

Empower SystemsQT for Software

This protocol document describes the process for performing the Installation Qualification (IQ) and Operational Qualification (OQ) for Waters® Empower® SystemsQT™ for Software, with or without Method Validation Manager (MVM) software.

Evaluate before qualification begins

The owner's management must review this protocol, the Empower SystemsQT for Software release notes (part number 716003298), the *Waters Qualification Overview* (part number 715511111), and Empower 3 software release notes:

- Empower 3 (base) Release Notes (part number 715002704)
- Service Release 1 Release Notes (part number 716003450)

To perform the qualification, you must be running Empower 3 Feature Release 1, minimum.

- Feature Release 1 Release Notes (part number 716003561)
- Feature Release 2 Release Notes (part number 716003923)
- Feature Release 3 Release Notes (part number 716004689)

Identify the scope:

- Personal, Workgroup, or Enterprise

Considerations for IQ or OQ execution:

- Execution for the Citrix® server requires it to be listed as a node. If the Citrix server is not listed as a node, login to the Citrix server and launch Empower. In Nodes, create a new node using the exact name of the Citrix server.
- Ensure computer connection to a printer, however each node does not require printer access.
- Enable the Run Empower SQT privilege for your User Type.
- If intending to use Electronic Signatures, perform the following:
 - Enable the Sign Off Results 1 for your User Type.
 - Check the Result Sign Off tab in System Policies for Valid Sign Off 1 Reasons.
 - Determine if Default Strings for Result Signoff 1 Meanings and Result Signoff 2 Meanings can be created. Create "Pass" and "Fail" default strings if possible.

In the Qualification Overview document, ensure that these forms are completed:

- Qualification Approval
- Identification of Performers and Reviewers

Overview

The Empower SystemsQT for Software is specific to the Empower 3 FR1 and above releases. The Empower SystemsQT uses a wizard to run the software IQ and OQ. The reports can be signed off electronically or printed. Reports that display the method parameters used may contain blank fields because the parameters may not be enabled or populated in the method.

The data set used for IQ is a blank injection and is used to create the IQ report and allows for electronic signature. The IQ data set was collected for Empower 3 FR3.

The data set used for internal standard calculations is identical to that used in Empower 2154, Empower 1154, or Millennium³² v3.2, v3.05.01, or v3.05.

The data set used for external standard calculations is identical to that used in Empower 2154, Empower 1154, or Millennium³² v4.0 or v3.2.

The data set used for the method validation manager is identical to that used in Empower 2154 FR 3.

You need not enable ApexTrack™ integration if your organization uses traditional integration.

Installation qualification (IQ)

The IQ represents the installation qualification process for a Waters Empower 3 Personal, Workgroup, Enterprise, or LAC/E³²™ module software system consisting of software and associated hardware components.

The purpose of the IQ portion of the qualification is to confirm these conditions:

- Personal, Workgroup, Enterprise, and/or LAC/E³² module software components are properly installed.
- Empower 3 software is properly installed.
- Empower 3 files you installed on the system are not corrupted and remain identical to the files shipped from Waters.
- Any Empower 3 software options are properly installed.
- The name of the operating system, build number, and all service packs apply.
- The total number of Empower 3 named user licenses and system licenses for Workgroup and Enterprise.
- Any Empower 3 service packs are properly installed and verified.

Software file verification

During installation of the Empower 3 software, the software automatically runs a file verification utility, which verifies that the disk files shipped from Waters were not corrupted during installation. The file used for the comparison is in \Empower\SCRIPT\DIR.CKS.

The file verification focuses on these file attributes:

- Cyclic Redundancy Checksum (CRC)
- File size
- File date and time stamp

If the file verification utility detects a change in any file, the installation is aborted. You can rerun the utility anytime, to requalify the installation.

Rule: The software does not overwrite the original CHECKSUM.TXT file each time you run the Verify Files utility. Instead, each subsequent CHECKSUM.TXT file name is annotated with the date and time: for example, \Empower\SCRIPT\Checksum_11.01.2010_12.23.41.txt.

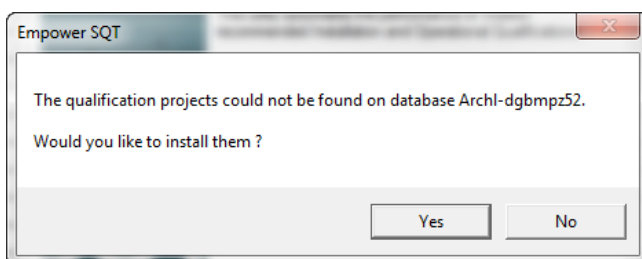
Operational qualification (OQ) for Empower SystemsQT for Software only

Evaluate and determine if traditional integration or ApexTrack integration will be used when executing the OQ.

Restore the appropriate projects based upon the integration chosen:

- Traditional Integration – Restore the Valid_OQ1 project
- ApexTrack Integration – Restore the Valid_OQ1 and Valid_OQApex projects

Ensure all appropriate projects are restored. If all of the projects (Valid_OQ1, Valid_OQApex, and Valid_OQMVM) are not restored the following message will appear when making requests from the SQT wizard:



It is not required to restore all the projects, only those appropriate. If the appropriate projects are restored, click "No" and continue.

The projects provided by Waters are limited to verifying and documenting the ability of Empower 3 software to perform these tasks:

- Restore projects
- Process standards
- Process unknowns
- Perform peak integration
- Perform quantification
- Perform calibration
- Generate a printed report or save a result to the database

Notes:

- When the ApexTrack Integration option is enabled and both the Valid_OQ1 and Valid_OQApex projects are restored, the result sets for the Internal Std Sample Set and External Std Sample Set will be available in both projects when an OQ request is initiated.
- The reports contain an "Integration Algorithm" field that indicates whether traditional or ApexTrack integration was used.

Operational qualification for Empower SystemsQT for Software with Method Validation Manager

If you activated the Empower SystemsQT for Software MVM qualification, the OQ uses the Valid_OQMVM project.

The Valid_OQMVM project is provided by Waters and limited to verifying and documenting the ability of the Empower 3 Method Validation Manager to perform these tasks:

- Restoring a validation working type project.
- Generating statistical validation results for all validation tests.
- Ensuring the correct value is generated during validation processing.
- Ensure you restore the appropriate project folders for Empower 3 Feature Release 3.

The report includes method validation results and protocol for these method validation tests:

- Linearity
- Linearity comparison
- LDL/LQL
- Specificity
- Accuracy
- Repeatability
- Reproducibility
- Intermediate precision
- Intermediate precision DOE
- Robustness
- Stability
- Filter validation
- System precision

Node Properties

The SQT license enables additional tabs in the node properties: IQ Info and IQ/OQ.

1. In Configuration Manager, select Nodes and then select a node to update its properties.
2. Right-click properties.
3. Select the IQ Info tab.
 - Identify the computer components associated with this software IQ in the spaces provided.
 - When you complete the Computer Components form, compare the information entered on it with the purchase order for the Empower 3 software system.
 - When you install software as part of a reloading operation or software support plan upgrade, the purchase order is sometimes unavailable. In such a case, type "RELOAD" or "UPGRADE" on the Purchase Order Number line of the Computer Component for that client.

4. Identify the documentation information required for qualification. When you complete the documentation information, identify each document as follows:
 - If the document was received, select Yes.
 - If the document was not received, select No.
 - If the document has a revision, enter the revision.
 - If the document is missing or not applicable, enter that information in the comments.
5. Identify the components and peripherals of the Empower 3 system associated with this software IQ.
 - When you complete the Configuring the Computer and Peripherals section, select either "Installed" or "N/A" on the line corresponding to each device you install.
 - If any comments apply to the installation, enter them in the comments section.

Note: If the Empower 3 system was purchased from Waters, you need not verify the configuration. Instead, in the configuring components and peripherals section, certify that the computer was configured at the factory by selecting Yes.
6. Click OK.

Running the Empower SystemsQT for Software

To run the Empower SystemsQT for Software, perform these tasks:

1. Log in to Empower, using the Pro interface, as a designated user with a full name. Do not log in as one of the default users.
2. Before the qualification begins, ensure these conditions are met:
 - a. The owner's management reviewed the *Qualification Overview*, this protocol, and any applicable release notes.
 - b. The Qualification Protocol Approval Form 1-1 and the Identifying Performers and Reviewers Form 1-2 (both available in the *Qualification Overview* document) are completed and signed.
3. From the Empower Pro window, click Configure System, and then select Projects.

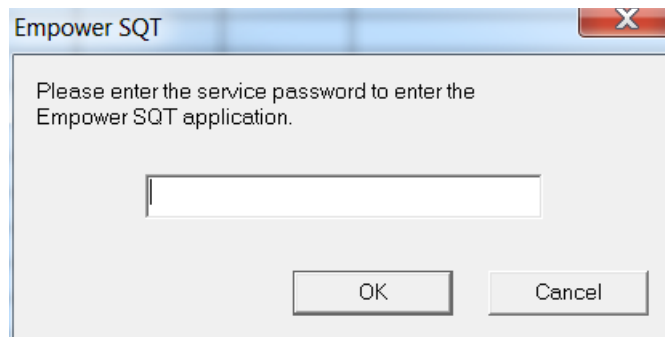
Requirements:

- To run the qualification, you must activate the Empower SQT for Software and the Empower SQT for Software MVM options, as applicable.
 - To run the Empower SystemsQT you must have enabled the Run Empower SQT privilege for your User Type.
4. Insert the Empower SystemsQT for Software DVD into the DVD drive.
 5. From the menu bar, select File > Restore Project.
 6. Browse to the Empower SystemsQT for Software DVD, and select the appropriate Empower version and language folder.
 7. Depending on the type of integration algorithm to be used in Empower, restore the following projects:
 - Valid_OQ1 project for IQ and OQ when using traditional integration.
 - Valid_OQ1 project and Valid_OQApex project for IQ and OQ when using ApexTrack integration.

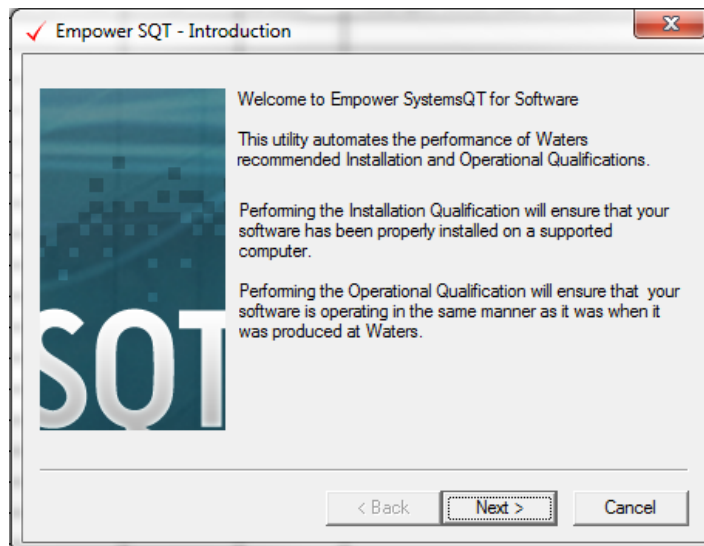
- Valid_OQMVM project (regardless of the integration algorithm used) if using the Method Validation Manager.
8. In Configuration Manager, view the properties of the restored project(s).
 9. Set the project access to allow for all required individuals to access the projects. If using owner and group access, ensure that the group access includes both the group in which you are a member and the groups of all other required individuals.

Requirement: The specific projects names are required by the wizard to run the SQT. If you change the name of a project before initiating the SQT request, the request will not be completed.

10. In Configuration Manager, select Tools > EmpowerSQT.
11. In the service password dialog box, enter the case-sensitive password, and click OK.

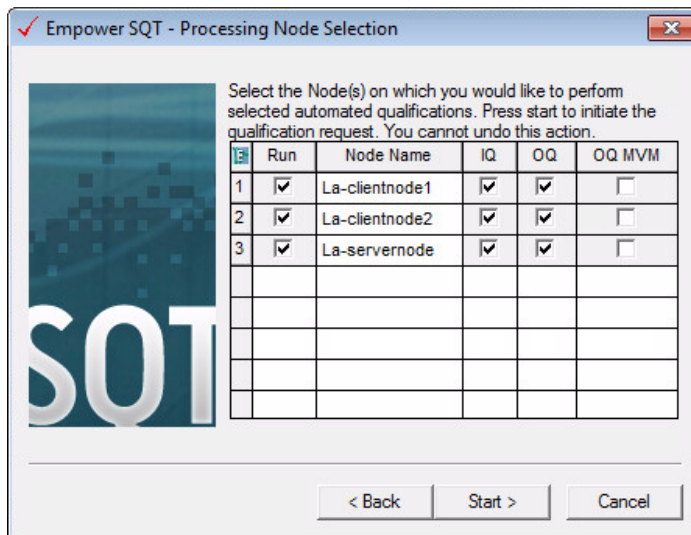


Result: When you correctly enter the case-sensitive password, and click OK, the Introduction wizard appears.



12. Click Next.

Result: The Processing Node Selection wizard page appears.



13. For Empower 3 FR3 users, select the node on which you would like to perform the automated qualification. This can be a workstation, client, Citrix server, or LAC/E³².

Notes:

- To deselect all displayed nodes, clear the checkmark for the first node and then press Ctrl+D to copy the clearing down for all displayed nodes.
- If the Citrix server is not listed as a node and is required, login to the Citrix server and launch Empower. In Nodes, create a new node using the exact name of the Citrix server.
- Ensure you select the appropriate qualification request:
 - IQ: To perform the Empower software installation qualification on that node.
 - OQ: To perform the Empower software operational qualification on that node.
 - OQ MVM: To perform the Empower software operational qualification for Method Validation Manager on that node.

14. Click Start. This action cannot be undone and initiates the qualification requests selected.

Result: Initiation of the qualification requests cause the Date of Execution field in the node properties to be automatically populated for the qualification requests selected. The Date of Execution cannot be manually modified, entered, or deleted.

	Node Name	Node Location	Node Type	Owner	Node Comments	IQ Status	IQ Date	IQ Comment
1	Archl-dgbmpz52		Empower	System			12/17/2015 11:02:17 AM EST	

Node 'Archl-dgbmpz52' Properties

General | Instruments | Serial Ports | Configure DHCP | Access | IQ Info | IQ/OQ |

IQ

Status: Date of Execution: 12/17/2015 11:02:17 AM EST

Comment:

OQ

Status: Date of Execution: 12/17/2015 11:02:24 AM EST

Comment:

OQ MVM

Status: Date of Execution:

Comment:

OK Cancel Help

15. The Complete wizard page appears. Click Close if the qualification requests are complete. This will exit the SQT wizard. Click New Request to resubmit, update, or create a new qualification request.

✓ Empower SQT - Complete

The request to qualify the nodes you selected is being processed. A log file has been created in the Empower log directory.

When your request is finished processing, open the project to review the data and sign off on the report.

To complete this qualification request, click Close. To resubmit the same qualification request or to start an additional request, click New Request

New Request Close

IQ Report

Perform this procedure:

1. From Configuration Manager, open the Valid_OQ1 project.
2. Select the Results Sets tab.

3. If multiple IQ qualification requests were performed, update the filtering by selecting Edit View and include IQ/OQ Node. This displays the node name associated with the result set created.
4. An individual IQ result set or multiple IQ result sets can be reported. Multiple Result Sets are selected by holding Ctrl and selecting each result or selecting the first IQ Result set and using Shift to select a group of IQ Result Sets.
5. Once all required IQ Result Sets are selected, right-click and select Preview/Publisher.
6. Select the appropriate report method.

Notes:

- Reports used for Electronic Signature are identified with a suffix of "_RS".
- When selecting the report, it is important to consider if it is appropriate to include the Empower Files because this increases the length of the report significantly and electronic signatures require each page to be viewed prior to performing electronic sign off. All reports contain an Installation Qualification Summary.

Report Methods for an Individual IQ Result Set:

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ Individual Detailed	√	√	√		√
IQ Individual Detailed_RS	√	√	√	√	
IQ Individual Summary	√		√		√
IQ Individual Summary_RS	√		√	√	

Report Methods for Multiple IQ Result Set:

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ All Selected Detailed	√	√	√		√
IQ All Selected Detailed_RS	√	√	√	√	
IQ All Selected Summary	√		√		√
IQ All Selected Summary_RS	√		√	√	

7. Review the report.

Note: When reviewing the IQ report, you may notice that the result set time is not the same as the current time displayed on the report. When the result set is stored, the server provides the date and time associated with the result set. The current date and time is provided from the node where the checksum report is created.

8. A node passes installation qualification if the Installation Qualification Summary states "no installation changes were detected". If another message is displayed, for example "the following changes were detected:", Waters recommends you:
 - a. Check for a standard operating procedure that notes the change and if the change means the installation qualification passes or fails.
 - b. Evaluate the change and document the effects of these changes to determine if installation qualification passes or fails.
 - c. Reinstall the software and perform the IQ again.
9. When installation errors are found and the operational qualification fails, the Empower 3 software must be reinstalled. Ensure that you deactivate the options before reinstalling Empower 3.
10. For hand-written signatures print the report(s), and then perform the following:
 - a. Complete the Qualification Status of the report to include: pass/fail status, any applicable comments, signature, and date.
 - b. Contact the approver to review, sign, and date the report.
 - c. File all reports, passed or failed, in your Waters binder under the Installation Qualification tab.
11. For Electronic Signatures, use the Sign Off button after you review each page of the report.
12. Perform Sign Off 1 by entering the user name and password. Depending on the system policies, perform one of the following for the Reason:
 - Select the appropriate default string that includes the text "Pass" or "Fail".
 - Select the appropriate default string and add the text "Pass" or "Fail".

Note: Append additional comments to a Reason when appropriate. For example, if installation changes were detected but the changes were determined non-critical, this information should be referenced in the Reason as appended text.
13. Notify the approver that he or she must electronically sign the results as "Sign Off 2".
14. It is optional to update the IQ/OQ tab in the node properties with IQ status (Pass or Fail) and Comment. This information is for administrative purposes only. The status and comments are provided in the handwritten or electronically signed report.

Verifying the results of the OQ: the Internal Standard OQ Sample Summary Report (Electronic or Printed)

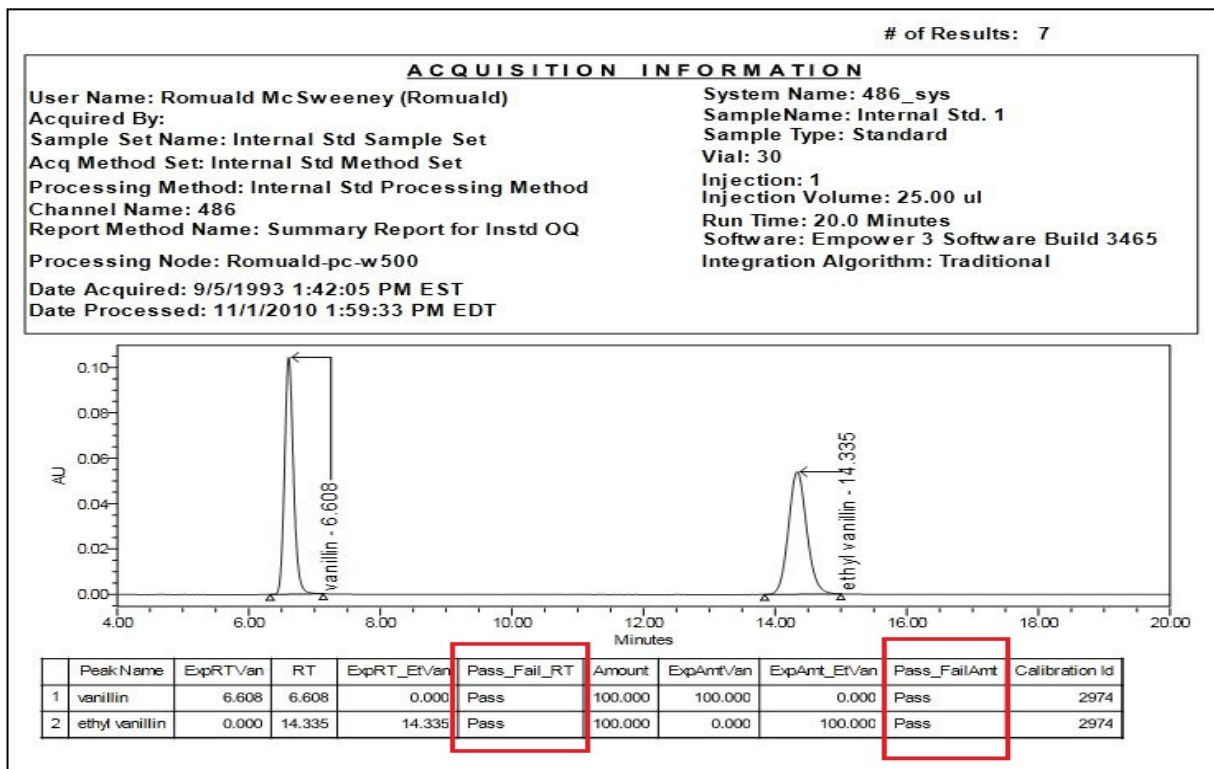
Perform this procedure:

1. From Configuration Manager, open the Valid_OQ1 (Traditional Integration) or Valid_OQApex project (ApexTrack Integration).

Note: When the ApexTrack Integration option is enabled and both the Valid_OQ1 and Valid_OQApex projects are restored, result sets for the Internal Std Sample Set and External Std Sample Set will be available in both projects when an OQ request is initiated. Perform this procedure for both of the projects to evaluate Traditional and ApexTrack Integration.
2. Select the Result Set tab and select the appropriate "Internal Std Sample Set".

Note: When multiple result sets are created, it is suggested to update the filtering by selecting Edit View and include the IQ/OQ Node. This displays the node name associated with the result set created.
3. Right-click and select Preview/Publisher.

4. Open the appropriate report method:
 - "Summary Report for Instd OQRS" for Electronic Signatures.
 - "Summary Report for Instd OQ" for Handwritten Signatures.
5. Review the report to ensure that "Pass" appears on each line of these two columns:
 - Pass_Fail_RT
 - Pass_FailAmt



6. When "Pass" appears on each line, no failures were found; all retention times (RT) equal the expected retention times (ExpRT), and all amounts equal the expected amounts (ExpAmt) indicated on each report page. Thus, this portion of the OQ has passed the test.
7. The minimum and maximum limits are set using custom fields for RT and Amount. When the actual RT or Amount falls within these limits, the OQ test returns a passing result. When "Fail" appears on any line, the RT or Amount falls outside these limits, and the test returns a failing result.
8. For hand-written signatures print the report, and then perform the following:
 - a. Complete the Certification section of the report to include: pass/fail status, any applicable comments, signature, and date.
 - b. Contact the Reviewer to review, sign, and date the report.
 - c. File all reports, passed or failed, in your Waters binder under the Operational Qualification tab.
9. For Electronic Signatures use the Sign Off button once you review each page of the report.

10. Perform Sign Off 1 by entering the user name and password. Depending on the system policies perform one of the following for the Reason:
 - Select the appropriate default string that includes the text "Pass" or "Fail".
 - Select the appropriate default string and add the text "Pass" or "Fail".

Note: Append additional comments to a Reason when appropriate.
11. Notify the Reviewer that he or she must electronically sign the results as "Sign Off 2".
12. It is optional to update the IQ/OQ tab in the node properties with OQ status (Pass or Fail) and Comment. This information is for administrative purposes only. The status and comments are provided in the handwritten or electronically signed report.

Verifying the results of the OQ: the External Standard OQ Sample Summary Report (Electronic or Printed)

Perform this procedure:

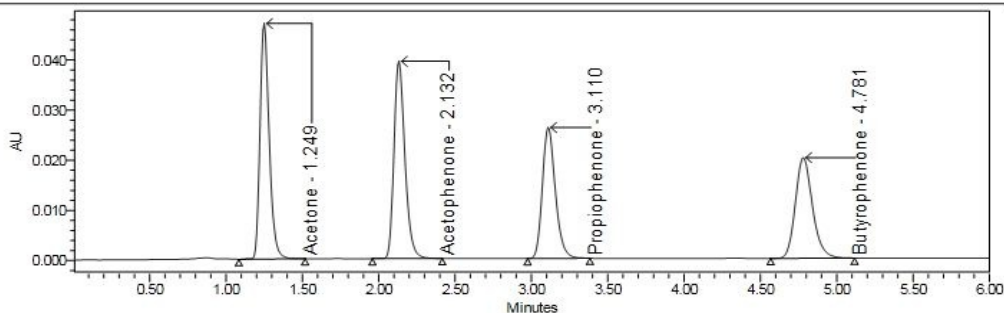
1. From Configuration Manager, open the Valid_OQ1 or Valid_OQApex project.

Note: When the ApexTrack Integration option is enabled and both the Valid_OQ1 and Valid_OQApex projects are restored, result sets for the Internal Std Sample Set and External Std Sample Set will be available in both projects when an OQ request is initiated. Perform this procedure for both of the projects to evaluate Traditional and ApexTrack Integration.
2. Select the Result Set tab and select the appropriate "External Std Sample Set".

Note: When multiple result sets are created, it is suggested to update the filtering by selecting Edit View and include the IQ/OQ Node. This displays the node name associated with the result set created.
3. Right -click and select Preview/Publisher.
4. Open the appropriate report method:
 - "Summary Report for Exstd OQRS" for Electronic Signatures
 - "Summary Report for Exstd OQ" for Handwritten Signatures
5. Review the report to ensure that "Pass" appears on each line of these two columns:
 - RT_Pass_Fail
 - Amt_Pass_Fail

ACQUISITION INFORMATION

User Name: Romuald McSweeney (Romuald)	System Name: Alliance
Acquired By: System	SampleName: External Std. 1
Sample Set Name: External Std Sample Set	Sample Type: Standard
Acq Method Set: External Std Method Set	Vial: 1
Processing Method: External Std Processing Method	Injection: 1
Channel Name: 486	Injection Volume: 20.00 ul
Report Method Name: Summary Report for Extstd OQ	Run Time: 6.0 Minutes
Processing Node: Romuald-pc-w500	Software: Empower 3 Software Build 3465
Date Acquired: 9/17/1997 4:56:03 PM EST	Integration Algorithm: Traditional
Date Processed: 11/1/2010 1:58:48 PM EDT	



	Channel Id	Result Id	Peak Name	ExpRTAcet	ExpRTAcetop	ExpRTProp	ExpRTButyr	RT
1	1035	2966	Acetone	1.249	0.000	0.000	0.000	1.249
2	1035	2966	Acetophenone	0.000	2.132	0.000	0.000	2.132
3	1035	2966	Propiophenone	0.000	0.000	3.110	0.000	3.110
4	1035	2966	Butyrophenone	0.000	0.000	0.000	4.781	4.781

	RT_Pass_Fail	ExpAmtAcet	ExpAmtAcetop	ExpAmtButyr	ExpAmtProp	Amount	Amt_Pass_Fail	Cal Id
1	Pass	937.500	0.000	0.000	0.000	937.500	Pass	2961
2	Pass	0.000	2.500	0.000	0.000	2.500	Pass	2961
3	Pass	0.000	0.000	0.000	2.500	2.500	Pass	2961
4	Pass	0.000	0.000	2.500	0.000	2.500	Pass	2961

6. When "Pass" appears on each line, no failures were found; all retention times (RT) equal the expected retention times (ExpRT), and the amount equals the expected amount (ExpAmt) indicated on each report page. Thus, this portion of the OQ has passed the test.
7. The minimum and maximum limits are set using custom fields for RT and Amount. When the actual RT or Amount falls within these limits, the OQ test returns a passing result. When "Fail" is printed on any line, the RT or Amount falls outside these limits, and the test returns a failing result.
8. For hand-written signatures print the report, and then perform the following:
 - a. Complete the Certification section of the report to include: pass/fail status, any applicable comments, signature, and date.
 - b. Contact the Reviewer to review, sign, and date the report.
 - c. File all reports, passed or failed, in your Waters binder under the Operational Qualification tab.
9. For Electronic Signatures use the Sign Off button after you review each page of the report.
10. Perform Sign Off 1 by entering the user name and password. Depending on the system policies perform one of the following for the Reason:
 - Select the appropriate default string that includes the text "Pass" or "Fail".

- Select the appropriate default string and add the text "Pass" or "Fail".

Note: Append additional comments to a Reason when appropriate.

11. Notify the Reviewer that he or she must electronically sign the results as "Sign Off 2".
12. It is optional to update the IQ/OQ tab in the node properties with OQ status (Pass or Fail) and Comment. This information is for administrative purposes only. The status and comments are provided in the handwritten or electronically signed report.

Verifying the results of the MVM OQ: the OQMVM Summary Report (Electronic or Printed)

When OQMVM is requested, the project folder Valid_OQMVM will contain a study name associated with the requested node. For example, the study name Valid_OQMVM Study: Node0013.

Perform this procedure:

1. Select the Valid_OQMVM project, and open it.
2. On the Validation Studies tab, select the appropriate Study Name, and then right-click and select Preview/Publisher.

Note: Expect 62 validation results for a validation study. If multiple OQMVM requests were made to a node, in the Edit View include the Study Modified Date to clarify the appropriate validation study to select.

3. Open the appropriate report method:
 - "OQMVM Summary ReportRS" for Electronic Signatures
 - "OQMVM Summary Report" for Handwritten Signatures
4. On the report, ensure that "No" appears on each line of these columns:
 - Faults
 - Summary Faults

Note: When "No" appears on each line, no faults were found and the OQ passed the test. When "Yes" appears on any line, the OQ has failed. "Yes" indicates the specific result differs from the target specified in the validation protocol.

Specificity Results

Specificity Results

	Validation Result Id	Component	Test Description	Area Mean Std Error	Retention Time Mean (min)	Retention Time Mean CI	Retention Time Mean Std Error	Faults
1	5352	Arg	AAA - Specificity	1257.164820	3.571633	0.007709	0.000607	No
2	5354	Cys	AAA - Specificity	1112.79189	6.612208	0.004641	0.000365	No
3	5353	Gly	AAA - Specificity	863.142274	3.687791	0.004877	0.000384	No

Accuracy Results

Accuracy Overall Results

	Validation Result Id	Component	Test Description	Overall Mean % Recovery	% RSD	Calculated Validation Target	Faults
1	5329	EtP	Parabens - Acc 3 Preps 3 Injs	100.386495	1.107765	30.115945	No
2	5330	MeP	Parabens - Acc 3 Preps 3 Injs	100.222303	2.487046	25.055576	No

Per Level Accuracy Results
Component: EtP Validation Result Id: 5329

	Level	# Points	Mean % Recovery at Level	Standard Deviation	Summary Faults
1	Level 1	3	100.973593	0.033857	No
2	Level 2	3	101.268875	0.089926	No
3	Level 3	3	98.917017	0.115734	No

5. For hand-written signatures:
 - a. Print the report.
 - b. The performer must initial and date the Pass line on the last page of the summary report.
 - c. The performer and reviewer sign and date the page.
 - d. The report is filed in the Waters binder under the Operational Qualification tab.
 6. For electronic signatures, review the report and electronically sign the results as "Sign Off 1".
 7. Enter the user name and password. Depending on the system policies, perform one of the following for the Reasons:
 - a. Select the appropriate default string that includes the text "Pass" or "Fail".
 - b. Select the appropriate default string and add the text "Pass" or "Fail".
- Note:** Append additional comments to a Reason when appropriate.
8. Notify the Approver that he or she must electronically sign the results as "Sign Off 2".
 9. It is optional, as an administrative tool, to update the IQ/OQ tab in the node properties with the OQMVM status (Pass or Fail) and Comment. The status and comments are provided in the handwritten or electronically signed report.

When the OQ returns a failing result

When the Empower SystemsQT for Software or Method Validation Manager OQ fails, do as follows:

1. In Configuration Manager, rename the Valid_OQ1, Valid_OQApex, or Valid_OQMVM project to Valid_OQ1_Failed, Valid_OQApex_Failed, or Valid_OQMVM_Failed. A date or time can also be appended after "_Failed".
2. Click File > Restore, to restore the Valid_OQ1, Valid_OQApex, or Valid_OQMVM project.
3. After the project is successfully restored, avoid making changes in the restored Valid_OQ1, Valid_OQApex, or Valid_OQMVM project, and then rerun the Empower SystemsQT for Software OQ again.
Note: Expect a passing result.
4. If required by your standard operating procedures (SOPs), compare the projects for the failed and passed results of the processing methods, to determine the cause of the failure.
5. Review the project audit trail, to determine who made changes to the processing method.
6. (For MVM users only) If required by your SOPs, compare the projects for the failed and passed results of the processing methods, validation protocol methods, or chromatographic results of each of the validation tests to determine the cause of the failure.
7. (For MVM users only) Review the project audit trail to determine who made changes to the methods.
8. (For MVM users only) If you are running Empower 3 Feature Release 3, ensure you restore the correct project from the folder on the disk for Empower 3 Feature Release 3, otherwise you will get failures.

To compare your results to those obtained by Waters technicians, use Microsoft XPS viewer to print these reports from the supplied CD:

- Internal Standard Data (Summary Report for IntStd OQ.pdf)
- External Standard Data (Summary Report for ExtStd OQ.pdf)
- Method Validation Data (OQMVM Summary Report.pdf)

Compare the data.

For the printed OQ, the performer and reviewer must sign and date the page, afterward filing it in the Waters binder under the Operational Qualification tab.

For electronic OQ, add a comment to the node properties regarding the comparison.