Adjustment results	*.mct	*.mct.SSIZIP

The packaging of UV-Visible ChemStation result files is a feature of the UV-Visible ChemStation OpenLAB ECM Compliance Pack. The packaging is automatically carried out when the data or results are uploaded to OpenLAB ECM. When the SSIZIP files are downloaded from OpenLAB ECM to UV-Visible ChemStation, they are automatically unpacked.

UV-Visible ChemStation method files can be uploaded to OpenLAB ECM, or transferred into OpenLAB ECM (where pre-existing method files are available), but can only be opened from within UV-Visible ChemStation.

Sample, standard and auxiliary files can be transferred into OpenLAB ECM (where pre-existing files are available) and then opened from within UV-Visible ChemStation, but cannot be saved to OpenLAB ECM without being part of a results file that also includes method and audit trail information.

For the Advanced Mode of ChemStation, automation and sample tables can be saved to and loaded from OpenLAB ECM. Once an automation table is used to generate results, this must be subsequently saved as a results file including method, audit trail and data to ensure complete traceability of electronic records.

Legacy data acquired with UV-Visible ChemStation prior to B.05.01 will have to be migrated to OpenLAB ECM before being able to be loaded into UV-Visible ChemStation. Legacy UV-Visible ChemStation results files (file extension: *.sr, *.ar, *.kr, *.tr or *.dr) will not be able to be loaded from the OpenLAB ECM database to UV-Visible ChemStation. Methods, automations and sample tables will be able to be loaded into OpenLAB ECM, and subsequently used in UV-Visible ChemStation under 21 CFR Part 11 conditions.

4. Working with UV-Visible ChemStation OpenLAB ECM Compliance Pack

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This chapter describes the basic workflows with UV-Visible ChemStation OpenLAB ECM Compliance Pack. There are three data-related workflows and two workflows for methods.

Data-related workflows

Workflow 1: Data acquisition and manual transfer to OpenLAB ECM

Raw data and the results file are uploaded to the OpenLAB ECM directly after a collection is complete. The user can determine in which location the file is saved in the OpenLAB ECM database. The results file is compressed as a SSIZIP file.

To save data to OpenLAB ECM manually after completion of a collection:

1. Open UV-Visible ChemStation and log in to OpenLAB ECM. Your ECM user name is automatically inserted as the operator name.
2. Create a method, or load a method from OpenLAB ECM.
3. Collect spectra as per the UV-Vis method.
4. When complete, the UV-Visible ChemStation will prompt your to save the file:
   - Navigate within OpenLAB ECM to the preferred folder.
   - Indicate a name for the new SSIZIP file.
5. A new OpenLAB ECM data set is created in the defined ECM location. The data set includes method, data and results, as a *.SSIZIP along with the application audit trail.

NOTE The upload process may take some time when large amounts of data are uploaded. During this time UV-Visible ChemStation is busy and you cannot perform tasks in ChemStation. Please wait until the upload is completed.

NOTE There is no forced save for the results of tests run using the Verification and Diagnostic mode.

Workflow 2: Data acquisition using UV-Visible ChemStation Automation and automatic transfer to OpenLAB ECM

UV-Visible ChemStation automation methods can be created in applicable modes. An automation method specifies a sequence of events that includes execution of the method, the file name and the file save location in OpenLAB ECM. The results file is saved automatically.

1. An automation method is generated by a user with the appropriate privileges and uploaded to OpenLAB ECM. The **ECM > Configure** menu is used to define where the file is to be saved.

2 A user with the appropriate privileges downloads the automation file from OpenLAB ECM and uses it to collect data.

3 At completion of the automation, the results file is automatically uploaded to OpenLAB ECM without any input from the user. The location in ECM where the file is saved and the file name is defined in the automation method.

4 The user is prompted to save the file before any other function can be performed in the UV-Visible ChemStation software.

Workflow 3: Data acquisition using an existing UV-Visible ChemStation results file

A UV-Visible ChemStation results file is created and saved in OpenLAB ECM as Version 1. As the result file contains the method, it can be loaded and used to collect more data, which changes the existing results file.

1 An existing UV-Visible ChemStation results file (version 1) is loaded from the OpenLAB ECM database. It contains method, data and audit trail information.

2 The user makes changes to this results file by collecting more data, changing the method or analyzing the existing data.

3 The new results file is saved using the **File>Save Results** command (or saved with the same file name).

4 Version 2 of the results file is created in OpenLAB ECM.

NOTE To review earlier versions of a file the user requires the ECM privilege Content: File Revisions – View.

Workflows for Methods

Overview of workflows for methods

Workflow 1: Uploading a new method

Newly created methods are manually uploaded to OpenLAB ECM.

1. A new method is created by a user with the appropriate privileges in UV-Visible ChemStation.
2. The method is uploaded to OpenLAB ECM using the path selected by the user in the **File > Save Method As** menu command.
3. Version 1 of the method is automatically created in OpenLAB ECM.

Workflow 2: Saving a changed method

An existing method can be opened in UV-Visible ChemStation and changed by a user with the appropriate privileges. The method can then be saved again in the ECM.

1. From UV-Visible ChemStation, an existing method is loaded from ECM.
2. The method is edited by a user with the appropriate privileges.
3. The method is uploaded to OpenLAB ECM using the path selected by the user:
    - In the **File > Save Method** menu command to save to the same location and with the same file name. In this case Version 2 of the method file will be created.
    - In the **File > Save Method As** menu command to save the method to a new location with a new file name.
4. After finishing the upload, the file is available in OpenLAB ECM.

Troubleshooting Saving and Retrieving Files to OpenLAB ECM

ECM Server is not available

If the ECM Server is not available while working with UV-Visible ChemStation, there are two possible scenarios.

- ECM Server is not available before/during login

  If the ECM Server is not available while logging in to OpenLAB ECM during UV-Visible ChemStation start up, the user cannot be authenticated by the system. Login is aborted and there will be no access to UV-Visible ChemStation.

- ECM Server is not available at the time a file is being saved

  If the ECM Server connection is interrupted at the time a file is being saved, the file save event will fail and the user will be notified by an error message. To prevent loss of data, UV-Visible ChemStation will not allow any further actions until the file has been saved.

  When the ECM Server becomes available again, the file save can occur, and the user can continue. As soon as the ECM Server is available again, all OpenLAB ECM tasks are available without restarting the application. A new login is not required.

If a successful file save has not occurred, the file can be recovered from a secure location on the hard disk (c:/Chem32/TMP). When the ECM Server is available, the file must be transferred to OpenLAB ECM before it can be opened by UV-Visible ChemStation. The file will only be at this location until a new file is created in UV-Visible ChemStation and saved to OpenLAB ECM.

For further troubleshooting, please contact your ECM administrator.

5. Administration for 21 CFR Part 11 Compliance

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This chapter explains the purpose of 21 CFR Part 11 and its implementation in UV-Visible ChemStation with ChemStation OpenLAB ECM Compliance Pack.

Introduction to 21 CFR Part 11

Effective August 20, 1997, the U.S. Food and Drug Administration (FDA) released and published a new rule to enable pharmaceutical companies to approve their results with electronic signatures and to transfer paper-trail documentation into electronic records. This rule is known as 21 Code of Federal Regulations Part 11 (referred to as 21 CFR Part 11) and applies to all industry segments regulated by the FDA.

The impact of this rule on current work practices and data handling in the pharmaceutical industry has been much higher than expected. “The industry wanted to have a rule on electronic signatures, but what they got was a rule on electronic records.” (Martin Browning, former FDA inspector, during a validation seminar in Washington D.C.)

21 CFR Part 11 places high emphasis on the implementation of all measures to protect and secure electronic records. Notwithstanding the uncertainties and the changes that 21 CFR Part 11 requires in the behavior of both the pharmaceutical industry and the vendors of chemical analysis equipment, it is well worth implementing in today’s laboratories because it can help the industry with one of the most important issues in pharmaceutical research-bringing new drugs on the market faster.

The major benefits of this shift towards electronic data management are in the potential productivity increase for the industry. The industry can decrease its data output on paper, speed up the data review and approval process, and benefit from new automation technology based on computerized system control, for example, in manufacturing or dissolution drug release testing.

In addition to this rule on electronic records, other general requirements for computerized systems are brought to the auditor’s attention. These rules cover the basic requirements of validation which are limiting data access and ensuring data integrity and data traceability.

It is, of course, the industry that must ensure that its work practices support the FDA rules, but most of the requirements also affect the chemical analysis systems and suppliers of these systems.

21 CFR Part 11 Requirements

To fulfill the FDA rules and guidelines for compliant electronic records and computerized systems, it is important to understand the basic aspects of secure data handling.

- Data security: physical protection of data by limiting access to the system and preventing unauthorized access.
- Data integrity: protecting raw data and metadata from corruption and unauthorized modification; linking raw data and results to allow the original results to be reproduced at any time, for example, for an audit.
- Audit traceability: documenting which user did what to the results and when; tracing any modifications to the original raw data.

General Aspects of Data Security in Computerized Networks – Open Versus Closed Systems

It is generally known that data transfer over a public network can be accessed by unauthorized external persons, “hackers”, who gain access either for personal amusement or intentional fraud.

If an electronic identification comprising user ID and a password is used to approve confidential or important data, users must be sure that their signatures are unbreakably linked to the data and that nobody can copy this signature or get access to the passwords. In a public system, this would require additional encryption technology, for example, a private/public key combination of data encryption. In contrast, if a computerized system is protected from unauthorized access, users can be sure that their signatures are private and are not accessible to unauthorized individuals.

The FDA also distinguishes between these two scenarios and defines them as open and closed systems. A public network system can therefore only be viewed as an open system and a protected network as a closed system, if it fulfills additional requirements.

In FDA terms, “closed system means an environment in which access is controlled by persons who are responsible for the content of electronic records on the system” (11.3.5). The evidence of a system being a closed system is not a one-time check but an ongoing process of executing and documenting the system controls that make sure that the system is closed. In contrast, in an open system, “those persons being responsible for the content of electronic records do not control the system access.”

As a result, open systems require additional encryption technology for all data transfer over the network.

UV-Visible ChemStation OpenLAB ECM Compliance Pack is designed for, and is supported in, closed systems.

Overview of Configuration Steps Required for Part 11

To configure UV-Visible ChemStation OpenLAB ECM Compliance Pack to be compliant with 21 CFR Part 11, you must ensure that your system complies with this checklist:

- LCDF structure on the ECM Server prepared according to your needs See *Data Storage in OpenLAB ECM* on page 11.
- UV-Visible ChemStation specific roles and privileges added to the ECM Server. See *Updating roles in existing OpenLAB ECM Accounts* on page 14.
- OpenLAB ECM Roles/Users/Groups configured. See *Configuring users, roles and privileges* on page 15.
- ECM Account configuration with active audit trail and mandatory reason. See *ECM Audit Trail* on page 35 and *Account configuration* on page 37.
- Password policy realized in ECM (including E-mail Notification). See *To configure the password settings for an ECM Account* on page 38.
- E-Signatures prepared (messages and privileges). See *Using electronic signatures* on page 40.
- UV-Visible ChemStation with ChemStation OpenLAB ECM Compliance Pack installed on the Client PC. See *Installation Tasks on the ChemStation Computer* on page 16.
- Audit trail will automatically be active and cannot be switched off.

Audit Trails and Logbooks

In order to comply with 21 CRF Part 11, UV-Visible ChemStation OpenLAB ECM Compliance Pack offers two audit trails and logbooks to document all activities associated with methods, results, reports, or with ECM files generally. These audit trails and logbooks track all changes that are made to any file, including data acquisition, re-analysis, and long-term archiving.

The audit trails are stored together with the sample data. The audit trail files are archived together with the other data in the associated SSIZIP files. The ECM logbooks are available only directly in ECM.

UV-Visible ChemStation Audit Trail

A single audit trail in UV-Visible ChemStation captures all actions associated with editing methods and results. The audit trail contains information on:

- A description of the action or event that has occurred in the software
- The ECM user that is the ChemStation operator at the time
- Time and date of the event
- Serial number of instrument (for online UV-Visible ChemStation)

NOTE The audit trail is only saved in SSIZIP files. A method that has not been used to generate data will not contain an audit trail.

Signature Logbook

In UV-Visible ChemStation you can add an electronic signature to a file if you have an ECM user ID and password. The signature logbook records the time and date of the signature, the user who applied the signature and the reason the signature was applied. In order to sign a UV-Visible ChemStation file, you must have the appropriate privileges.

ECM Audit Trail

The ECM Audit Trail is a record showing who accessed the system and what operations he or she performed during a given period of time.

You can view file-related, system administration, folder administration, and scheduler-related entries. For example, you can see when a file was added and who added it.

For each operation, ECM prompts you to provide a reason. This *Reason* is also shown in the ECM Audit Trail. For automatic uploads there are default reasons given by the system. The *Reason* entry may be optional or mandatory, depending on the ECM configuration (see *Account configuration* on page 37). If the system is configured to be compliant with 21 CFR Part 11, providing a reason is mandatory.

ECM System Log

The System Log is a record that shows changes to the system, including configuration changes, e-mail notifications, and additions or changes of Locations, Cabinets, Drawers, or Folders.

You can view file-related, system administration, folder administration, or scheduler-related entries. For example, you can see when a Location was added and by whom.

The System Log is always active; you do not need to enable it.

To view the ECM System Log

1. In ECM, select the Administration page.
2. In the navigation pane, select the **Activity Log > System Log** node.

All general actions related to ECM are listed here, together with the date, ECM user name who performed the action, and a reason provided by the respective user. Depending on the ECM Account administration, the reason may be optional or mandatory (see *Account configuration* on page 37).

You can search the entries, for example, for a specific date or date range, or for entries related to specific categories (Files, Folders, System, Scheduler, or Instrument). Also you can print the entries or export them to a file.

Administration in ECM

When you install UV-Visible ChemStation OpenLAB ECM Compliance Pack, you need to carry out certain basic configuration tasks in ECM (see *Installation and Configuration Tasks on the Server* on page 14). In addition, there are several other settings in ECM that are relevant with regard to 21 CFR Part 11. These settings are described in the following section.

Account configuration

To configure the ECM Account

1. In ECM, select the Administration page.
2. In the Navigation Pane, select the Account Administration node.
3. Double-click the Configuration item.
4. The Account Administration dialog opens.
5. Apply the following settings:

Setting	Description	21 CFR Part 11 Requirements
Lockout	A user who tries too often to log in with invalid user credentials is locked out of the system and no longer log in — even with valid user credentials. You can define the number of login attempts permitted.	Limit the number of allowed login attempts to three.
Inactivity Timeout	A user who does not perform any action in UV-Visible ChemStation or the ECM Web Client for the given period of time is automatically logged out.	Specify a timeout
System administrator email	Specifies an e-mail address that is notified when a user is locked out after too many unsuccessful login attempts.	Provide an email address
Minimum Password Length	Specify the minimum number of characters required in any new password. The default setting is 5.	Require a minimum password length of at least 5 characters
Require entry in Reason fields	In each ECM Audit Trail or System Log entry, users can enter a reason for the action. If this check box is selected, the reason entry is mandatory.	The ECM Audit Trail and System Log reasons must be mandatory

Users/Groups/Roles

To configure the password settings for an ECM Account

NOTE 21 CFR Part 11 requires that a company/laboratory has a password policy.

1 In ECM, select the **Administration** page.

2 In the navigation pane, select the **Account Administration** node.

3 Double-click the **Users/Groups/Roles** item.

The Account Administration dialog opens.

21 CFR Part 11 does not define any specific rules for the password settings. However, your company must have defined a password policy. You may consider the following settings:

- User cannot change password
- User must change password after next login

Note that the minimum password length is defined in the ECM Account configuration (see *Account configuration* on page 37).

Roles and folders

ECM allows you to assign specific roles to users or user groups. This can be done at the global level for the entire ECM Account, or individually for specific folders. For example, a specific user group may have the Contributor role for folder A, but at the same time have only the Reader role for folder B.

If you want to assign roles at the folder level, you must first enable this feature in ECM. The setting is valid for the complete ECM Account.

To enable roles for folders:

1 In ECM, select the **Administration** page.

2 In the navigation pane, select the **Account Administration** node.

3 Double-click the **Users/Groups/Roles** item.

The Account Administration dialog opens.

4 On the Roles tab, select the required role and click **Edit.**

5 Select the **Available in folder** access tab check box.

Electronic Signature

Electronic signatures provide a means to sign documents as equally binding as a handwritten signature. In addition, electronic signatures are reproducible, because they are recorded in a secure, time stamped audit trail. Manipulation is prevented by enabling only users with specific privileges to sign electronically.

An electronic signature contains the user name (full name), date, and time when the signature was applied, the location where the signing occurred, and a user-configurable definition associated with the signature. The signature is always related to the complete SSIZIP container, not to a single file inside the container.

CFR 21 Part 11 requires that companies, especially ones that employ any type of approval process, use electronic signatures. With the help of the Agilent OpenLAB Business Process Manager (BPM) module, you can create highly automated review or approval processes including e-mail notification.

Preparation

Privileges

An ECM user must have the privilege Content: File Signatures to sign electronically. This privilege is, for example, assigned to the ECM default role: **:Approver**.

Reasons for the signature

With each signature the ECM users must either select a given reason or, if they are allowed to, provide their own reason.

To configure the reasons for signatures:

1. In ECM, select the Administration page.
2. In the navigation pane, select the Account Administration node.
3. Double-click the Electronic Signature item.

   The Account Administration dialog opens.

   To provide a new reason, enter the required text into the Reasons field and click.

   To delete an existing reason, select the reason in the Default reasons list and click

If you want to allow users to provide their own reason with a signature, select the **User can specify reason** check box.

Note that if you clear this check box, the users can only select one of the given default reasons.

4 If necessary, adjust the timeout settings:

- The **Signature screen timeout** defines how long an e-signature dialog will stay open if no signature is submitted. The default setting is 5 minutes.
- The **Consecutive signature timeout** is relevant if an ECM user carries out several successive e-signatures. If the next e-signature takes place within the given timeout interval, the location and the reason provided in the first e-signature will be pre-filled in the next dialog. The default setting for the consecutive signature timeout is 5 minutes.

Using electronic signatures

To apply an electronic signature

1 Right-click the required SSIZIP container and select Electronically Sign > Electronic Signature from the context menu.

The Electronic Signature dialog opens.

NOTE The other command in the context menu, **Electronically Sign > Acrobat Plug-In Signature**, works only for PDF documents and only if you purchased the appropriate plugin. It enables you to add signatures directly inside PDF documents.

2 Enter your ECM user credentials (username, password, and domain).

3 Enter your current location. With this information, the location from where you provide the signature is reproducible.

4 Select a reason for the signature from the **Default reason** drop-down list.

- Or -

Select the **User specified** check box and enter a different reason into the text field. Note that this option is only available if the ECM Account is configured accordingly.

5 Click **Sign.**

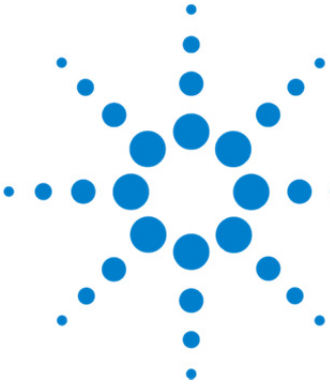
6 The file is now signed electronically. The e-signature is shown in the file properties in the eSig tab. The e-signature is also included in the ECM Audit Trail.

The user preferences in ECM can be configured in such a way that the number of e-signatures applied to a file is shown by default in the ECM content display, together with the file name and status.

The electronic signature itself is shown in the file properties in the eSig tab, and it is also part of the ECM Audit Trail.

To adjust the user preferences:

1. In ECM, select the **Administration** page.
2. In the navigation pane, select the **Account Administration** node.
3. Double-click the **User Preferences** item.
4. Click **Modify...** to modify the column settings.
5. Select **# of signatures** and click to add this property to the selected columns.
6. Click **OK**.
7. The number of e-signatures is then shown on every content page in ECM.



6. Appendix

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ChemStation Privileges in ECM

Privilege	Description
UV: Standard Mode Method	Edit: Change any method in Standard mode.
UV: Advanced Mode Method	Edit: Change any method in Advanced mode.
UV: Thermal Denaturation Mode Method	Edit: Change any method in Thermal Denaturation mode.
UV: Kinetics Mode Method	Edit: Change any method in Kinetics mode.
UV: Dissolution Mode Method	Edit: Change any method in the Dissolution modes: Dissolution Testing Multibath Dissolution Testing
UV: Sample	Run: Ability to measure a sample, or load Samples from the ECM database
UV: Standards	Run: Ability to measure a standard, or load Standards from the ECM database
UV: Auxiliary	Run: Ability to measure an auxiliary, or load Auxiliaries from the ECM database
UV: Standard Mode Analyze	Run: Change a results file by analyzing. Access the Math menu.
UV: Advanced Mode Analyze	Run: Change a results file by analyzing. Access the Math and Optimize menus.
UV: Thermal Denaturation Mode Analyze	Run: Change a results file by analyzing. Access the Math menu.
UV: Kinetics Mode Analyze	Run: Change a results file by analyzing. Access the Math menu.

Privilege	Description
UV: Dissolution Mode Analyze	Run: Change a results file by analyzing. Access the Math menu.
UV: Report Setup	Run: Enables editing of reports in applicable ChemStation modes: Advanced, Dissolution Testing, Multibath Dissolution Testing and Combined Reports
UV: Combined Report Dissolution Mode	Edit: Provides access to 'Acceptance' menu to allow setting of type of release Run: Allows reports to be calculated
UV: Validation	Run: Access to Verification and Diagnostic Mode tasks
UV: Sign	Add: Ability to add a Signature (using user ID and password) to a UV-Visible ChemStation file. View: View access to signature logbook
UV: Approve	Add: Ability to lock a result by checking the 'lock' box on the Add Signature dialog
UV: Break Session Lock	Run: Ability to unlock sessions that have been locked by any user
UV: Configuration	Edit: Provides access to the ECM > Configure menu, which allows setting of default file save locations (for utomations) and also time based lock settings. See *The ECM menu* on page 23

UV-Visible ChemStation Roles in ECM

Please note: the default UV-Visible ChemStation roles do not contain any ECM privileges.

Default UV:Administrator privileges

Privilege	View	Edit	Add	Run
UV: Report Setup				X
UV: Combined Report Dissolution Mode				X
UV: Validation				X
UV: Sign	X			
UV: Break Session Lock				X
UV: Configuration		X		

Default UV:Analyst privileges

Privilege	View	Edit	Add	Run
UV: Standard Mode Method		X		
UV: Advanced Mode Method		X		
UV: Thermal Denaturation Mode Method		X		
UV: Kinetics Mode Method		X		
UV: Dissolution Mode Method		X		
UV: Sample				X
UV: Standards				X

Default UV:Analyst privileges

Privilege	View	Edit	Add	Run
UV: Auxiliary				X
UV: Standard Mode Analyze				X
UV: Advanced Mode Analyze				X
UV: Thermal Denaturation Mode Analyze				X
UV: Kinetics Mode Analyze				X
UV: Dissolution Mode Analyze				X
UV: Report Setup				X
UV: Combined Report Dissolution Mode		X		X
UV: Sign	X		X	
UV: Break Session Lock				X

Default UV:Operator privileges

Privilege	View	Edit	Add	Run
UV: Sample				X
UV: Auxiliary				X
UV: Standard Mode Analyze				X
UV: Advanced Mode Analyze				X
UV: Thermal Denaturation Mode Analyze				X
UV: Kinetics Mode Analyze				X

Default UV:Operator privileges

Privilege	View	Edit	Add	Run
UV: Dissolution Mode Analyze				X
UV: Report Setup				X
UV: Combined Report Dissolution Mode				X
UV: Sign	X		X	

Default UV:Lab Manager privileges

Privilege	View	Edit	Add	Run
UV: Standard Mode Method		X		
UV: Advanced Mode Method		X		
UV: Thermal Denaturation Mode Method		X		
UV: Kinetics Mode Method		X		
UV: Dissolution Mode Method		X		
UV: Standard Mode Analyze				X
UV: Advanced Mode Analyze				X
UV: Thermal Denaturation Mode Analyze				X
UV: Kinetics Mode Analyze				X
UV: Dissolution Mode Analyze				X
UV: Report Setup				X
UV: Combined Report Dissolution Mode		X		X

Default UV:Lab Manager privileges

Privilege	View	Edit	Add	Run
UV: Sign	X			
UV: Approve			X	
UV: Break Session Lock				X

Default UV:Service privileges

Privilege	View	Edit	Add	Run
UV: Standard Mode Method		X		
UV: Advanced Mode Method		X		
UV: Thermal Denaturation Mode Method		X		
UV: Kinetics Mode Method		X		
UV: Dissolution Mode Method		X		
UV: Standard Mode Analyze				X
UV: Advanced Mode Analyze				X
UV: Thermal Denaturation Mode Analyze				X
UV: Kinetics Mode Analyze				X
UV: Dissolution Mode Analyze				X
UV: Report Setup				X
UV: Combined Report Dissolution Mode				X
UV: Validation				X

Default UV:Service privileges

Privilege	View	Edit	Add	Run
UV: Sign	X		X	

Default UV:Read Only privileges

Privilege	View	Edit	Add	Run
UV: Sign	X			

ECM related privileges for the UV-Visible ChemStation configuration

The privileges described in the following table must be assigned to at least one of your roles in order to become active. For more information about ECM privileges and profiles refer to the ECM Administrator's Guide.

Privilege	View	Edit	Delete	Add	Run	Description
Content: File	X			X		Minimum privilege for UV-Visible ChemStation to access ECM
Content: File Filtering		X				Minimum privilege for UV-Visible ChemStation to access ECM
Content: File Revisions	X					Privilege to view revisions
Content: File Type [XLS]		X		X		Privilege to add and check in files with an .xls extension
Content: Folder	X	X		X		Minimum privilege for UV-Visible ChemStation to access OpenLAB ECM

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In This Book

The manual describes the following:

- Introduction
- Installation
- Basic concepts of UV-Visible ChemStation ECM Compliance Pack
- Working with UV-Visible ChemStation Open Lab ECM Compliance Pack
- Administration for 21 CFR Part 11 compliance

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