



Agilent MassHunter Compliance

Administrator Guide



Agilent Technologies

Notices

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Manual Part Number

G6845-90022

Edition

November 2018

Printed in USA

Agilent Technologies, Inc.
5301 Stevens Creek Boulevard
Santa Clara, CA 95051 USA

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A **WARNING** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a **WARNING** notice until the indicated conditions are fully understood and met.

In This Guide...

1. Agilent OpenLab ECM - Overview

2. MassHunter GC/MS Acquisition - Setup and Configuration

3. MassHunter GC/MS Acquisition - Routine Tasks

4. MassHunter Quantitative Analysis - Setup and Configuration

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6. Audit Trails

In the Compliance mode, MassHunter GC/MS Acquisition and Quantitative Analysis, in conjunction with Agilent OpenLab Enterprise Content Manager (ECM), supports the requirements of the U.S. Food and Drug Administration (FDA) regulations on the handling of electronic records and electronic signatures published as 21 CFR Part 11. **Records are treated as regulated records.**

This book describes how to set up and use MassHunter GC/MS Acquisition B.07.03 and MassHunter Quantitative Analysis B.07.01, in the Compliance mode. OpenLab ECM version 3.4.1 SP2 or higher is required to support MassHunter Compliance mode.

NOTE: The Compliance mode does not support Qualitative Analysis.

Chapter 1 describes the general steps you should follow to set up ECM when used with MassHunter GC/MS Acquisition and Quantitative Analysis running in the Compliance mode. It also details the differences between retrieving and checking out a file directly from ECM.

Details for setting up and managing ECM users, groups, roles, etc, are beyond the scope of this document. Those details are included in the OpenLab ECM Online Help.

Chapter 2 describes how to install MassHunter GC/MS Acquisition in Compliance mode, depending on which version is currently installed. It then details how to assign users to Windows security groups and configure instruments and settings.

Chapter 3 describes routine tasks performed in MassHunter GC/MS Acquisition in Compliance mode.

Chapter 4 provides general guidance on how to install and set up MassHunter Quantitative Analysis depending on which version is currently installed. It then details how to associate ECM roles with MassHunter Quantitative Analysis command groups.

Chapter 5 describes routine tasks performed in MassHunter Quantitative Analysis in Compliance mode.

Chapter 6 describes how to view or print audit-trail logs and how to enable or disable the audit reasons shown in logs in both MassHunter GC/MS Acquisition and Quantitative Analysis.

7. MassHunter Quantitative Analysis Command Groups

Chapter 7 provides a complete list of all the commands in each MassHunter Quantitative Analysis command group: Batch Analysis, Method Development, Batch Review, and Report.

8. MassHunter Acquisition Windows Security Groups

Chapter 8 provides a list of the default privileges assigned to the pre-defined Windows security groups Analyst I, Analyst II, Analyst III, and Manager which are used in MassHunter GC/MS Acquisition. The permissions are grouped by their function.

9. Supported Network Topologies for Compliance Security Mode

Chapter 9 includes examples of the network configurations supported by MassHunter compliance mode.

All supported configurations require an ECM server installation of version 3.4.1 SP2 or greater.

Where to find more information

In addition to MassHunter's online Help, the Federal Registry 21 CFR Part 11, and the ECM documentation accompanying your hardware and software, Agilent also provides a comprehensive collection of:

- Manuals
- Videos
- User Applications
- Method development tools
- A MassHunter GC/MS Software Compliance Assessment document

These are located on the:

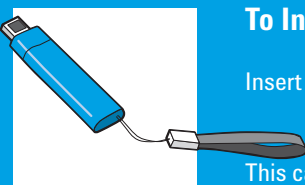
- Agilent GC and GC/MS Manuals and Tools DVD set or Agilent Hardware DVD
- Agilent GC/MS Software Information and Manuals memory stick



To Install Your Hardware Library

Insert Disk 1 into your DVD drive and follow the prompts.

This can be installed by anyone who has authority to copy information onto the receiving computer.



To Install Your Software Library

Insert the memory stick into a USB port and follow the prompts.

This can be installed by anyone who has authority to copy information onto the receiving computer.

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Agilent OpenLab ECM - Overview

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Chapter 1 describes the general steps you should follow to set up ECM when used with MassHunter GC/MS Acquisition and Quantitative Analysis running in the Compliance mode. It also details the differences between retrieving and checking out a file directly from ECM.

Details for setting up and managing ECM users, groups, roles, etc, are beyond the scope of this document. Those details are included in the OpenLab ECM Online Help.



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Introduction

OpenLab ECM version 3.4.1 SP2 must be installed and tested prior to installing MassHunter.

When using MassHunter in the Compliance mode, all regulated records are stored in ECM, with digital signatures being applied using ECM.

The workstation on which MassHunter is running must be connected to an ECM server (version 3.4.1 SP2 or greater) and the ECM client must be installed on the workstation and be operational.

MassHunter GC/MS Acquisition and MassHunter Quantitative Analysis programs must both be configured to the same ECM database account.

Users of both MassHunter GC/MS Acquisition and Quantitative Analysis require an ECM user account on the ECM database account that is configured for their MassHunter workstation.

ECM stores user IDs and privileges that apply to the ECM database as well as to the MassHunter GC/MS Acquisition and Quantitative Analysis programs.

ECM user account information can be authenticated directly by ECM (Built-In) or by a Windows Domain server.

MassHunter GC/MS Acquisition running in the Compliance mode uses Windows security groups on the local MassHunter workstation to associate Windows users with MassHunter privileges.

- A GC/MS Acquisition user is assigned to an ECM user group, and the group is then assigned to a Windows security group.
- The Agilent GCMS Configuration Editor associates MassHunter GC/MS Acquisition commands with these Windows security groups.

MassHunter Quantitative Analysis running in ECM Compliance mode uses roles created in ECM to associate users with MassHunter privileges. For MassHunter Quantitative Analysis:

- A Quantitative Analysis user is assigned to an ECM user group, and the group is then assigned to an ECM role.
- The MassHunter Audit Trail Map (ATM) program associates MassHunter Quantitative Analysis command groups to ECM roles.

Set up the ECM server

1. Create an ECM database account for MassHunter workstations.

Follow these steps to prepare your OpenLab ECM for use with MassHunter Compliance mode.

Details for setting up and managing ECM users, groups, roles, etc, are beyond the scope of this document. Those details are included in the OpenLab Enterprise Content Manager Administrator's Guide. Please refer to that document for complete details.

2. Set up MassHunter users in ECM.

A single ECM database account is required to allow sharing of users across MassHunter GC/MS Acquisition, Quantitative Analysis, and ECM.

ECM privileges will be used to control access to database folder Locations from MassHunter.

MassHunter GC/MS Acquisition and MassHunter Quantitative Analysis, must both be configured to the same ECM database account.

3. Create ECM user groups for MassHunter Quantitative Analysis users and add members to the groups.

Both MassHunter GC/MS Acquisition and Quantitative Analysis require that every user be identified in ECM and granted ECM file privileges.

ECM Users can be added through the ECM built in account or from your Windows Domain users list.

4. Create ECM user groups for MassHunter GC/MS Acquisition users.

Consider how you organization will be operating and create appropriate groups in ECM for Quantitative Analysis users. Then assign users to each group.

Two such groups could be:

- Developers = Who could have access to all Quantitative Analysis commands.
- Analysts = Who could have access to just a part of the Quantitative Analysis commands.

5. Create ECM Quantitative Analysis roles and add Quantitative Analysis groups to these roles.

Similar to the groups you established for Quantitative Analysis users, create appropriate groups for the Acquisition users. Then assign users to this group. A typical group could be:

- MassHunter GC/MS Acquisition Users.

Two such roles could be:

- Developers = Who could have access to all Quantitative Analysis privileges. See ["Sample ECM Developer Role for Quantitative Analysis"](#) on page 12.
- Analysts = Who could have access to just a part of the Quantitative Analysis commands. See ["Sample ECM Analyst Role for Quantitative Analysis"](#) on page 13.

6. Assign the built in ECM Contributor role to both MassHunter GC/MS Acquisition and MassHunter Quantitative Analysis users or groups.

Sample ECM Developer Role for Quantitative Analysis

In addition to assigning users to the custom roles (such as Developer and Analyst), also include them in the built-in ECM role entitled: **Contributor**. The Contributor role contains ECM privileges such as:

- File reading
- File Creation
- File retrieving

This role could allow a developer access to all the Quantitative Analysis commands.

Edit Role

Name:

Description:

☐ Available in folder access tab

Privileges

☐ Show selected items only

	View	Edit	Delete	Add	Run
Content: Move Folder					
Content: Record Retention					
Content: Rekey File					
System: Advanced Search					
System: Archive Agent					
System: Archive Configuration					
System: Archive Files					
System: Archive Storage Configuration					

OK Cancel

Sample ECM Analyst Role for Quantitative Analysis

Install the ECM Workstation Client

- 1. Gather the following from the ECM server Administrator.

- 2. From Internet Explorer, go to the ECM server URL.

This role could allow the analyst access to all commands except those required for editing the Quantitation method.

Edit Role

Name:Analysts

Description:

☐ Available in folder access tab

Privileges

☐ Show selected items only

	View	Edit	Delete	Add	Run
Content: Move File					
Content: Move Folder					
Content: Record Retention					
Content: Rekey File					
System: Advanced Search					
System: Archive Agent					
System: Archive Configuration					
System: Archive Files					

OK

Cancel

After the ECM server is installed and accessible over a network from the MassHunter workstation, you can install the ECM workstation client as described below.

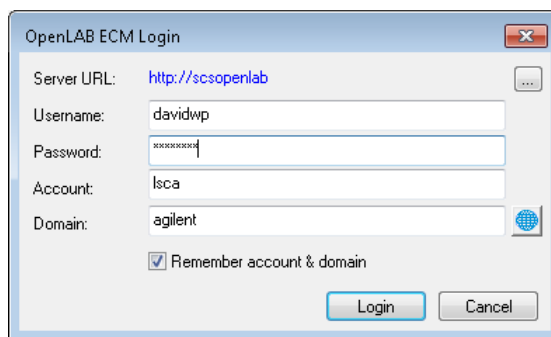
Record your details here for future reference, if desired.

Item	Typical Value	Your Values
ECM Server URL	http://ECMServerName/ecm	
ECM Username	UserName	
ECM Password	*****	
ECM Account	ABCD	
Domain	Local or Domain ^a	
ECM LCDF location	GCMS ^b	

a. If you do not have a corporate domain, ECM supports a “Built-in” domain.
b. In ECM file system terminology, this could be an L, LC, LCD, or LCDF depending on your ECM storage structure.

An ECM Login screen is displayed.

3. Enter a valid user name, password, account, and domain provided by the ECM account Administrator, and click **Login**.



OpenLAB ECM Login

Server URL: <http://scsopenlab>

Username: davidwp

Password: xxxxxxxxxx

Account: lsca

Domain: agilent

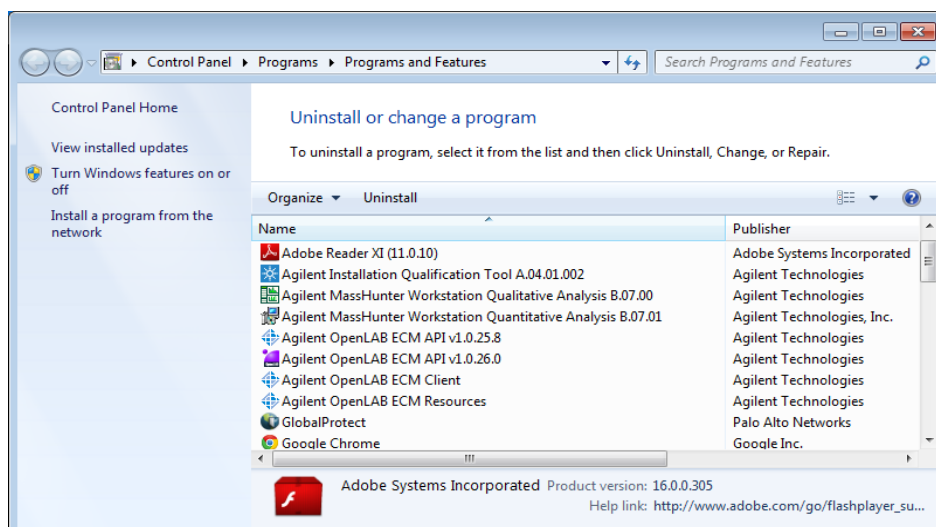
☒ Remember account & domain

Login Cancel

4. ECM Components are downloaded.

The first time you access the ECM server from the computer where your MassHunter workstation is installed, the ECM server will download and install the following components onto the MassHunter workstation:

- Agilent OpenLab ECM API
- Agilent OpenLab ECM Client
- Agilent OpenLab ECM Resources



We recommend you do not install the ECM Scheduler or ECM Cyberprinter because the MassHunter GCMS Acquisition software is not tested with these components.

5. To complete the installation, restart your machine.

Test User's ECM Credentials

1. Log into the workstation.
2. Open Internet Explorer and go to the ECM URL.
3. Create a folder within their assigned ECM environment.
4. Upload a file to their assigned ECM environment.

Retrieve Versus Checkout

Important!

To verify file access rights are properly configured in both Windows and ECM, have each user do the following before attempting to log in to MassHunter.

When users log into ECM directly from Internet Explorer, they may, depending on their privilege, be able to **retrieve** or **checkout** a file.

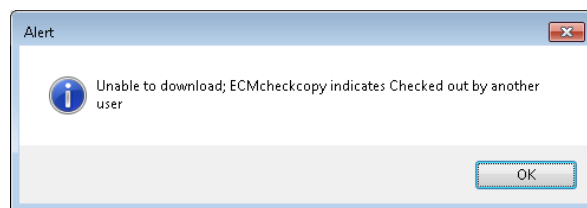
- *Retrieved* files **are not locked** in ECM.
The file in ECM is still available to anyone else.
- *Checked out* files **are locked** in ECM.
Only the individual who checked out the file can check the file back in to ECM, or undo the Checkout. However, with appropriate permissions, users may retrieve a copy of a checked out file.

Please remember that users can access and check out files from ECM in two ways:

- By logging in to ECM via Internet Explorer
- By logging in to ECM via MassHunter

Regardless of how a user accesses ECM, files that are checked out of ECM remain unavailable to MassHunter until they are checked back in to ECM, or the checkout is canceled. A batch file that is checked out can be accessed as Read-Only.

If a file is checked out by anyone, and MassHunter GC/MS Acquisition attempts to load that file, a message similar to the following is displayed.



In MassHunter GC/MS Acquisition, files (methods, sequences, and mass spectral data) are automatically checked in to ECM.

Files downloaded from ECM by GC/MS Acquisition (e.g., methods and sequences) are **retrieved**, by default. They are not checked out and locked.

To retrieve a file:

1. Add the ECM server to the list of *Trusted Sites* in Internet Explorer on your workstation.
2. Access the file in OpenLab ECM Explorer via Internet Explorer.
3. Right-click and select **Retrieve**.
4. Navigate to the designation folder and click **OK**.

In Internet Explorer, select **Tools > Internet Options > Security > Trusted Sites > Sites**. In the window that appears, uncheck **Require server verification (https:) for all sites in this zone**. In the **Add websites to the zone:** field, type the URL for your ECM server and click **Add**. Click **Close > OK**. Restart Internet Explorer to apply the changes.

- The file is copied to your selected destination.
- The file in ECM is still available to anyone else.

See your ECM documentation for more complete details on using the checkout option in ECM.



2

MassHunter GC/MS Acquisition - Setup and Configuration

Review the Installation and Setup Steps [18](#)

Assign Users to a Windows security group [22](#)

Installation where no previous version of MassHunter GC/MS
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Chapter 2 describes how to install MassHunter GC/MS Acquisition in Compliance mode, depending on which version is currently installed. It then details how to assign users to Windows security groups and configure instruments and settings.



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Review the Installation and Setup Steps

1. Verify the prerequisites.

Before installing MassHunter GC/MS Acquisition in Compliance mode, ensure:

- The LAN is an Agilent supported LAN ([page 81](#)) layout.
- You are logged on with Local Windows Workstation Administrator credentials.
- The PC is running under Windows 7 Professional SP1 (64-bit).
- The standalone ECM (3.4.1 SP2) server is operational.
- [Agilent OpenLab ECM - Overview \(Page 9\)](#) has been set up for MassHunter GC/MS Acquisition and MassHunter Quantitative Analysis.
- The ECM client ([page 13](#)) has been installed on the MassHunter workstation.

2. Select your installation type, and Install MassHunter GC/MS Acquisition.

NOTE: Details for installing MassHunter GC/MS Acquisition are included in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide.

The instructions here provide general guidance only. Please refer to the above document for complete installation details.

There are three general conditions under which you may be installing MassHunter GC/MS Acquisition in Compliance mode. See the pages listed below for details on your particular setup.

- The workstation has no previous version of MassHunter GC/MS Acquisition Installed ([page 24](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the Standard Workflow mode ([page 25](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the User Management and Audit Trail mode ([page 26](#)).

3. Review Windows security groups and privileges.

During installation, MassHunter GC/MS Acquisition created four Windows security groups:

- Acquisition Analysts I
- Acquisition Analysts II
- Acquisition Analysts III
- Acquisition Managers

Each of these groups has a different set of access privileges (called Roles and Responsibilities).

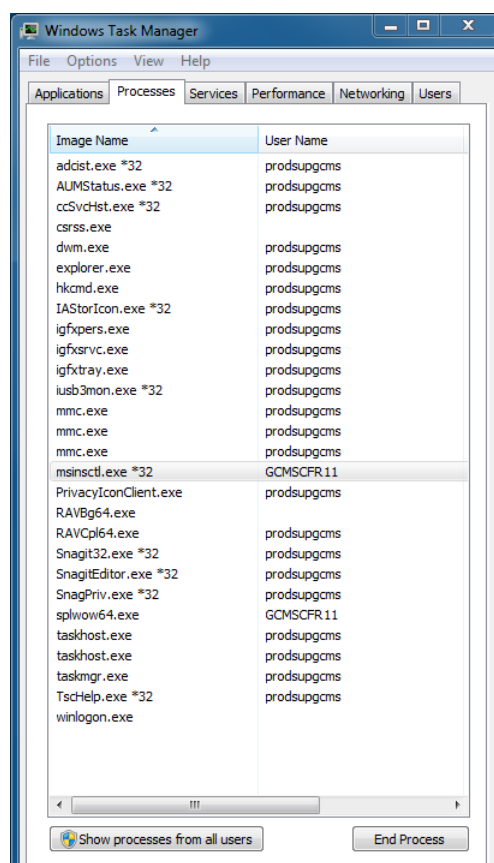
- The **highest level** group is **Manager**. This group has access to all privileges. Each lower level group has a subset of the privileges of the next higher level.
- The **lowest level** group is Analyst I.

Before assigning users to groups, review the default privileges assigned to each group and edit the privileges, if required, for your organization.

See *"MassHunter Acquisition Windows Security Groups"* on page 73.

See *"Change Group Privileges"* on page 79 for details on how to change these settings.

MassHunter GC/MS Acquisition also created a new user "GCMSCFR11" as part of the local administrator group. This user has the needed windows privileges to run the MassHunter GC/MS Acquisition application, and the Configuration Editor. Task manager here shows that the user GCMSCFR11 is running the msinsctl.exe (MassHunter GC/MS Acquisition) program.



4. Assign each user to a group.

After reviewing the four MassHunter GC/MS Acquisition Windows security groups, assign each user to one of the groups.

See *“Assign Users to a Windows security group”* on page 22 for details on how to do this.

REMEMBER: Before a user can access MassHunter GC/MS Acquisition, they must:

- Be assigned to one of the four MassHunter Windows security groups. (page 22) The userID and Password must be the same as those set up for this user in ECM.
- Have a valid ECM user account. Refer to your ECM documentation for details on how to set up ECM user accounts.

If either one of these two requirements is missing, users will not be able to access MassHunter GC/MS Acquisition.

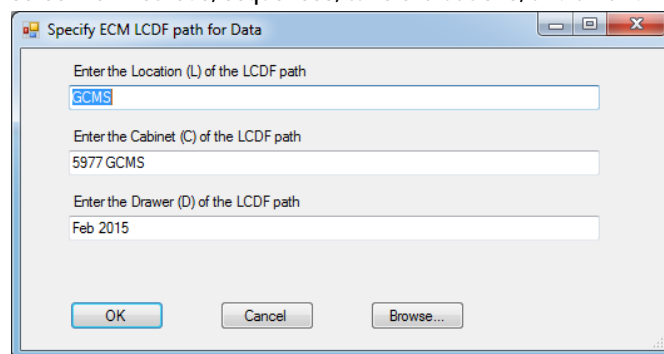
5. Configure one instrument.

After you have installed the ECM components and MassHunter GC/MS Acquisition on your workstation, you may configure one instrument. See *“Configure an Instrument”* on page 27 for details.

6. Create the initial LCDF structure.

After configuring ECM on the ECM server, and downloading the ECM components to the workstation, the first time you login to MassHunter GC/MS Acquisition as the Administrator, you will be presented with a series of screens to identifying the ECM server path for your **Data**, **Methods**, **Sequences**, **Tune Evaluations**, and **Air and Water** reports.

This first screen identifies where in ECM your **Data** will be saved. This will be followed by a screen for methods, sequences, tune evaluations, and air and water.



- **To accept the default and continue**, click **OK**. If the path is not already set up in ECM, the system will set it up now and display the next screen. This may take several seconds.
- **To create a new Cabinet, Directory or Folder in ECM, and click Browse** to access ECM and create the path.

7. Tune the instrument.

At the completion of the wizard, tune the instrument. Initializing the instrument will have overwritten the default tune, atune, etune, etc.

8. Configure MassHunter GC/MS Acquisition.

To complete your installation process, access the Configuration Editor, and:

- Configure an instrument ([page 27](#))
- Set the User Password Reset interval ([page 28](#))
- Set the Idle Timeout interval for MassHunter GC/MS Acquisition ([page 29](#))
- Review Roles and Responsibilities ([page 73](#))
- Enable/Disable Audit Reasons ([page 56](#))
- Edit the Pre-defined "Reason for Change" List ([page 57](#))

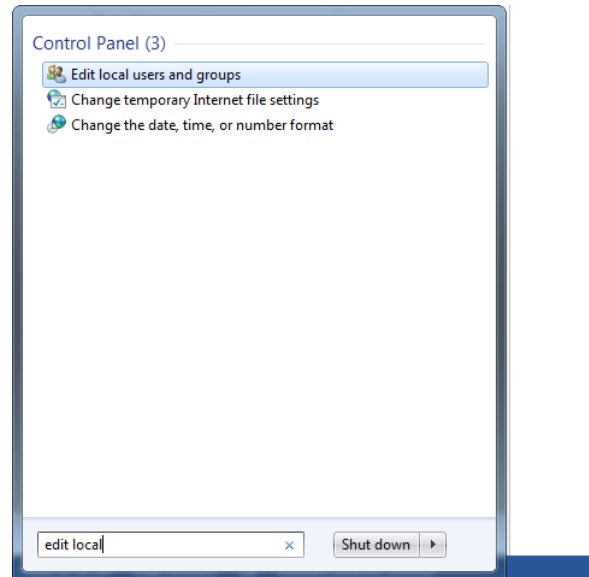
9. Assign users to a Windows security group.

The privileges each user has in MassHunter GC/MS Acquisition are based on the Windows security group to which they have been assigned. After you have reviewed the roles and responsibilities associated with these groups, assign each MassHunter GC/MS Acquisition user to one of the groups. See *"Assign Users to a Windows security group"* on page 22.

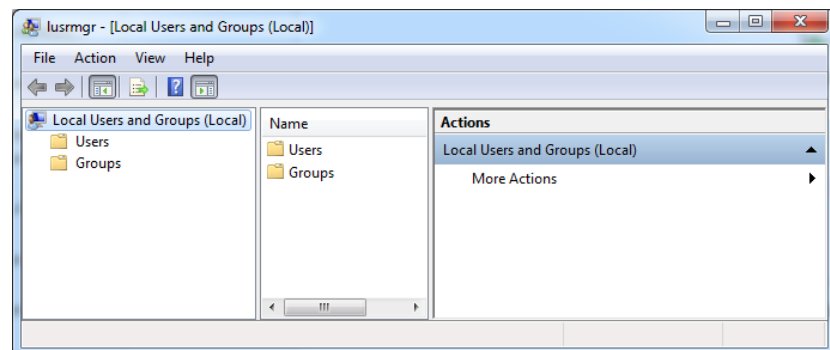
- To review the default privileges, see *"MassHunter Acquisition Windows Security Groups"* on page 73.
- See *"Change Group Privileges"* on page 79 for details on how to change these defaults.

Assign Users to a Windows security group

1. Click **Start** then type **edit local** and press **Enter**.

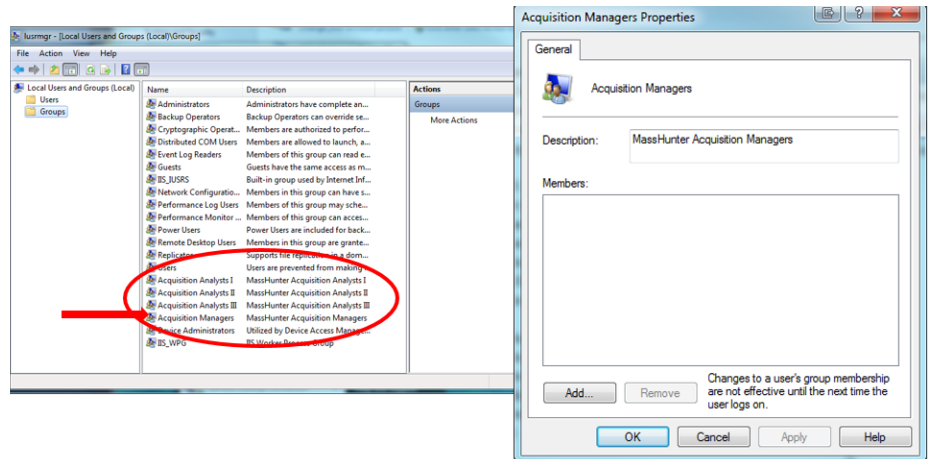


2. The Local Users and Groups dialog displays. Double-click **groups**.



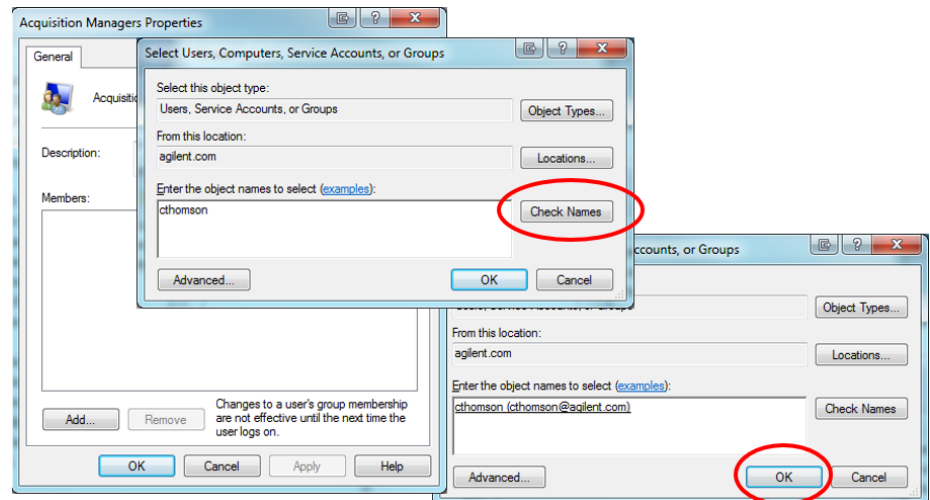
2. MassHunter GC/MS Acquisition - Setup and Configuration *Assign Users to a Windows security group*

3. To add local or domain users to the Acquisition Groups, double-click the group to which the user needs to be added, and click **add**.

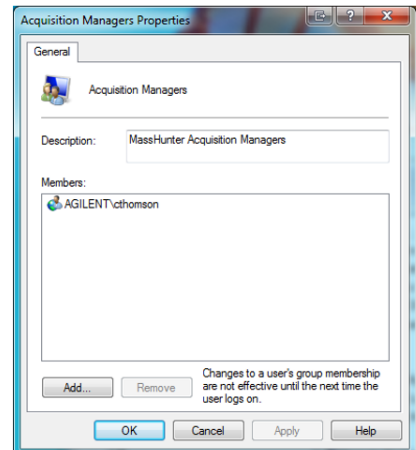
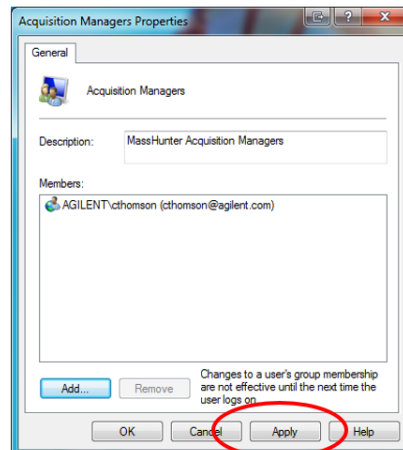


- If adding a domain user and the domain is not shown in From this location, click **Locations** and select the domain name.
- If adding a local user and the workstation is not shown in From this location, click **Locations** and select the workstation name.

4. Enter the user id and click **Check Names**. If the user id entered is correct, then click **OK**. In this example, the updated user name would be under the **Acquisition Managers** properties.



5. Click **Apply** to update the page.



Installation where no previous version of MassHunter GC/MS Acquisition is installed

1. Insert the DVD and follow the prompts to access this screen.
2. Select **Activate Compliance**, and click **Next** to continue.

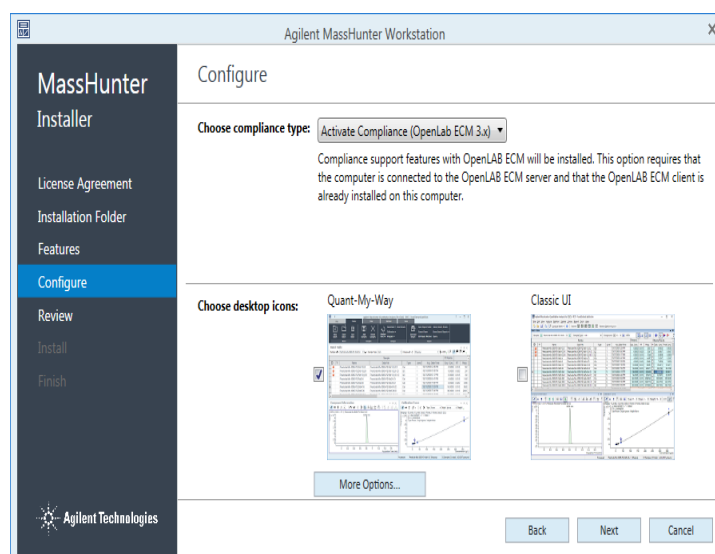
3. During the installation of MassHunter GC/MS Acquisition, you may be prompted to install or update some Windows components and reboot your PC.

NOTE: Details for installing MassHunter GC/MS Acquisition are included in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. The instructions here provide general guidance only. Please refer to the above document for complete installation details.

There are three general conditions under which you may be installing MassHunter GC/MS Acquisition in Compliance mode. See the pages listed below for details on your particular setup.

- The workstation has no previous version of MassHunter GC/MS Acquisition Installed (shown below, on this page) ([page 24](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the Standard Workflow mode ([page 25](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the User Management and Audit Trail mode ([page 26](#)).

To install MassHunter GC/MS Acquisition B.07.03 in the Compliance mode on a workstation that has no previous version of MassHunter GC/MS Acquisition installed:



After you reboot and log in to your PC, the Installation wizard will proceed to complete the installation of the required Windows components.

Installation where MassHunter GC/MS Acquisition is installed in the Standard Workflow mode

1. From the Control Panel, select **Programs and Features**.
2. Select *Agilent MassHunter GC/MS Acquisition* and click **Change**.
3. Select **Activate Compliance** and click **next**.
4. Follow the installer program prompts to complete the process.

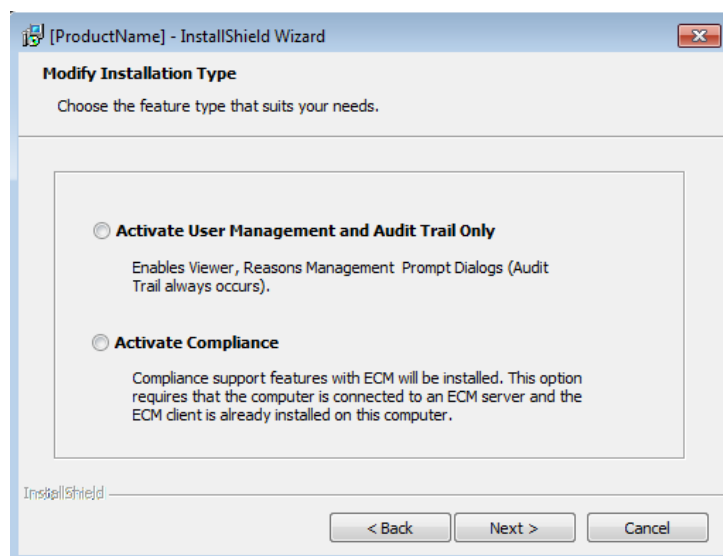
NOTE: Details for installing MassHunter GC/MS Acquisition are included in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. The instructions here provide general guidance only. Please refer to the above document for complete installation details.

There are three general conditions under which you may be installing MassHunter GC/MS Acquisition in Compliance mode. See the pages listed below for details on your particular setup.

- The workstation has no previous version of MassHunter GC/MS Acquisition Installed ([page 24](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the Standard Workflow mode (shown below, on this page) ([page 25](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the User Management and Audit Trail mode ([page 26](#)).

If MassHunter GC/MS Acquisition B.07.03 is already installed on your workstation in the Standard Workflow mode, you may use this procedure to activate the MassHunter GC/MS Acquisition B.07.03 Compliance mode.

Note: If MassHunter GC/MS Acquisition was pre-installed on your Agilent supplied workstation at the factory, it will be in the Standard Workflow mode.



Installation where MassHunter GC/MS Acquisition is installed in the User Management and Audit Trail mode

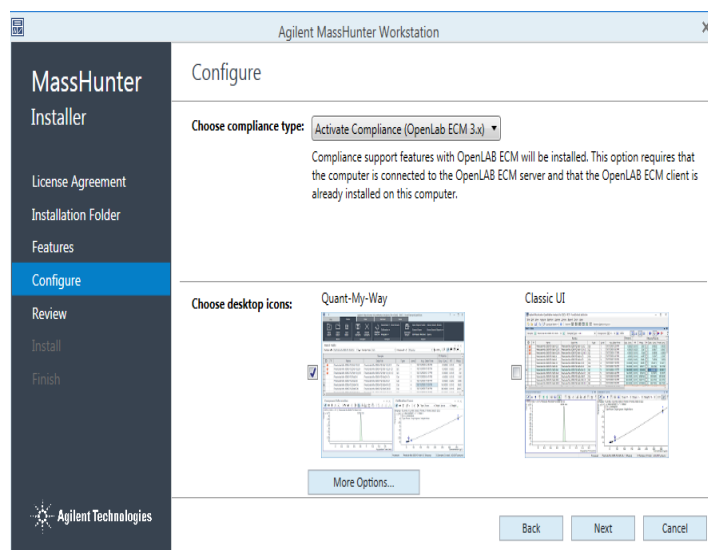
To activate the Compliance mode, uninstall the current version then, insert the MassHunter GC/MS Acquisition B.07.03 installation disk and select Activate Compliance during the re-installation procedure.

NOTE: Details for installing MassHunter GC/MS Acquisition are included in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. The instructions here provide general guidance only. Please refer to the above document for complete installation details.

There are three general conditions under which you may be installing MassHunter GC/MS Acquisition in Compliance mode. See the pages listed below for details on your particular setup.

- The workstation has no previous version of MassHunter GC/MS Acquisition Installed ([page 24](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the Standard Workflow mode ([page 25](#)).
- The workstation has MassHunter GC/MS Acquisition installed in the User Management and Audit Trail mode (shown below, on this page) ([page 26](#)).

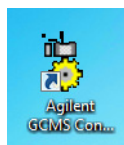
MassHunter GC/MS Acquisition Compliance cannot be activated on a workstation that currently has MassHunter GC/MS Acquisition installed in the User Management and Audit Trail mode.



Configure an Instrument

1. Login to your workstation with Windows Administrator privileges.
2. Double-click the **Configuration Editor Icon**.
3. Provide a valid user name and password, and click **Login**.
4. Complete the configuration for your instrument as applicable. Notice that, because you have installed MassHunter GC/MS Acquisition in the Compliance mode, the **Regulated Workflow Mode** is selected in the configuration editor. This cannot be changed.
5. Click **OK** to complete the configuration. Your configured instrument may look similar to this in the Configuration Editor.

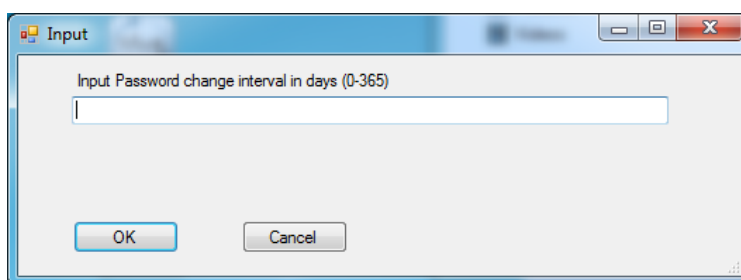
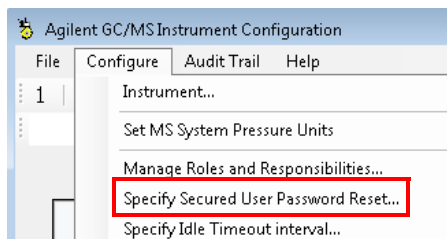
After you have installed ECM on the server, downloaded ECM components to the workstation, and installed MassHunter GC/MS Acquisition B.07.03 in Compliance mode, you may configure one instrument.

The OpenLAB ECM Login dialog box. It contains fields for Server URL (http://scsopenlab.scs.agilent.com), Username (prodsupgms), Password (masked with asterisks), Account (Isca), and Domain (agilent). There is a checkbox for 'Remember account & domain' and 'Login' and 'Cancel' buttons at the bottom.The Agilent GC/MS Instrument Configuration dialog box. It shows configuration for 'Simulator QQQ'. Fields include Laboratory ID Number, Mass Spectrometer Model (7000), Address (192.168.254.12), Gas Chromatograph Model (7890 GC), Address (130.27.109.131), and Headspace Type (none). A 'Workflow Mode' dropdown menu is highlighted with a red oval and set to 'Regulated'. There are 'OK', 'Cancel', and 'Help' buttons at the bottom.

Set the Password Reset Interval

1. In the Configuration Editor, select **Configure > Specify Secured User Password Reset**.
2. Enter the number of days after which the password must be changed, and press **OK**.

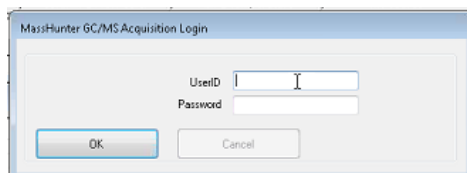
To set or modify the interval required for users to reset their password:



Set the Idle Timeout Interval

Part of the requirements of FDA CFR21 Part 11 is that unattended workstations should automatically lock. For MassHunter GC/MS Acquisition that timeout interval is set in the Configuration Editor.

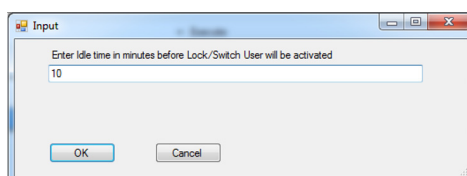
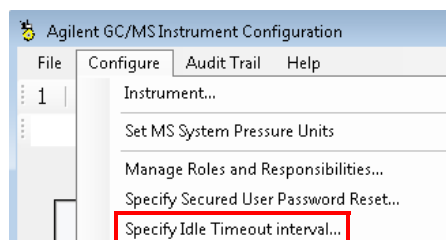
If MassHunter GC/MS Acquisition detects no activity from the current user for a specified time, it will automatically lock the system and display the MassHunter GCMS Account Login dialog.



Once MassHunter GC/MS Acquisition is locked, any user with a valid UserID and Password may log into the system and unlock it. The menu items available are those permitted to the user that unlocks MassHunter GC/MS Acquisition.

To modify the inactivity timeout interval:

1. In the Configuration Editor, select **Configure > Specify Idle Timeout interval**.
2. Enter the time, in minutes, you wish to use for the idle timeout interval, and press **OK**.







3

MassHunter GC/MS Acquisition - Routine Tasks

- Manually Lock and Switch Users [32](#)
- Review User Access Privileges [32](#)
- Understand ECM Storage Locations and File Types [33](#)
- Save and Retrieve Data, Methods, and Sequence Files [34](#)
- Change the ECM Storage Locations [35](#)
- Test the Communication with the ECM Server [36](#)
- View the Current LCDF path to the ECM Server [37](#)
- Open the ECM Server via Internet Explorer [38](#)
- Import a Method from a Location Outside the ECM Server [39](#)

Chapter 3 describes routine tasks performed in MassHunter GC/MS Acquisition in Compliance mode.

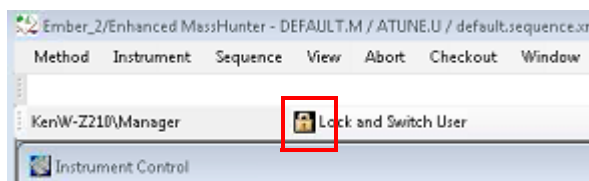


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Manually Lock and Switch Users

1. To manually lock MassHunter GC/MS Acquisition, click the Lock and Switch User icon.

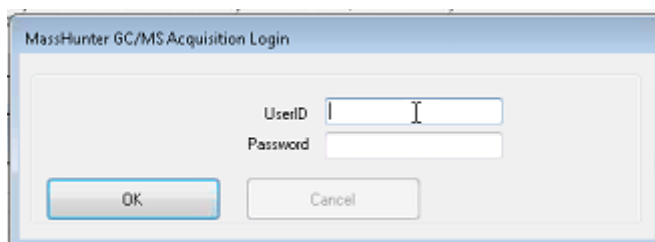
MassHunter GC/MS Acquisition defers the electronic signatures of records to an ECM activity. Therefore, the operator doesn't have to sign every record. However, it is the operator's responsibility to manually lock the MassHunter GC/MS Acquisition program each time they walk away from the workstation.



The system displays a login box with the cancel button disabled.

2. When a valid UserID and Password are entered, the system resets the MassHunter GC/MS Acquisition allowed operations to those assigned to the windows security group that the logged in user is a member.

The only way to unlock MassHunter GC/MS Acquisition is to login with valid user credentials.



Review User Access Privileges

When using MassHunter GC/MS Acquisition in the Compliance mode, menu options that are displayed to each user are based on the user's access privileges. For MassHunter GC/MS Acquisition, those privileges are control by the Windows security group to which they are assigned.

See *"MassHunter Acquisition Windows Security Groups"* on page 73... for the default settings of menu items available to each group.

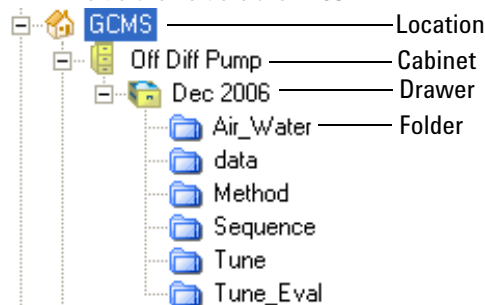
See *"Change Group Privileges"* on page 79 for details on how to change these defaults.

Understand ECM Storage Locations and File Types

When using MassHunter GC/MS Acquisition in the Compliance mode, all regulated records are stored in ECM, with digital signatures being applied using ECM.

Default settings will look similar to this structure, however, your ECM administrator can modify this as needed for your organization.

- **L** = Location, identifies the physical place where file cabinets are stored
- **C** = A file **Cabinet**
- **D** = Contains **Drawers**
- **F** = Inside the Drawers are **Folders**
- **F** = Inside the Folders are **Files**



Files saved to ECM from MassHunter GC/MS Acquisition may include the following files types:

- Data (.D.SSIZIP)
- Method (.M.SSIZIP)
- Sequence (.XML.ZIP)
- Tune (.CSV)
- Air Water (.CSV)
- Tune Evaluation (.CSV)

Data files (.D.SSIZIP) include a zipped version of the data folder with all its contents (including a audit-trail log file if one exists) in a single compressed file.

Method files (.M.SSIZIP) include all method components, including the method's cumulative audit-trail log if one exists, in a single compressed file.

Sequence files (.XML.Zip) includes the sequence dataset file and the cumulative audit-trail log file (if one exists) in a single compressed file.

Save and Retrieve Data, Methods, and Sequence Files

Access to Method and Sequence files (while operating in the Compliance mode) is through standard Load and Save menus. For example:

- To Load a Method, select **Method > Load Method**
- To Save a Method, select **Method > Save Method**
- To Save a Method as a different name, select **Method > Save Method As...**

- To Load a Sequence, select **Sequence > Load Sequence**
- To Save a Sequence, select **Sequence > Save Sequence**
- To Save a Sequence as a different name, select **Sequence > Save Sequence As...**

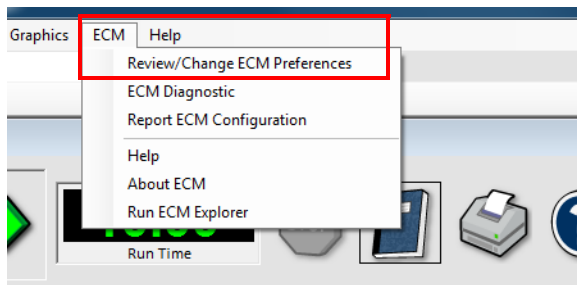
When data, methods, and sequences are stored in ECM, all the associated data is packaged together in a single file with a SSZIP extension.

This file type is a standard ZIP file and can be extracted with standard unzip applications.

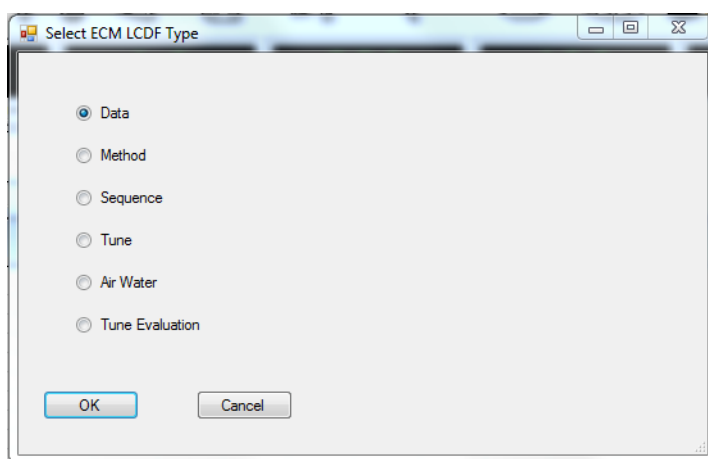
When you save a file to ECM or retrieve a file from ECM the packaging and un-packaging of the files is automatically handled for you.

Change the ECM Storage Locations

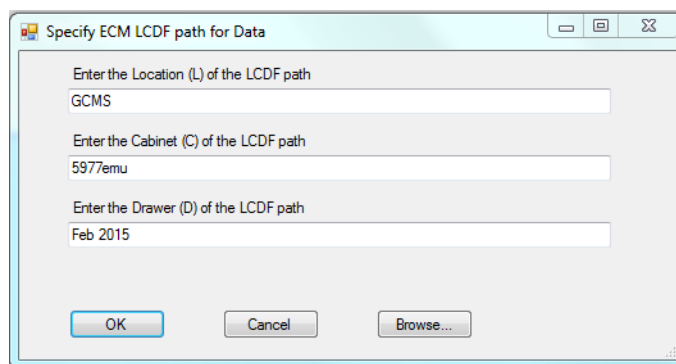
1. Select **ECM > Review/Change ECM Preferences**.



2. Select the folder you wish to change, and click **OK**.



3. Modify the path as required and click **OK**.



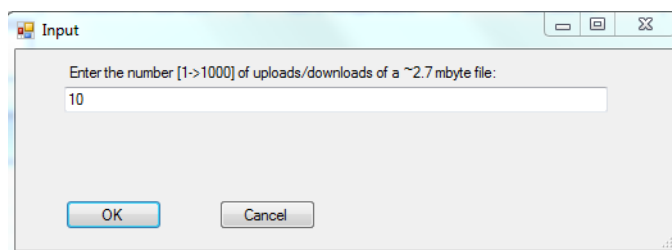
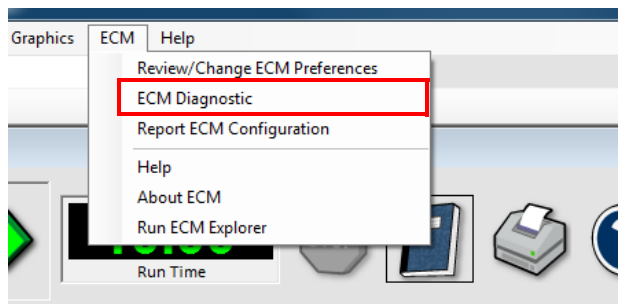
Test the Communication with the ECM Server

1. Select **ECM > ECM Diagnostic**.

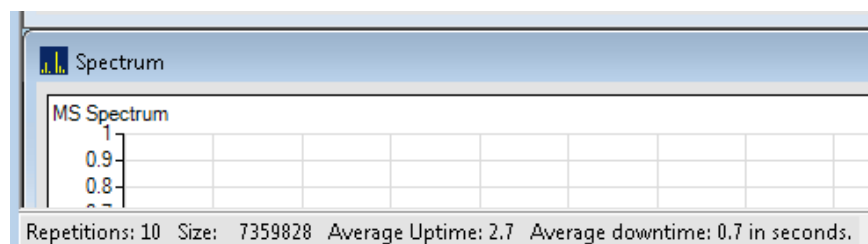
2. At the prompt, enter the number of times you wish to test the connection (10, for example), and click **OK**.

3. Review the test results in the bottom line of the instrument control screen.

The ECM diagnostic option allows you to check your connection to OpenLab ECM by uploading a test file to ECM and reporting the results in a dialog to you.

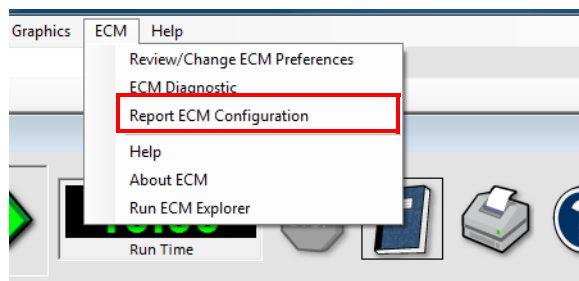


The system attempts to upload and download a test file the number of times specified (e.g., 10 in this example), and reports the results of the test in a dialog.

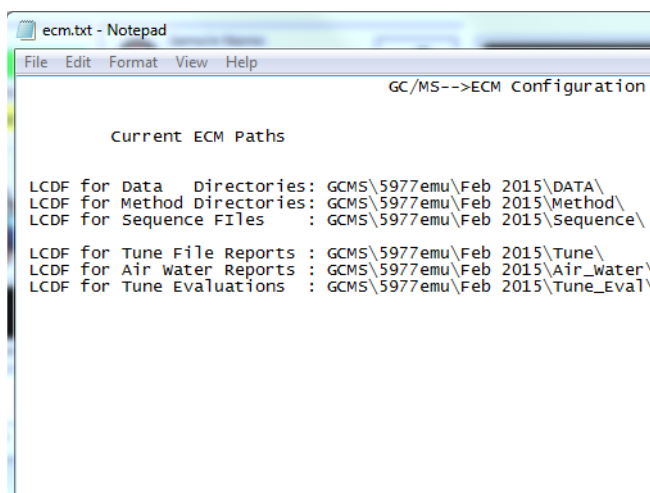


View the Current LCDF path to the ECM Server

1. Select **ECM > Report ECM Configuration**.

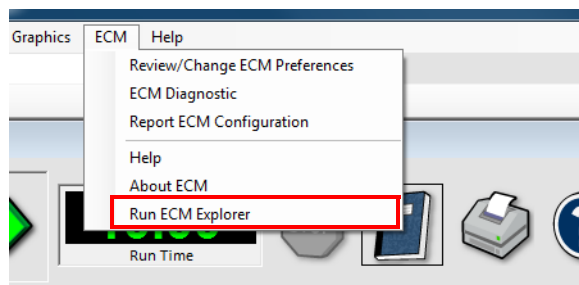


2. Review the path shown.

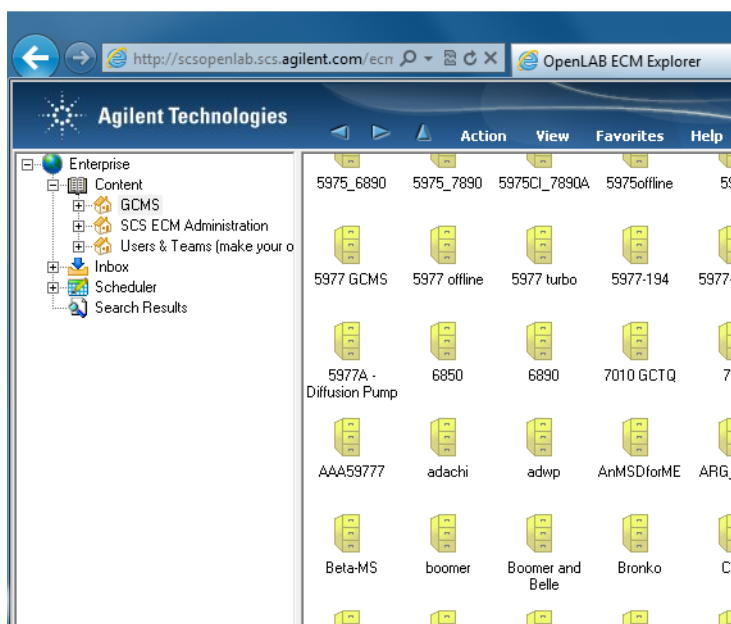


Open the ECM Server via Internet Explorer

1. Select **ECM > Run ECM Explorer**.

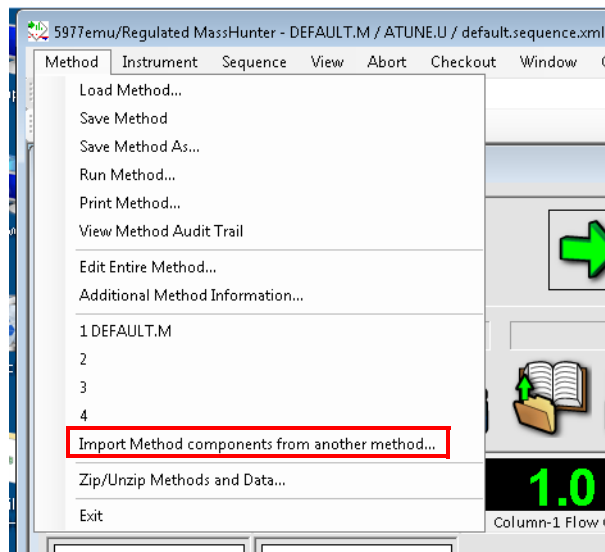


2. View the ECM server from Internet Explorer.

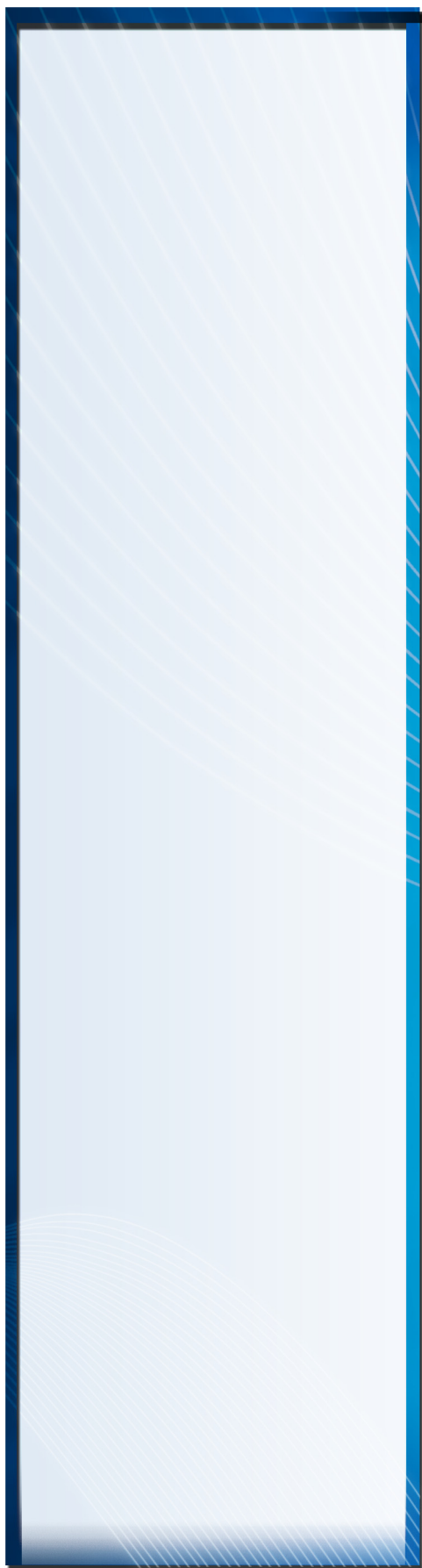


Import a Method from a Location Outside the ECM Server

1. Select **Method > Import Method components from another method...**



2. Navigate to and select the desired file.





4

MassHunter Quantitative Analysis - Setup and Configuration

Review the Installation and Setup Steps [42](#)

Installation where there was no previous version of MassHunter
Quantitative Analysis [43](#)

Installation where MassHunter Quantitative Analysis B.07.01 is installed
in the Standard Workflow mode [44](#)

Installation where MassHunter Quantitative Analysis B.07.01 is installed
in the User Management and Audit Trail mode [45](#)

Installation where an older version of MassHunter Quantitative Analysis
is installed (pre B.07.01) [46](#)

Associate ECM Roles to MassHunter Quantitative Analysis Command
Groups [47](#)

Chapter 4 provides general guidance on how to install and set up MassHunter
Quantitative Analysis depending on which version is currently installed. It then
details how to associate ECM roles with MassHunter Quantitative Analysis
individual commands and command groups.



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Review the Installation and Setup Steps

1. Verify the prerequisites.

Before installing MassHunter Quantitative Analysis in ECM Compliance mode verify the following:

- The LAN layout is supported by Agilent.
- You have local Windows workstation administrator credentials.
- The workstation is running Windows 7 Professional SP1 (64-bit) or Windows 10.
- The standalone ECM (3.4.1 SP2 or newer) server is operational.
- The ECM client is installed on the MassHunter workstation.

2. Select your installation type, and Install MassHunter Quantitative Analysis.

NOTE: The installation of MassHunter Quantitative Analysis is covered in detail in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. Refer to that document for complete details. This section is intended to provide general guidance only.

There are four general conditions under which you may be installing MassHunter Quantitative Analysis in the Compliance mode. Each of these cases is described on the pages indicated below:

- The Workstation has no previous installation of MassHunter Quantitative Analysis ([page 43](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in Standard Workflow mode. ([page 44](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in the User Management and Audit Trail mode. ([page 45](#))
- The Workstation has a version of MassHunter Quantitative Analysis that pre-dates B.07.01. ([page 46](#))

3. Associate ECM Roles with MassHunter Quantitative Analysis Roles (Command Groups).

Before anyone can access MassHunter Quantitative Analysis:

- They must have a valid ECM user account that is associated to an ECM role. (Refer to your ECM documentation for details on how to set up ECM user accounts).
- ECM roles can contain MassHunter Quantitative Analysis commands. Quantitative Analysis commands are associated with ECM roles in ECM or in the Quantitative Analysis ATM Configuration program.

See *“Associate ECM Roles to MassHunter Quantitative Analysis Command Groups”* on page 47 for details.

Installation where there was no previous version of MassHunter Quantitative Analysis

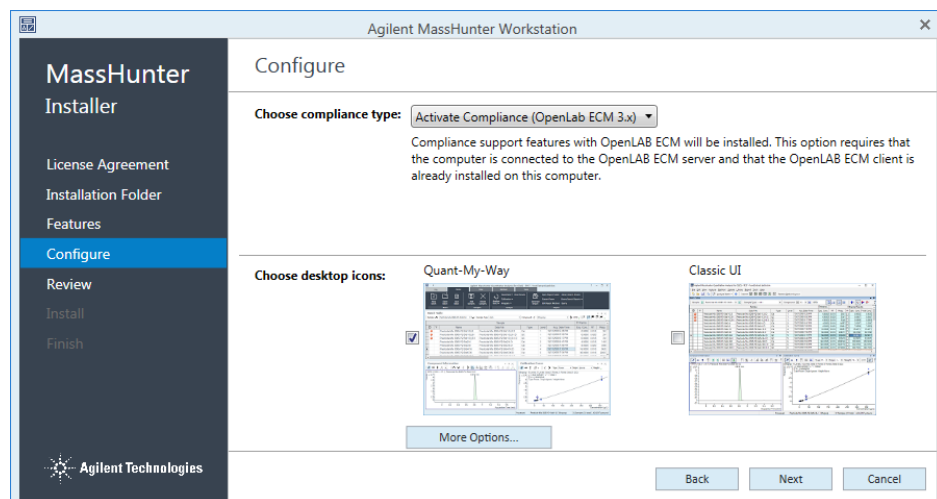
1. Insert the DVD and follow the prompts to access this screen.
2. Select **Activate Compliance**, and click **Next** to continue.
3. During the installation, you may be prompted to install or update some Windows components and reboot your PC. After you reboot and log in to your PC, the Installation Wizard will proceed to complete the installation of the required Windows components.
4. If Report Templates were copied to the workstation, upload them from the workstation to a location in ECM that MassHunter Quantitative Analysis users will be able to access.

NOTE: The installation of MassHunter Quantitative Analysis is covered in detail in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. Refer to that document for complete details. This section is intended to provide general guidance only.

There are four general conditions under which you may be installing MassHunter Quantitative Analysis in the Compliance mode. Each of these cases is described on the pages indicated below:

- The Workstation has no previous installation of MassHunter Quantitative Analysis (shown below on this page) ([page 43](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in Standard Workflow mode. ([page 44](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in the User Management and Audit Trail mode. ([page 45](#))
- The Workstation has a version of MassHunter Quantitative Analysis that pre-dates B.07.01. ([page 46](#))

If the Workstation has **no previous version of MassHunter Quantitative Analysis installed**:



Report templates used must be from the same version of MassHunter Quantitative Analysis that is being used.

Remember: Upload the report templates from your local drive to ECM.

Installation where MassHunter Quantitative Analysis B.07.01 is installed in the Standard Workflow mode

NOTE: The installation of MassHunter Quantitative Analysis is covered in detail in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. Refer to that document for complete details. This section is intended to provide general guidance only.

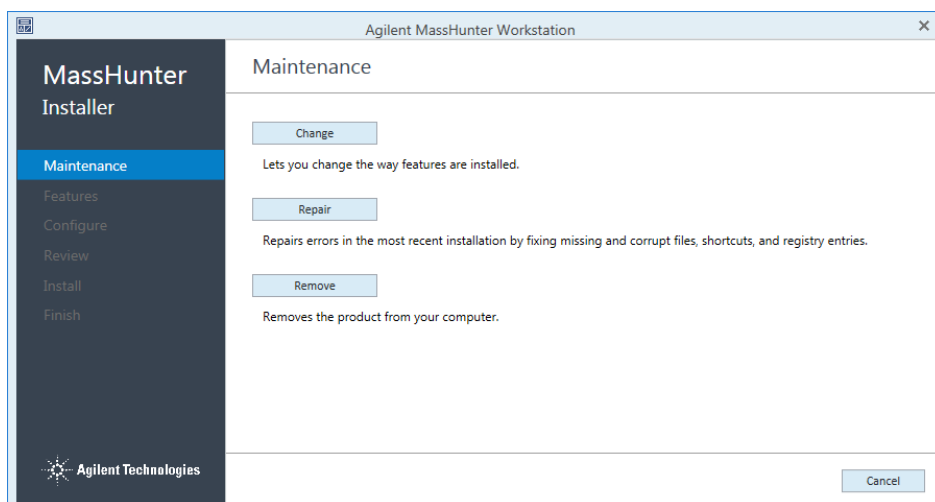
There are four general conditions under which you may be installing MassHunter Quantitative Analysis in the Compliance mode. Each of these cases is described on the pages indicated below:

- The Workstation has no previous installation of MassHunter Quantitative Analysis ([page 43](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in Standard Workflow mode (shown below on this page). ([page 44](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in the User Management and Audit Trail mode. ([page 45](#))
- The Workstation has a version of MassHunter Quantitative Analysis that pre-dates B.07.01. ([page 46](#))

If MassHunter Quantitative Analysis B.07.01 is already installed on your workstation in the Standard Workflow mode, you may use this procedure to activate the MassHunter Compliance mode.

Note: If MassHunter Quantitative Analysis was pre-installed on your Agilent supplied Workstation at the factory, it will be in the Standard Workflow mode.

1. Click **Control Panel > Start** and enter Programs and Features.
2. Select Agilent MassHunter Quantitative Analysis and click **Change**.
3. Click Change.
4. Select Activate Compliance.
5. Continue to follow the prompts.
6. If Report Templates were copied to the workstation, upload them from the workstation to a location in ECM that Quantitative Analysis will have access.



Installation where MassHunter Quantitative Analysis B.07.01 is installed in the User Management and Audit Trail mode

NOTE: The installation of MassHunter Quantitative Analysis is covered in detail in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. Refer to that document for complete details. This section is intended to provide general guidance only.

There are four general conditions under which you may be installing MassHunter Quantitative Analysis in the Compliance mode. Each of these cases is described on the pages indicated below:

- The Workstation has no previous installation of MassHunter Quantitative Analysis ([page 43](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in Standard Workflow mode. ([page 44](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in the User Management and Audit Trail mode (shown below on this page). ([page 45](#))
- The Workstation has a version of MassHunter Quantitative Analysis that pre-dates B.07.01. ([page 46](#))

MassHunter Compliance cannot be activated on a workstation that currently has MassHunter Quantitative Analysis B.07.01 installed in the User Management and Audit Trail mode. To activate the Compliance mode, uninstall the current version then, reinstall version B.07.01 and select Activate Compliance during the installation procedure.

If Report Templates were copied to the workstation, upload them from the workstation to a location in ECM that Quantitative Analysis will have access.

Installation where an older version of MassHunter Quantitative Analysis is installed (pre B.07.01)

NOTE: The installation of MassHunter Quantitative Analysis is covered in detail in the Agilent MassHunter Workstation Offline Qualitative and Quantitative Analysis for GCMS Installation Guide. Refer to that document for complete details. This section is intended to provide general guidance only.

There are four general conditions under which you may be installing MassHunter Quantitative Analysis in the Compliance mode. Each of these cases is described on the pages indicated below:

- The Workstation has no previous installation of MassHunter Quantitative Analysis ([page 43](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in Standard Workflow mode. ([page 44](#))
- The Workstation has MassHunter Quantitative Analysis B.07.01 installed in the User Management and Audit Trail mode. ([page 45](#))
- The Workstation has a version of MassHunter Quantitative Analysis that pre-dates B.07.01 (shown below on this page). ([page 46](#))

MassHunter Compliance is not supported in versions prior to B.07.01. If you have a version of MassHunter Quantitative Analysis that is earlier than B.07.01, uninstall that version and install version B.07.01 or higher, and select Activate Compliance when prompted during installation.

If Report Templates were copied to the workstation, upload them from the workstation to a location in ECM that Quantitative Analysis will have access.

Associate ECM Roles to MassHunter Quantitative Analysis Command Groups

1. Start the Audit Trail Map (ATM) program.
2. Enter ECM system administrator credentials.
3. Notice the four MassHunter Quantitative Analysis Roles (Command Groups) and ECM roles.

See *“Overview”* on page 74 for a complete listing of the commands in each group.

Access privileges for MassHunter Quantitative Analysis are controlled through the Audit Trail Map (ATM) program. The following describes how to associate ECM roles to MassHunter Quantitative Analysis roles using the Audit Trail Map (ATM) program.

A screenshot of the 'ECM Login' dialog box. It contains fields for 'Server URL' (http://quant-dsdev.scs.agilent.com/ec), 'Username' (admin), 'Password' (masked with dots), 'Account' (GCMS), and 'Domain' (built-in). There is a 'Remember account & domain' checkbox and 'Login' and 'Cancel' buttons.

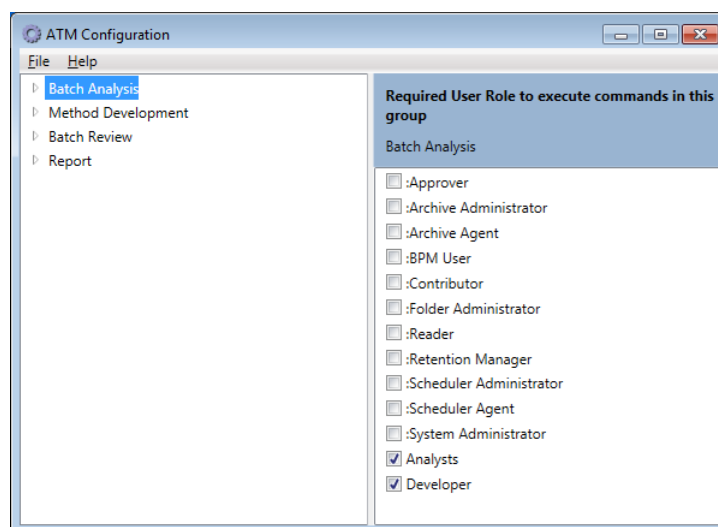
MassHunter Quantitative Analysis Roles

A screenshot of the 'ATM Configuration' dialog box. The 'Batch Analysis' group is selected in the left pane. The right pane, titled 'Required User Role to execute commands in this group', lists various roles with checkboxes. The roles are: :Approver, :Archive Administrator, :Archive Agent, :BPM User, :Contributor, :Folder Administrator, :Reader, :Retention Manager, :Scheduler Administrator, :Scheduler Agent, :System Administrator, Analysts (checked), and Developer (checked).

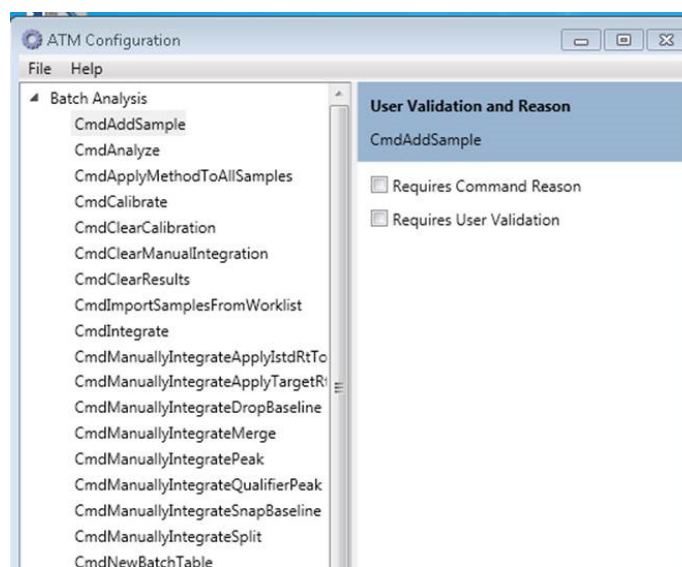
ECM Roles

4. Select the **Batch Analysis** command group or select individual commands under **Batch Analysis**, and enable the ECM roles that should be allowed these privileges (e.g., Analyst and Developer).

Users assigned to this role may create a batch, review the results of a batch, integrate and quantitate the results, and print batch reports.



Click the arrow in front of Batch Analysis to display the full list of commands associated with this role.



Click the arrow once again to return to the previous view.

5. Select the **Method Development** command group or select individual commands under **Method Development**, and enable the ECM roles that should be allowed these privileges (e.g., Developer).

Users assigned this role may run all the commands in the Method Development command group. For example, they may create, modify, delete, and save methods.

6. Select the **Batch Review** command group or select individual commands under **Batch Review**, and enable the ECM roles that should be allowed these privileges (e.g., Analyst and Developer).

Users assigned this role may open and review a batch.

7. Select the **Report** command group or select individual commands under **Report**, and enable the ECM roles that should be allowed these privileges (e.g., Analyst and Developers).

Users assigned this role may generate reports.

8. Select **File > Save** to save your changes before exiting ATM.





5

MassHunter Quantitative Analysis - Routine Tasks

Review User Access Privileges 52

Understand ECM Storage Locations and File Types 52

Access Files from Quantitative Analysis 53

Add Quantitative Analysis Report Templates to ECM 53

Chapter 5 describes routine tasks performed in MassHunter Quantitative Analysis in Compliance mode.



Agilent Technologies

Review User Access Privileges

When using MassHunter Quantitative Analysis Compliance software, menu options that are displayed to each user are based on the user's role assignment in ECM.

The ECM roles are then assigned to Quantitative Analysis individual commands or command groups in the Quantitative Analysis ATM program. A Users privileges in the Quantitative Analysis program are limited to the ATM command groups to which their ECM role is assigned.

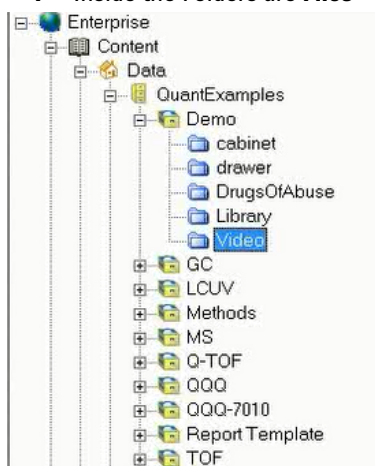
See *"Associate ECM Roles to MassHunter Quantitative Analysis Command Groups"* on page 47 for details on changing privileges for a user in the Quantitative Analysis program.

Understand ECM Storage Locations and File Types

All regulated records are stored in ECM, with digital signatures being applied using ECM.

Default settings will look similar to this structure, however, your ECM administrator can modify this as needed for your organization.

- **L** = Location, identifies the physical place where file cabinets are stored
- **C** = A file **Cabinet**
- **D** = Contains **Drawers**
- **F** = Inside the Drawers are **Folders**
- **F** = Inside the Folders are **Files**



Files saved to ECM may include the following files types:

- Data (.D.SSIZIP)
- Method (.M.SSIZIP, .quantmethod.xml)
- Batch (batch.bin.ssizip)
- Libraries (.L.SSIZIP, mslibrary.xml, reflibrary.xml)

Data files (.D.SSIZIP) include a zipped version of the data folder with all its contents (including a audit-trail log file if one exists) in a single compressed file.

Method files (.M.SSIZIP, .quantmethod.xml) include all method components, including the method's cumulative audit-trail log if one exists, in a single compressed file.

The .SSIZIP file type is a standard ZIP file and can be extracted with standard unzip applications.

Access Files from Quantitative Analysis

Add Quantitative Analysis Report Templates to ECM

1. Open Internet Explorer and go to the ECM URL.
2. Create the LCDF structure required by your organization, such as the example shown here.

Access to files (while operating in Compliance) is through standard menus. For example:

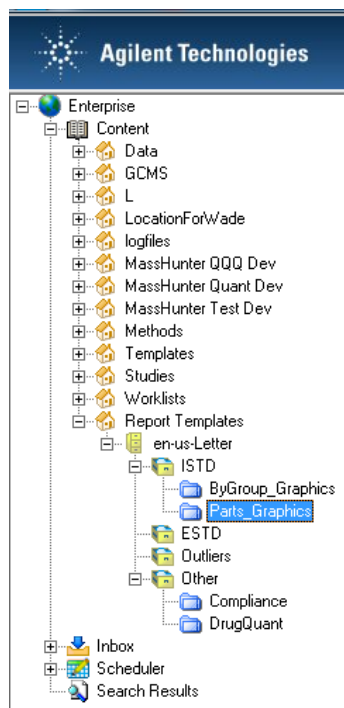
- To create a new Batch, select **File > New Batch**
- To Save a Batch, select **File > Save Batch**
- To generate a report, select **File > Generate**

When you save a file to ECM or retrieve a file from ECM the packaging and un-packaging of the .SSZIP files is automatically handled for you.

See your ECM administrator or the ECM Online help for information on the ECM privileges required to perform this procedure.

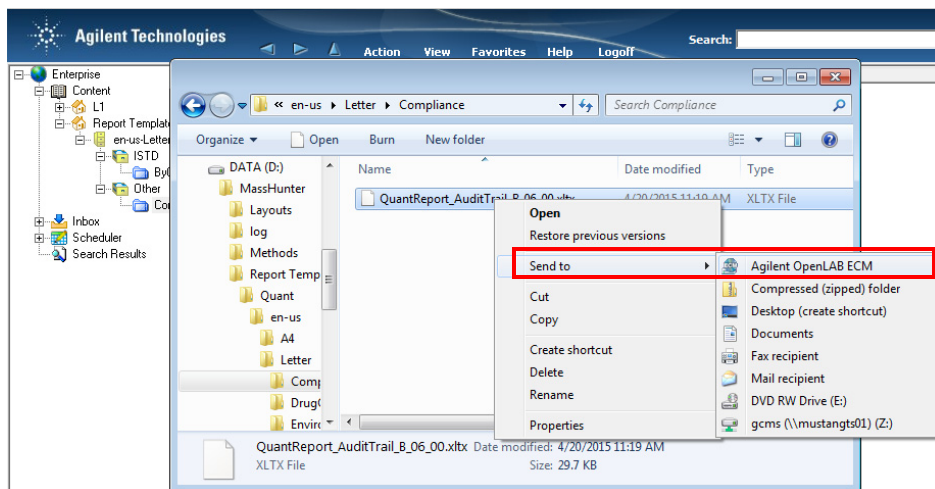
To use report templates for Quantitative Analysis, users must have access to the ECM location where the templates are stored.

See *"Associate ECM Roles to MassHunter Quantitative Analysis Command Groups"* on page 47 for details on changing privileges for a user in the Quantitative Analysis program



3. Add the report templates to the ECM folders.

See the ECM Online help for details on adding files including installing and using the **Send To > Agilent OpenLab ECM** menu.





6 Audit Trails

- GC/MS Acquisition - Enable/Disable Audit Reasons [56](#)
- GC/MS Acquisition - Edit the Pre-defined "Reason for Change" List [57](#)
- GC/MS Acquisition - View Instrument Audit Trail [58](#)
- GC/MS Acquisition - View and Print a Method Audit-Trail Log [58](#)
- GC/MS Acquisition - View and Print a Sequence Audit-Trail Log [59](#)
- GC/MS Acquisition - View and Print an Instrument Configuration Audit-Trail Log [59](#)
- Quantitative Analysis - Audit Trail Overview [60](#)
- Quantitative Analysis - Generate an Audit Report [61](#)
- Quantitative Analysis - Enable/Disable Audit Reasons [63](#)

Chapter 6 describes how to view or print audit-trail logs and how to enable or disable the audit reasons shown in logs in both MassHunter GC/MS Acquisition and Quantitative Analysis.



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GC/MS Acquisition - Enable/Disable Audit Reasons

Depending on how you configure MassHunter GC/MS Acquisition, each time a user initiates an action which may result in modification to a sequence file, method file, or instrument configuration, they may be prompted for a reason for that modification. The reasons they enter are recorded in the audit-trail log.

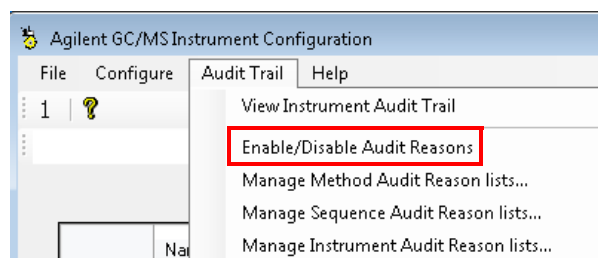
With this feature enabled, when a user modifies a regulated record they will be prompted for a reason for the change. The user may then:

- Select a reason from a pre-defined list of reasons.
(There are three separate pre-defined lists; one for Methods, one for Sequences, and one for Instrument Configurations.)
- Enter a custom reason as free-form text. The length of the free-form text will be limited only by available system resources.

With this feature disabled, when a user modifies a regulated record, the date, time, and user's name of the change is still recorded; however, the reason for the change (the description column) is left blank.

To enable or disable this feature:

1. Access the Configuration Editor.
2. Select: **Audit Trail > Enable/Disable Audit Reasons.**



GC/MS Acquisition - Edit the Pre-defined "Reason for Change" List

To modify one of these pre-defined lists:

1. In the Configuration Editor, select **Audit Trail > (Manage Method Audit Reason lists), (Manage Sequence Audit Reason lists), or (Manage Instrument Audit Reason Lists)**.

2. To edit or delete an item:

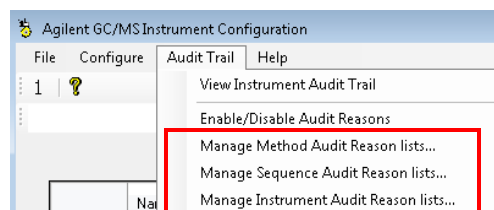
3. To add a new item to the list:

If the *Audit Reasons* feature is enabled, when a user modifies a method, sequence, or instrument configuration, he will be prompted for a reason for the change. He can then:

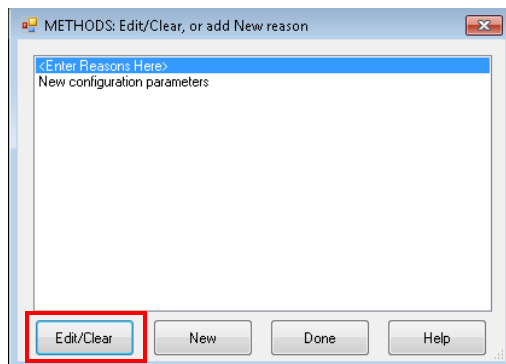
- Select a reason from a pre-defined list of reasons, or
- Enter a custom reason as free-form text.

There are three separate pre-defined lists, one for:

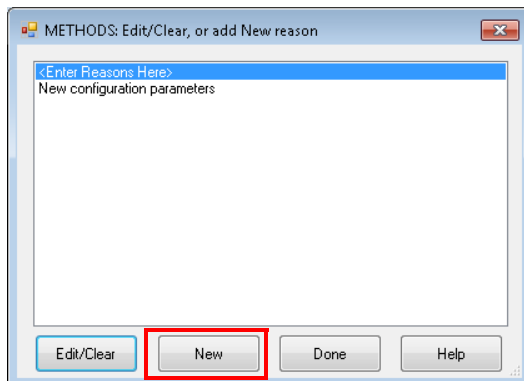
- Method changes
- Sequence changes
- Instrument Configuration changes



- a Select the pre-defined reason you want to edit or delete, and click **Edit/Clear**.
- b Edit the pre-defined text or clear the text shown to delete the reason, and click **OK**.

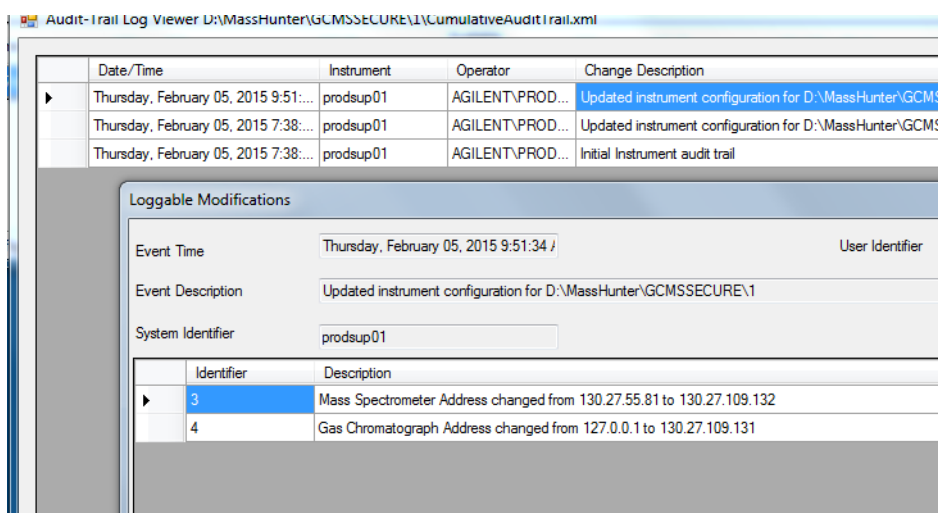
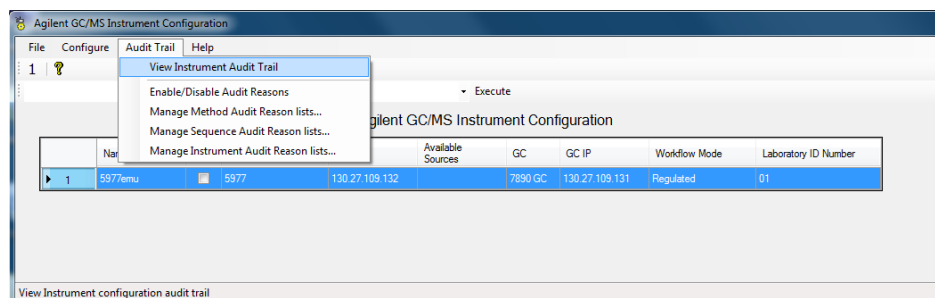


- a Click **New**.
- b Enter the text you want to show in the list of pre-defined reasons (for example, changed oven ramp parameters), and click **OK**.



GC/MS Acquisition - View Instrument Audit Trail

To view a log of any edit made to the instrument configuration, in the Configuration Editor, select **Audit Trail > View Instrument Audit Trail**.



GC/MS Acquisition - View and Print a Method Audit-Trail Log

In MassHunter GC/MS Acquisition, select **Method > View Method Audit-Trail Log**. (Displays the Audit-Trail log for the currently loaded Method.)

- To print the Summary Audit-Trail log, view the log, and then click **Print**.
- To print the Details Audit-Trail log, view the log, select **Detailed Print**, and then click **Print**.
- To preview the log before printing, view the log, and then click **Print Preview**. This displays a copy of the report in the Microsoft Report View, which you may review before printing.

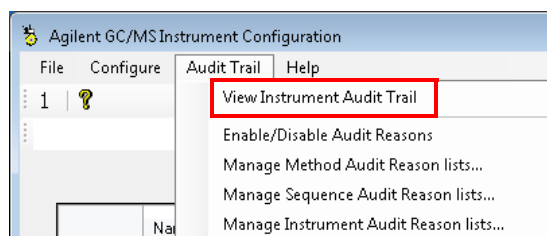
GC/MS Acquisition - View and Print a Sequence Audit-Trail Log

GC/MS Acquisition - View and Print an Instrument Configuration Audit-Trail Log

In the Configuration Editor, select **AuditTrail > View Instrument Audit-Trail**. (Displays the log for each configured instrument.)

In MassHunter GC/MS Acquisition, select **Sequence > View Sequence Audit-Trail Log**. (Displays the Audit-log for the currently loaded Sequence.)

- To print the Summary Audit-Trail log, view the log, and then click **Print**.
- To print the Details Audit-Trail log, view the log, select **Detailed Print**, and then click **Print**.
- To preview the log before printing, view the log, and then click **Print Preview**. This displays a copy of the report in the Microsoft Report View, which you may review before printing.



- To print the Summary Audit-Trail log, view the log, and then click **Print**.
- To print the Details Audit-Trail log, view the log, select **Detailed Print**, and then click **Print**.
- To preview the log before printing, view the log, and then click **Print Preview**. This displays a copy of the report in the Microsoft Report View, which you may review before printing.

Quantitative Analysis - Audit Trail Overview

MassHunter GC/MS Quantitative Analysis operating in the Compliance mode provides audit reports that include details of each time a Batch Analysis, Method Development, Batch Review or Report command is used.

Additionally, as this mode is designed to support the requirements of the U.S. Food and Drug Administration (FDA) regulations and the handling of electronic records and electronic signatures published as 21 CFR Part 11, **records are treated as regulated records.**

Based on the settings in the Audit Trail Management program (ATM), each time a user issues a command in MassHunter Quantitative Analysis, they may be prompted to supply one, or both, of the following:

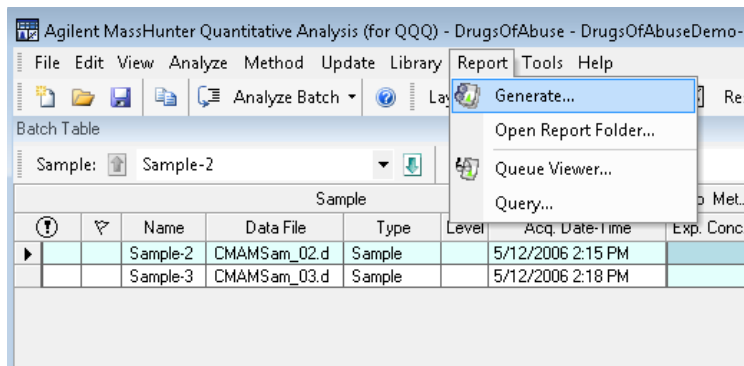
- Supply a reason for the change
- Supply their valid user name and password

The information entered at the time they issue the command is included in the audit reports.

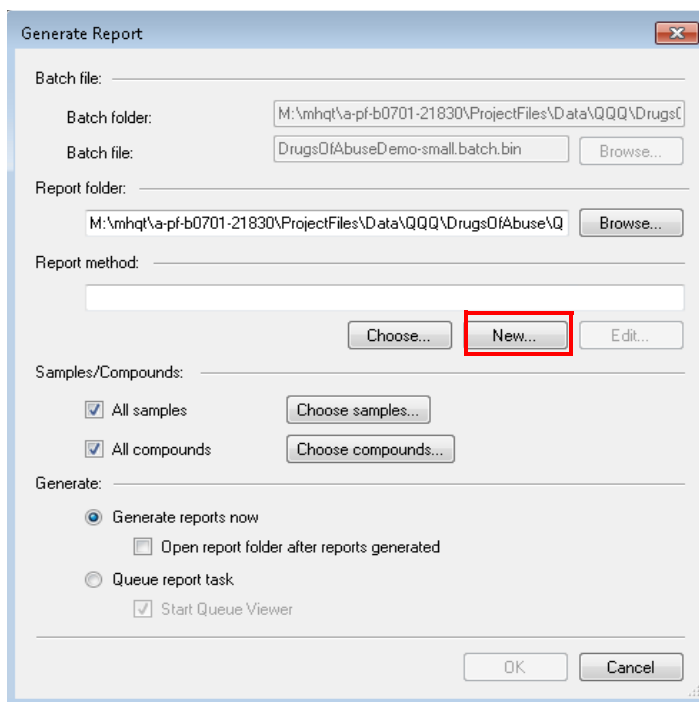
Quantitative Analysis - Generate an Audit Report

1. Select **Report > Generate...**

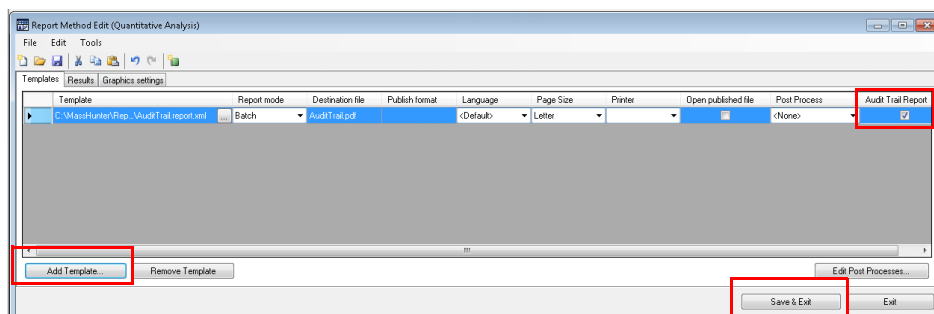
Audit reports are generated in the same manner as all other reports in MassHunter Quantitative Analysis. Refer to your online Help for more details on generating reports. The following is a brief summary of generating a batch audit trail report.



2. Click **New** to create a method template for the Audit Trail Report.



3. Click **Add Template...** . Navigate to the location in ECM where you saved your report templates, and select, the report template you wish to use. (For example, **AuditTrail.report.xml**.)



4. Be sure to check the Audit Trail box. If using the PDF report template, you do not need to check the Audit Trail box.
5. Click **Save and Exit**.
6. Click **OK**. The report is generated to the destination listed.

The 'Generate Report' dialog box is shown with the following settings:

- Batch file:** M:\mnhq\va-pf-b0701-21830\ProjectFiles\Data\QQQ\DrugsC
- Batch folder:** DrugsOfAbuseDemo-small.batch.bin
- Batch file:** DrugsOfAbuseDemo-small.batch.bin
- Report folder:** M:\mnhq\va-pf-b0701-21830\ProjectFiles\Data\QQQ\DrugsOfAbuse\Q
- Report method:** M:\mnhq\va-pf-b0701-21830\ProjectFiles\Data\QQQ\DrugsOfAbuse\DOA_ReportMethc
- Samples/Compounds:**
 - ☒ All samples
 - ☒ All compounds
- Generate:**
 - ☒ Generate reports now
 - ☐ Open report folder after reports generated
 - ☐ Queue report task
- ☒ Start Queue Viewer

Quantitative Analysis - Enable/Disable Audit Reasons

To enable or disable this feature for a command:

1. Start the Audit Trail Map (ATM).
2. Enter ECM system administrator credentials.
3. There are four MassHunter Quantitative Analysis Roles (Command Groups).

Select the group to which the command belongs. For example, select the Batch Analysis group if the command is a Batch Analysis command.

The Audit reason feature is enabled on an individual command basis.



ECM Login

Server URL:

Username:

Password:

Account:

Domain:

☒ Remember account & domain

Login Cancel

ATM Configuration

File Help

Batch Analysis
Method Development
Batch Review
Report

Required User Role to execute commands in this group

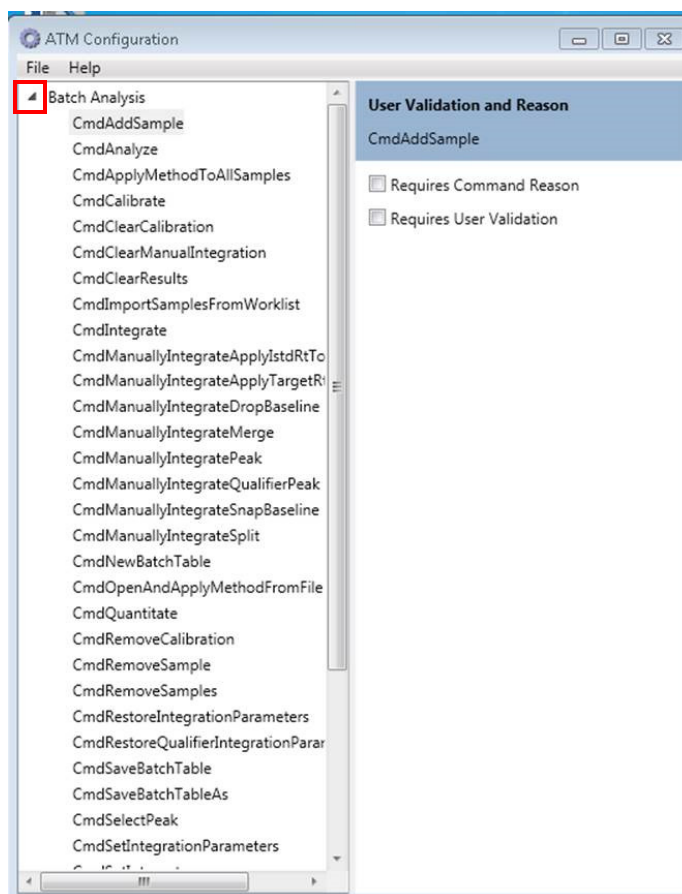
Batch Analysis

☐ Approver
☐ Archive Administrator
☐ Archive Agent
☐ BPM User
☐ Contributor
☐ Folder Administrator
☐ Reader
☐ Retention Manager
☐ Scheduler Administrator
☐ Scheduler Agent
☐ System Administrator
☒ Analysts
☒ Developer

MassHunter Roles
(Command Groups)

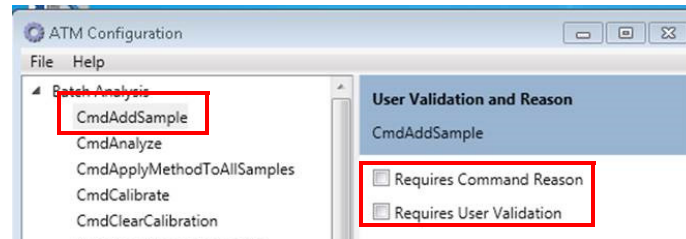
ECM Roles

- Click the arrow in front of the group name to display the full list of commands associated with this group.

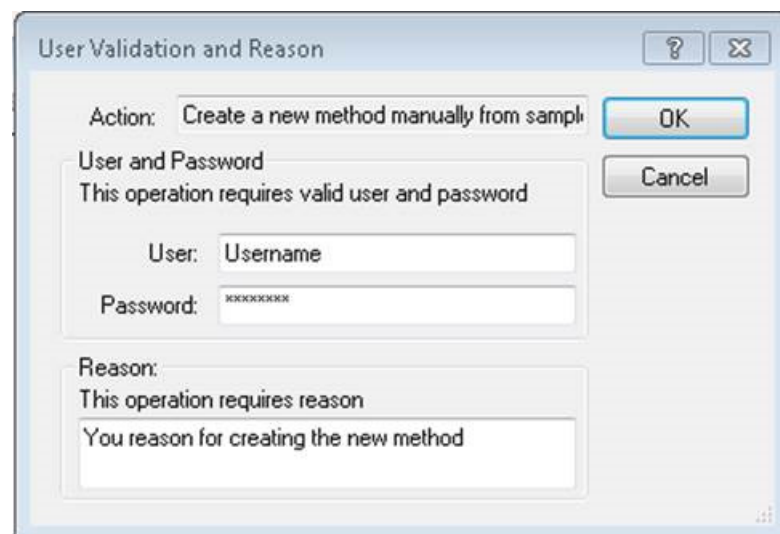


5. Select the command for which you want to activate the User Validation and Reason feature.
6. Enable either one or both of the validation requirements.
7. Select any additional commands in this group and set their validation requirements, as desired.
8. Click the arrow once again to return to the previous view and repeat the process for commands in another group, if desired.
9. When you are finished, select **File > Save** to save the changes.
10. Now, when a user completes this command in MassHunter, they will be presented with a screen similar to the following.

In this example the AddSample command is selected.



If either one of the validation reasons was unchecked in ATM, it will be greyed out on this screen. If both "Required Command Reason" and "Requires User Validation" were checked in ATM, both must be completed in MassHunter, as shown in this example.







7 MassHunter Quantitative Analysis Command Groups

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Batch Analysis Command Group 69

Method Development Command Group 70

Batch Review Command Group 71

Report Command Group 71

Chapter 7 provides a complete list of all the commands in each MassHunter Quantitative Analysis command group: Batch Analysis, Method Development, Batch Review, and Report.

See *“Associate ECM Roles to MassHunter Quantitative Analysis Command Groups”* on page 47 for details on how to associate these to Quantitative Analysis users.



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Overview

Before using MassHunter Quantitative Analysis, each user must be assigned to an ECM Role (listed in the right column of the ATM program).

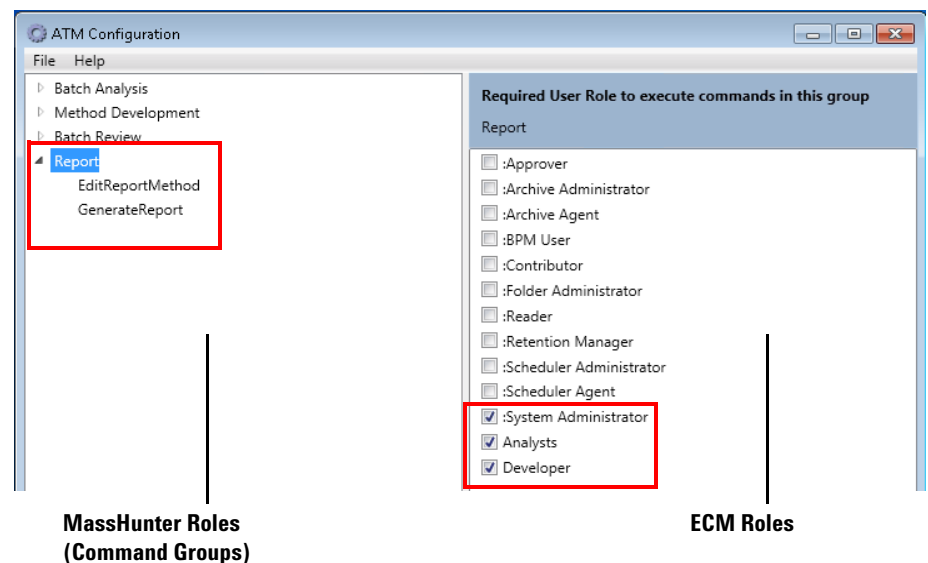
Each ECM Role is associated with one or more MassHunter Quantitative Analysis individual commands or command groups (shown in the left column of the ATM program).

There are four MassHunter Quantitative Analysis command groups in ATM:

- Batch Analysis
- Method Development
- Batch Review
- Report

The tasks a user may perform in MassHunter Quantitative Analysis are based on which Command groups are associated with the ECM Role to which they are assigned. See [“Associate ECM Roles to MassHunter Quantitative Analysis Command Groups”](#) on page 47 for details.

For example, here all users included in the System Administrator, Analysts, and Developer ECM Roles, have access to the MassHunter **Report** commands.



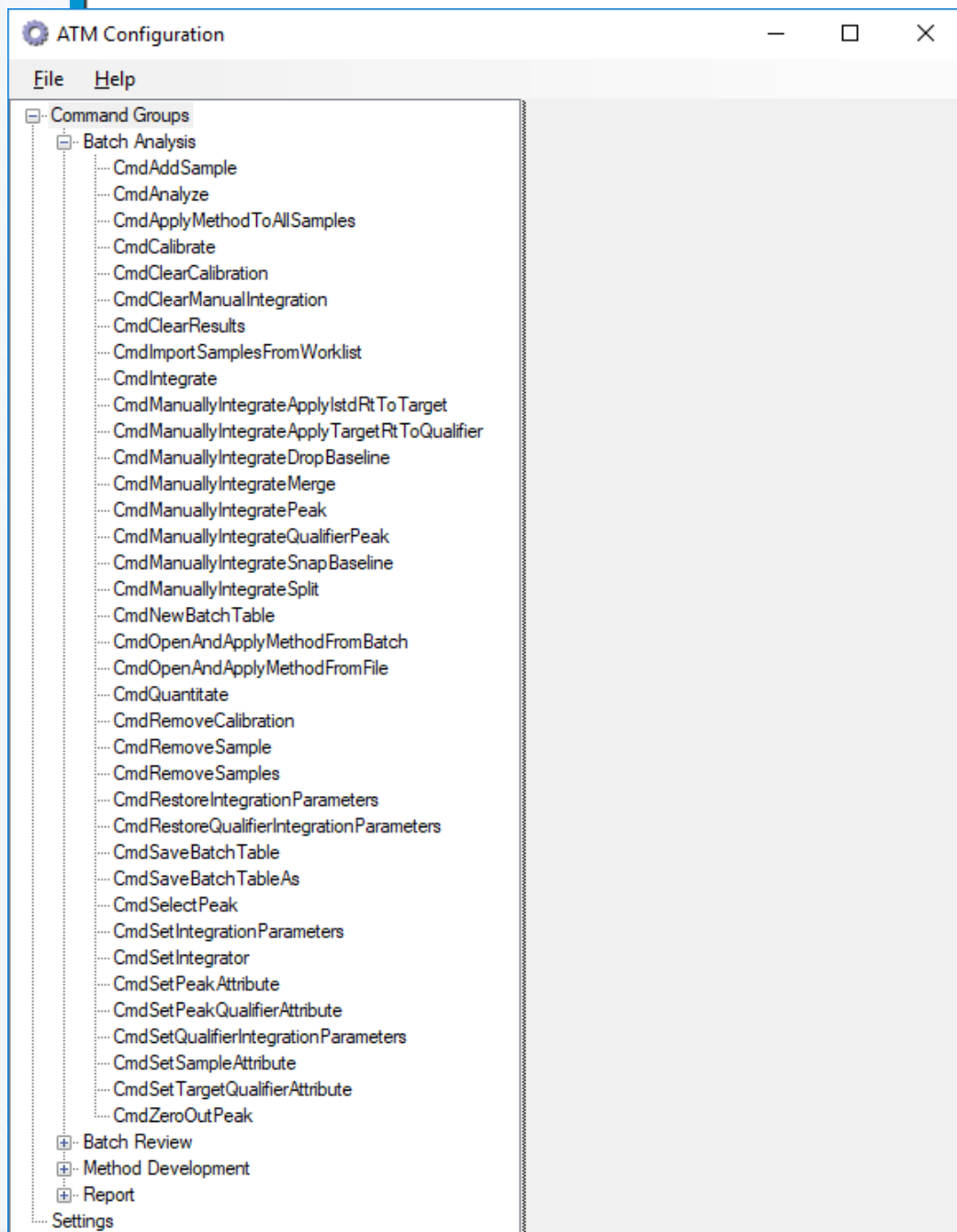
Each Command group is described below.

Batch Analysis Command Group

In the Batch Analysis command group there are commands used for routine batch analysis tasks such as:

- Add or Remove samples
- Analyze, Calibrate, and Integrate the Batch
- Save

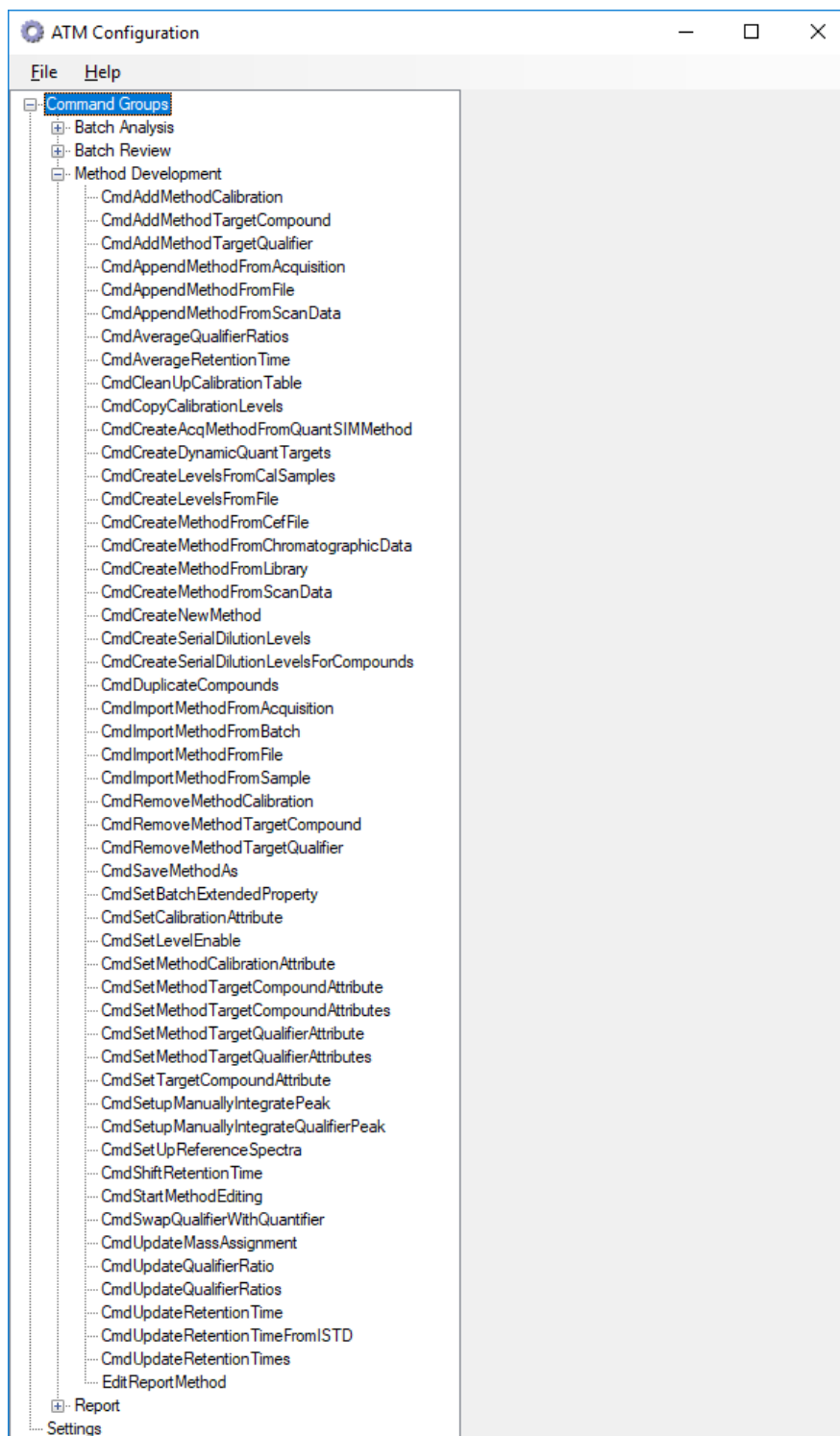
The complete list is shown below. **Notice**, in this example, only those users assigned to either the Analysts or Developer group will have access to these commands in MassHunter Quantitative Analysis.



Method Development Command Group

In the Method Development command group there are commands used for routine method development tasks such as Create, Import, and Save a new Method.

The complete list is shown below. **Notice**, in this example, only those users assigned to the Developer group will have access to these commands in MassHunter Quantitative Analysis.

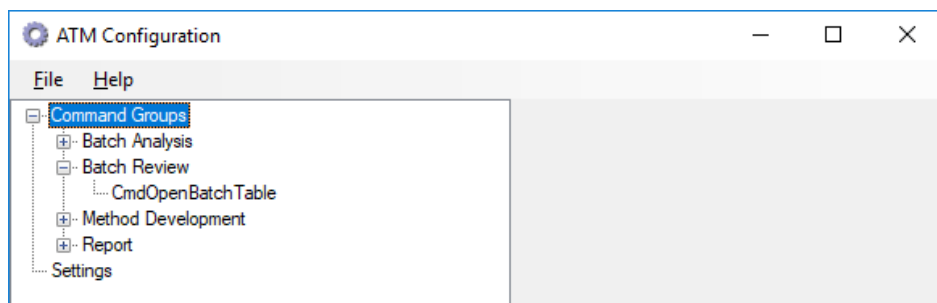


Batch Review Command Group

In the Batch Review group there is a single command:

- OpenBatchTable

Notice, in this example, those users assigned to either the Analysts or Developer group will be able to Open a Batch in MassHunter Quantitative Analysis.

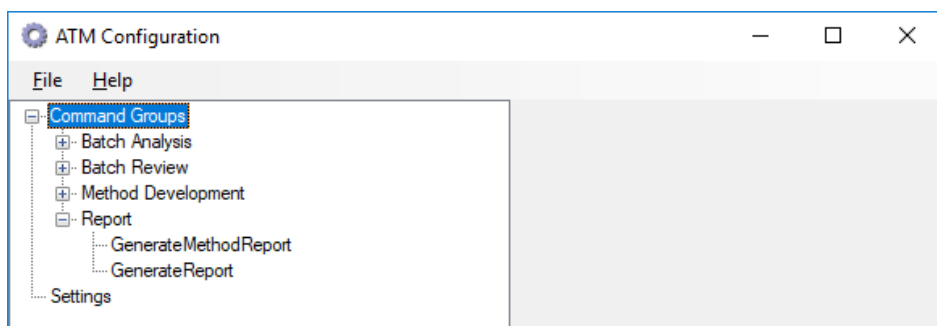


Report Command Group

In the Report group there are two commands:

- EditReportMethod
- Generate Report

Notice, in this example, those users assigned to the System Administrator, Analysts, and Developer group will be able to use these commands in MassHunter Quantitative Analysis.







8

MassHunter Acquisition Windows Security Groups

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Chapter 8 provides a list of the default privileges assigned to the pre-defined Windows security groups QuantAdministrators, QuantBatchAnalyzer, QuantBatchReviewer, QuantMethodDeveloper, and Quant Report Generator, which are used in MassHunter GC/MS Acquisition. The permissions are grouped by their function.

The privileges each user has in MassHunter GC/MS Acquisition are based on the Windows security group to which they have been assigned. After you have reviewed the roles and responsibilities associated with these groups, assign each MassHunter GC/MS Acquisition user to one of the groups. See [“Assign Users to a Windows security group”](#) on page 22



Overview

The privileges each user has in MassHunter GC/MS Acquisition are based on the Windows security group to which they have been assigned. After you have reviewed the roles and responsibilities associated with these groups, assign each MassHunter GC/MS Acquisition user to one of the groups. See [“Assign Users to a Windows security group”](#) on page 22

Method Menu

Default privileges to entries under the Method menu and Method icons are listed in the following table. See [“Change Group Privileges”](#) on page 79 for details on how to change these settings.

Method Menus and Icons	Analyst I	Analyst II	Analyst III	Manager
Additional method information	✓	✓	✓	✓
Load Method	✓	✓	✓	✓
Run Method	✓	✓	✓	✓
RTL – Acquire RTL Calibration Data		✓	✓	✓
RTL – Unlock Method or Relock Method		✓	✓	✓
Edit Entire Method			✓	✓
Edit Method Information			✓	✓
Print Method			✓	✓
Save or Save As Method			✓	✓
Intelligent Sequence Parameters – Edit or Print			✓	✓
Use Classic DA menu			✓	✓
Edit Intelligent Sequence Parameters			✓	✓
Edit Method			✓	✓
Set Default Paths				✓
View Method Audit Trail				✓
Zip/Unzip Method and Data				✓

Sequence Menu

Default privileges to entries under the Sequence menu and icons are listed in the following table. See *"Change Group Privileges"* on page 79 for details on how to change these settings.

Sequence Menus and Icons	Analyst I	Analyst II	Analyst III	Manager
Simulate Sequence	✓	✓	✓	✓
Load Sequence	✓	✓	✓	✓
Run Sequence	✓	✓	✓	✓
Save Sequence		✓	✓	✓
View Sequence Log		✓	✓	✓
View Sequence Quality Log		✓	✓	✓
Edit Sequence		✓	✓	✓
Position and Run Sequence		✓	✓	✓
Print Sequence Log		✓	✓	✓
Save Sequence As			✓	✓
Additional Sequence Options			✓	✓

GC - Instrument Menu

Default privileges to entries under the GC segment of the Instrument menu and icons are listed in the following table. See *"Change Group Privileges"* on page 79 for details on how to change these settings.

GC - Instrument Menus and Icons	Analyst I	Analyst II	Analyst III	Manager
GC Show/Hide Status	✓	✓	✓	✓
GC Sleep	✓	✓	✓	✓
GC Wake	✓	✓	✓	✓
GC Parameters			✓	✓
GC Real Time Plots			✓	✓
GC Sample Prep			✓	✓
GC Configuration				✓

MS - Instrument Menu

Default privileges to entries under the MS segment of the Instrument menu and icons are listed in the following table. See [“Change Group Privileges”](#) on page 79 for details on how to change these settings.

MS - Instrument Menus and Icons	Analyst I	Analyst II	Analyst III	Manager
MS Vacuum Control		✓	✓	✓
MS Tune File		✓	✓	✓
MS CI Control			✓	✓
Tune MSD			✓	✓
Edit Tune Parameters			✓	✓
MS Edit Parameters			✓	✓
MS Temperatures			✓	✓
Configure MS Source			✓	✓
Select MS Tune File			✓	✓
MS Status Panel				
Apply button			✓	✓
Edit button			✓	✓
Override button			✓	✓

CTC/PAL - Instrument Menu

Default privileges for access to entries under the CTC/PAL segment of the Instrument menu and icons are listed in the following table. See [“Change Group Privileges”](#) on page 79 for details on how to change these settings.

CTC/PAL Instrument Menus and Icons	Analyst I	Analyst II	Analyst III	Manager
Change Configuration				✓
Configuration				✓
Edit Cycles			✓	✓
Edit Method			✓	✓
Import Cycles			✓	✓
Parameters			✓	✓

Miscellaneous Instrument Menu

Default privileges to miscellaneous entries under the Instrument menu and icons are listed in the following table. See *"Change Group Privileges"* on page 79 for details on how to change these settings.

Miscellaneous Items on the Instrument Menu and Icons	Analyst I	Analyst II	Analyst III	Manager
Switch Filament		✓	✓	✓
ALS Parameters			✓	✓
Backflush Wizard			✓	✓
HeadSpace Parameters			✓	✓
Inlet/Injection types			✓	✓
Edit Monitors			✓	✓
QTOF MassCal			✓	✓
HeadSpace Parameters				✓

View Menu

Default privileges to entries under the View menu and icons are listed in the following table. See *"Change Group Privileges"* on page 79 for details on how to change these settings.

View Menus and Icons	Analyst I	Analyst II	Analyst III	Manager
Data Analysis	✓	✓	✓	✓
Instrument Control	✓	✓	✓	✓
Arrange Monitors	✓	✓	✓	✓
Chromatogram	✓	✓	✓	✓
Save Layout	✓	✓	✓	✓
Spectrum	✓	✓	✓	✓
Tile Horizontal	✓	✓	✓	✓
Tune and Vacuum Control			✓	✓

Batch Menu

Default privileges for access to entries under the Batch menu and icons are listed in the following table. See *"Change Group Privileges"* on page 79 for details on how to change these settings.

Batch Menu and Icons	Analyst I	Analyst II	Analyst III	Manager
Run Batch	✓	✓	✓	✓
Load and Run Batch	✓	✓	✓	✓
Load Batch	✓	✓	✓	✓
Set Up and Run Batch – short menu	✓	✓	✓	✓
Simulate Batch	✓	✓	✓	✓
Position and Run Batch		✓	✓	✓
Print Batch		✓	✓	✓
Print Batch Log		✓	✓	✓
Print Post-Batch Sequence Table		✓	✓	✓
Print Pre-Batch Sequence Table		✓	✓	✓
View Batch Log		✓	✓	✓
Save Batch		✓	✓	✓
Edit Batch		✓	✓	✓
Select Post Batch Reports			✓	✓
More Batch			✓	✓

Checkout Menu

Default privileges to entries under the Checkout menu and icons are listed in the following table. See *"Change Group Privileges"* on page 79 for details on how to change these settings.

Checkout Menu and Icons	Analyst I	Analyst II	Analyst III	Manager
Evaluate Tune	✓	✓	✓	✓
High Mass Check	✓	✓	✓	✓
Sensitivity Check	✓	✓	✓	✓
Checkout Tune	✓	✓	✓	✓
View Previous Tunes...	✓	✓	✓	✓

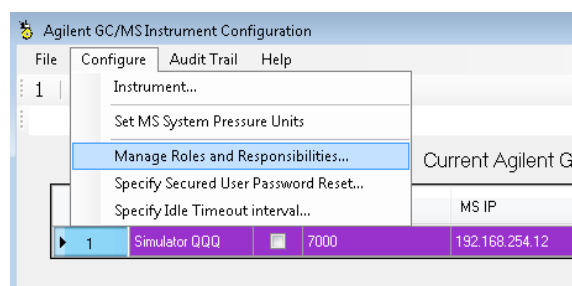
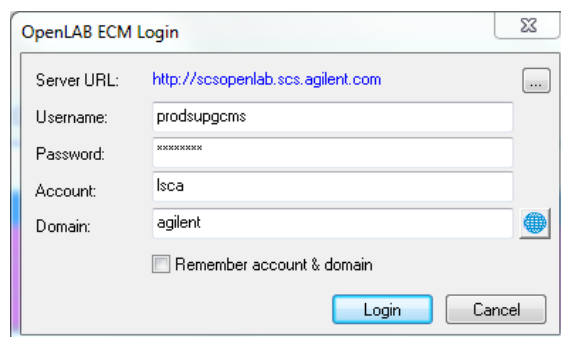
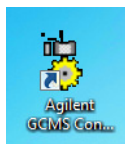
Change Group Privileges

To change these settings:

1. Login to your workstation with Windows Administrator privileges.
2. Double-click **Configuration Editor**.
3. Provide a valid user name and password, and click **Login**.
4. In the Configuration Editor, select **Configure > Manage Roles and Responsibilities**.

During installation, MassHunter GC/MS Acquisition created four Windows security groups.

- Manager (The highest level of privileges)
- Acquisition Analysts III
- Acquisition Analysts II
- Acquisition Analysts I (The lowest level of privileges)

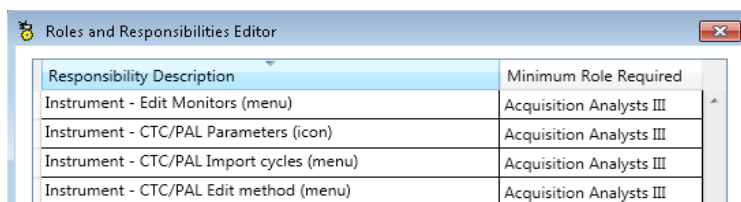


5. Click the column heading to sort the list by Description, and locate the responsibility you want to change.

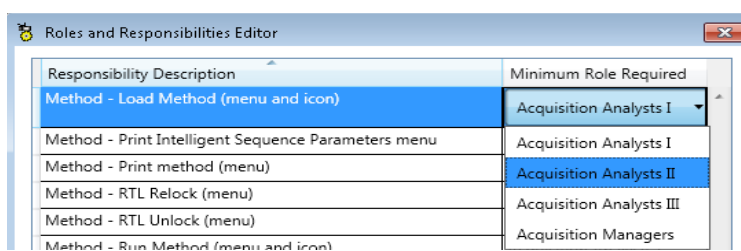
6. In the Responsibility column, select the item you want to modify, **Method load menu**, for example.

7. Double click the corresponding entry in the Role column to display a drop-down selection list.

8. Select the new Minimum Role you want to use for this Responsibility.



Responsibility Description	Minimum Role Required
Instrument - Edit Monitors (menu)	Acquisition Analysts III
Instrument - CTC/PAL Parameters (icon)	Acquisition Analysts III
Instrument - CTC/PAL Import cycles (menu)	Acquisition Analysts III
Instrument - CTC/PAL Edit method (menu)	Acquisition Analysts III



Responsibility Description	Minimum Role Required
Method - Load Method (menu and icon)	Acquisition Analysts I
Method - Print Intelligent Sequence Parameters menu	Acquisition Analysts I
Method - Print method (menu)	Acquisition Analysts II
Method - RTL Relock (menu)	Acquisition Analysts III
Method - RTL Unlock (menu)	Acquisition Analysts III
Method - Run Method (menu and icon)	Acquisition Managers

For example, you could change the Load Method menu:

- From a minimum role requirement of Analyst I
- To a minimum role requirement of Analyst II



9

Supported Network Topologies for Compliance Security Mode

Single GC/MS Workstation (Acquisition PC) [82](#)

GC/MS Workstation (Acquisition PC) Plus a Data Review Station (Review PC) [82](#)

GC/MS Workstation (Acquisition PC) Plus Data Processing (Process PC) Plus Data Review (Review PC) [83](#)

Scaled Network Solution Multiple GC/MS Systems [83](#)

Scaled Network Solution Multiple GC/MS Systems + Multiple Processing and Review Stations [84](#)

Chapter 9 includes examples of the network configurations supported by MassHunter compliance mode.

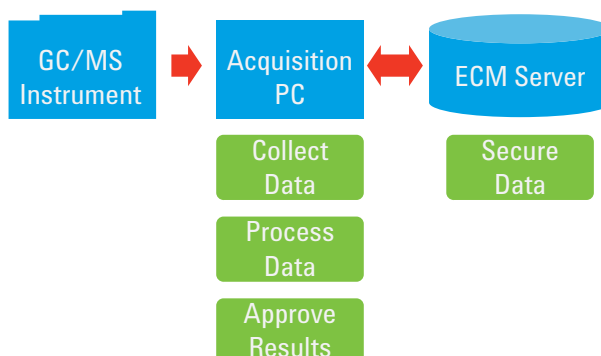
All supported configurations require an ECM server installation of version 3.4.1 SP2 or greater.



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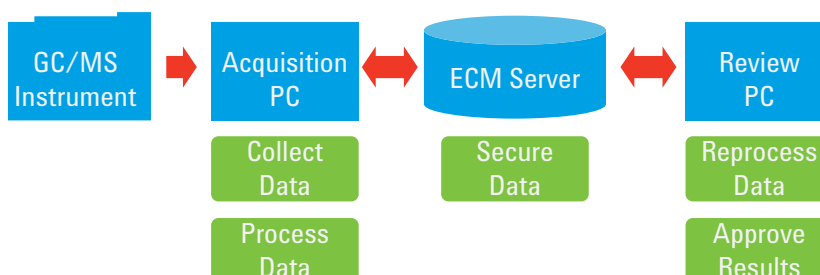
Single GC/MS Workstation (Acquisition PC)

- Data is acquired, processed, reviewed and approved on a single GC/MS Workstation (Acquisition PC).
- Data and Results are secured using OpenLab ECM Server.



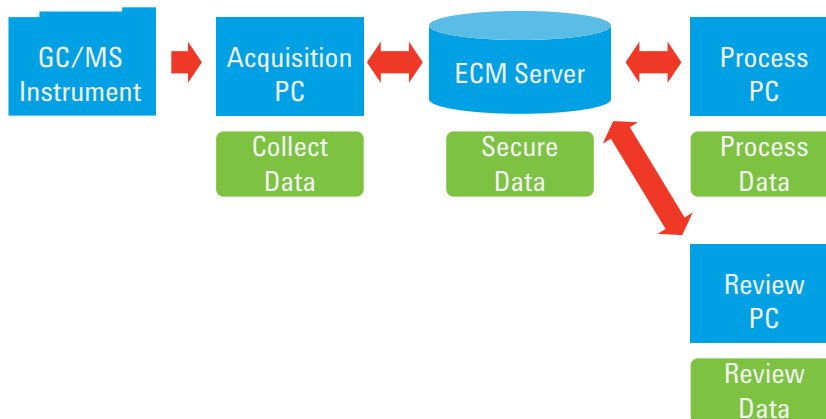
GC/MS Workstation (Acquisition PC) Plus a Data Review Station (Review PC)

- Data is collected and processed on a GC/MS Workstation (Acquisition PC).
- All data is secured using OpenLab ECM Server.
- Results are reprocessed and approved on a second PC (Review PC).



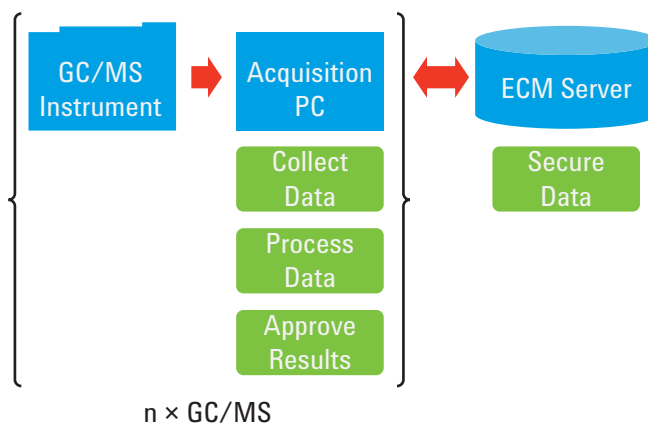
GC/MS Workstation (Acquisition PC) Plus Data Processing (Process PC) Plus Data Review (Review PC)

- Data is collected and processed on a GC/MS Workstation (Acquisition PC).
- All data is secured using OpenLab ECM Server.
- Results can be reprocessed and approved on a separate PC (Process PC).
- Results can also be reviewed on an additional PC (Review PC).



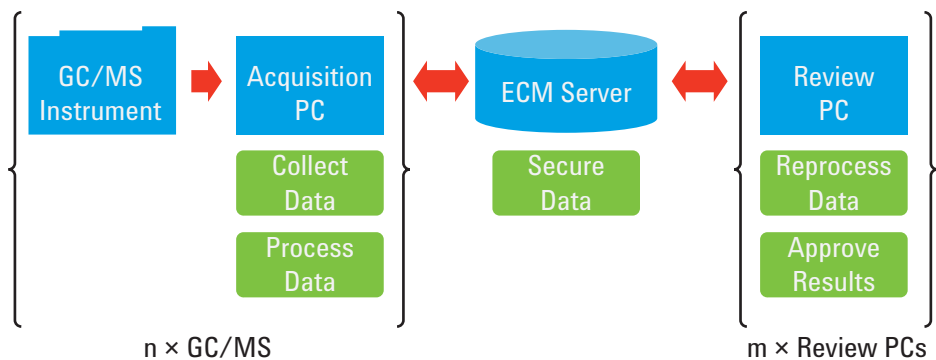
Scaled Network Solution Multiple GC/MS Systems

- A Lab acquires, processes, reviews, and approves data from a single instrument on a single PC, as illustrated in the brackets below.
- Data and Results from multiple instruments are secured using OpenLab ECM Server. Therefore, a lab could have multiple versions of what is in the brackets, all going in to the same OpenLab ECM server.



Scaled Network Solution Multiple GC/MS Systems + Multiple Processing and Review Stations

- A lab collects and processes data on one acquisition PC.
- Results from any instrument can be reprocessed and reviewed from alternate PCs.
- All data is secured using OpenLab ECM Server.





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Printed in USA, November 2018

G6845-90022

