

Empower SystemsQT Automated Qualification Tool for Waters and Agilent Systems

Maximize productivity, improve audit readiness

EMPOWER SYSTEMSQT PROVIDES COMPLETE DATA RECORDS FOR ALL YOUR QUALIFICATION RESULTS

Empower™ SystemsQT™ (Qualification Tool) enhances the Installation Qualification (IQ), Operational Qualification (OQ), and data management of your Waters and Agilent systems.

COMPREHENSIVE DATA INTEGRITY AND FULL RESULTS TRACEABILITY

You must ensure data integrity and full traceability of your results in the event of an audit. Business success includes knowing that your systems perform to specification and comply with regulations. You need quick and easy access to all the results and metadata; not just printouts missing the real data to back them up. You purchased the Empower Chromatography Data System to ensure the integrity of your laboratory results. Use it to provide practical information about your systems and to make your qualification data compliant with 21 CFR Part 11 and Part 211 requirements.

To ensure that you satisfy the stringent requirements of regulatory agencies worldwide, Empower SystemsQT offers:

- A whole system test approach for more accurate indication of overall system level compliance
- Secure, online qualification data storage for easy access and traceability
- Simplified data review with capability of electronic sign off
- Elimination of most manual calculations, reducing the opportunity for human-error and enabling faster, easier system-level tests

EMPOWER SYSTEMSQT INSTALLATION QUALIFICATION (IQ) AND OPERATIONAL QUALIFICATION (QC) ARE AVAILABLE FOR:

- ACQUITY™ UPLC™ Systems
- PATROL UPLC™ Analyzer
- Alliance™ HPLC Systems
- Agilent HPLC and UHPLC Systems
- Agilent GC Systems
- Arc™ Systems
- Modular 1525 Systems
- eSATIN

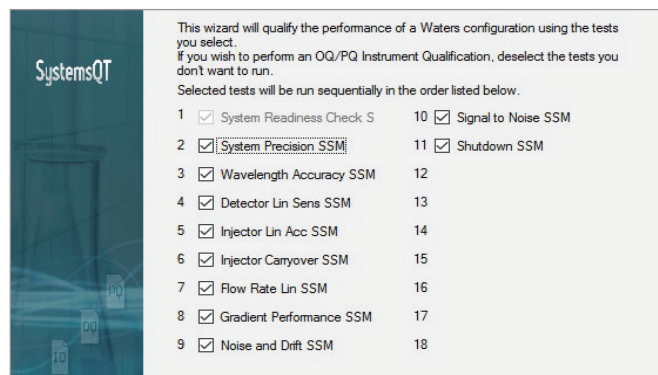


QUALIFICATION FOR THE REAL WORLD

Traditional qualification can have a significant disconnect between the measurements being taken (indirect tests being run because they are easy to measure) and what you actually do every day in your laboratory. Sometimes they provide information that does not relate to how your systems will perform running actual analyses. A series of tests that don't relate to the actual performance of the system translates into a series of tick boxes showing tests were conducted just to pass an inspection. What if qualification could give you practical information about your system that gives you an understanding of how your system will perform when running real world analyses?

Empower SystemsQT is the only qualification tool that actually demonstrates suitability of your chromatography system to run real chromatography. It provides data that you can actually relate to the work you are doing daily. Experience the benefits of getting more out of your qualification data. Experience the added value that Empower SystemsQT provides for the qualification of your Waters and Agilent LC and GC Systems.

From account and password policies, through audit trail requirements, to complete electronic signature capabilities, Empower Software is the only all-inclusive 21 CFR Part 11 compliant-ready software solution. Data generated using SystemsQT is stored, managed, and protected within Empower Software.



Example of Empower SystemsQT Test Selection Screen.

UV SYSTEM PRECISION REPORT									
ACQUISITION INFORMATION									
System Name: TR2_OSM_FTN_TUV									
Project Path: R03_SOT_E_OSM_FTN_CH_TUV									
Processing Method: 020 System Precision PM									
Sample Kit Expiration Date: 11/18/2020 12:00:00 AM EST									
Sample Kit Lot Number: W04040602									
Report Method: 020 System Prec RM									
Sample Set Name: System Precision SSM									
Sample Set ID: 10117									
Acquired By: fsp									
Column Serial Number: 017130167157 42									
Result Set ID: 10121									
System precision is determined by running injections of a caffeine solution at the same concentration and injection volume. The %RSD of the area and height gives the injection precision, and the standard deviation of the retention time is the system precision.									
Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.									
Caffeine Area and Height Results									
Area	%RSD	Area	Height	%RSD	Height	Area	Height	%RSD	Height
Specification	Area	Area	Pass/Fail	Specification	Height	Pass/Fail	Pass/Fail	Pass/Fail	Pass/Fail
1	%RSD < or = 0.5	0.1	PASS	%RSD < or = 1.1	0.3	PASS			
Caffeine Retention Time Results									
Retention Time	Standard Deviation	Retention Time	Pass/Fail	Retention Time	Pass/Fail	Retention Time	Pass/Fail	Retention Time	Pass/Fail
Specification	Retention Time (sec)	Retention Time	Pass/Fail	Retention Time	Pass/Fail	Retention Time	Pass/Fail	Retention Time	Pass/Fail
1	10.0 RT < or = 1.0 sec	0.1	PASS						

Example of Empower SystemsQT Test Report Results Portion.

AUTOMATION, TRACEABILITY, AND SECURITY

Does your current qualification process utilize multiple software packages that may compromise traceability or worse yet, generated data?

Empower SystemsQT utilizes an automated whole system test approach for a more accurate indication of overall system-level compliance. It tests a system in the manner in which it will be used.

The SystemsQT performs the tests and Empower Software manages the data process – acquisition, processing, reporting, and archival – with minimal human intervention. Elimination of most manual calculations reduces the opportunity for human-error and enables faster, easier system-level tests.

PRODUCTIVITY

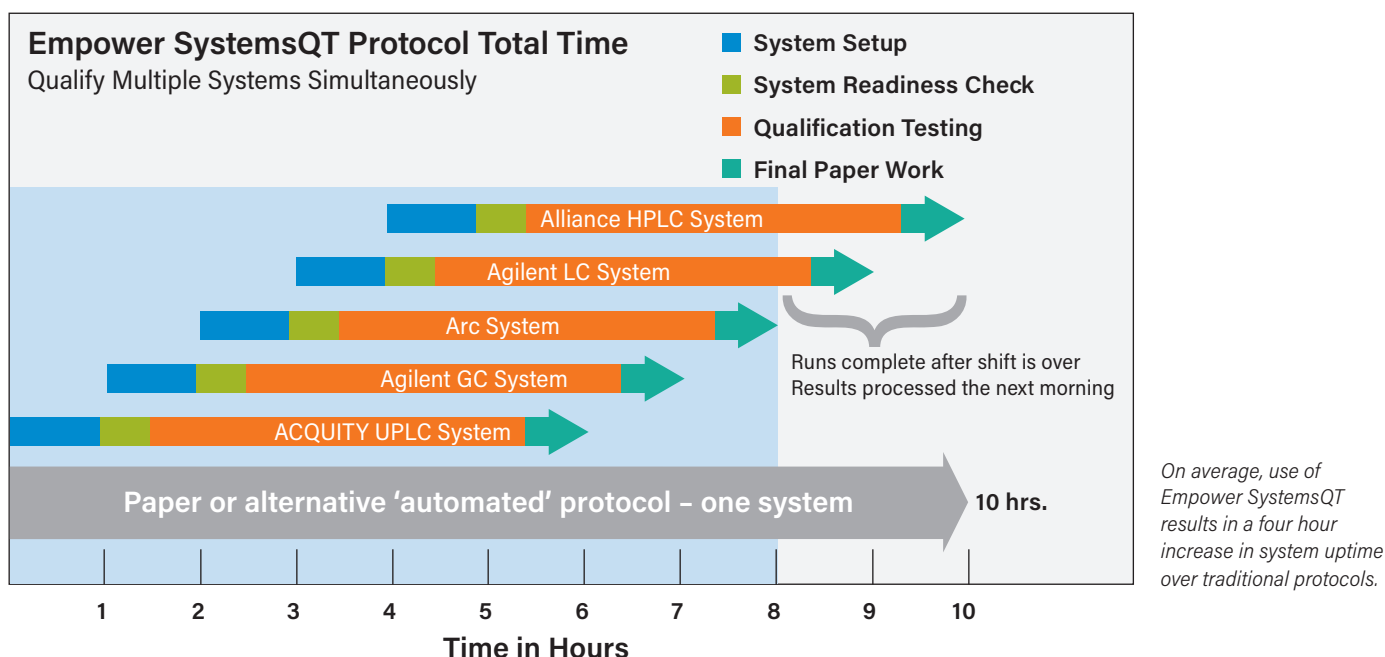
Does your current qualification process minimize downtime?

Empower SystemsQT allows for a multi-system qualification approach that efficiently brings systems online as quickly as possible. The tool utilizes Empower Software's ability to run multiple systems at once. By leveraging system-level testing, Empower SystemsQT saves time and minimizes manual testing predominantly used today.

Empower SystemsQT is developed specifically with a particular system in mind. This ensures that no documentation needs to be generated other than what is required. Review of copious amounts of unrequired documents is prevalent when using 'universal' or 'multi-vendor' qualification tools.

Waters Compliance Specialists are trained not only on Waters Systems but also on Agilent 1260 HPLC, 1290 UHPLC, and 7890 and 8890 GC Systems operation and maintenance procedures under Empower Software control. Some vendors perform minimal maintenance on systems before qualification. Waters provides a higher level of maintenance when re-qualifying existing systems. Replacing normal wear items as part of your maintenance and qualification service provides guaranteed value for your money and assures you of a high level of up-time going forward. This allows you to concentrate on your work rather than on unplanned service visits caused by insufficient maintenance.

Empower SystemsQT Protocol compared to traditional protocols*



TRANSPARENCY AND STANDARDIZATION

Does your qualification process demonstrate clear transparency as to how testing was done?

A lack of procedural detail is a risk at time of audit. Empower SystemsQT has specific protocol and test descriptions and all methods are available to view in Empower Software. Avoid minimal descriptions and procedures by vendors stating that it is not a regulatory requirement to have them.

It is easier to demonstrate compliance when systems have been qualified using a standardized template. Empower SystemsQT allows for the standardization of all qualification for Waters UPLC and HPLC systems, and Agilent HPLC, UHPLC, and GC systems.

Does your current qualification process comply with industry regulatory standards?

Waters Empower SystemsQT provides you with peace of mind for any upcoming audit:

■ 21 CFR 11 Definition of Part 11 Records

"Records that are required to be maintained under predicate rules, that are maintained in electronic format in addition to paper format, and are relied on to perform regulated activities."

■ 21 CFR 211.68 cGMP Equipment

Automatic, mechanical and electronic equipment... including computers: "...equipment so used shall be routinely calibrated, inspected or checked according to a written program designed to assure proper performance. Written records of these calibration checks and inspections shall be maintained."

■ 21 CFR 211.160 General Requirements, Laboratory Controls

"Laboratory controls shall include... The calibration of instruments, apparatus gauges and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules and limits for accuracy and precision..."

■ 21 CFR 211.180(d) General Requirements, Records, and Reports

"Records required under this section may be retained either as original records or as true copies"... (Note: A paper print out without access to the metadata is not a true copy)

■ 21 CFR 211.194(a) Laboratory Records

"Laboratory records shall include complete data"...

* Traditional protocols qualify systems on a modular basis and use primarily manual tests.

EMPOWER SOFTWARE QUALIFICATION

A Waters or Agilent LC or GC system controlled by Empower Software operating in a regulated environment requires qualification, not only for the hardware but also for the controlling software.

Empower SystemsQT at a Glance

Empower SystemsQT is based on an advanced, patented Waters technology, available exclusively to Empower Software users. It offers the following features:

- Workflow-based, automated qualification solution for your LC or GC system, including system level testing of accuracy, linearity, and precision (where possible)
- Simple wizard interface built into Empower Software – using Run Samples
- Qualification tests based on the Empower Software project
- Documents saved to a user specific location for easy access, review, and retrieval
- System qualification data stored in a single database for complete data security, traceability, trending, and tracking capabilities
- Automated qualification tests that reduce the hands on approach where possible, which means more qualifications on available systems
- Reports that can be signed-off online, or printed and signed-off manually
- IQ reports that can be generated in Empower Software
- Full audit trailing of qualification activity
- Use of simple well-defined compounds that do not contaminate the system
- Complies with 21 CFR 211.180(d) requirement for having an exact and true copy of the raw test data maintained (on the CDS)
- Assists with the compliance to U.S. FDA, EPA GLPS (21 CFR Part 58), and 40 CFR Part 160, as well as OECD versions of GLPS adopted worldwide



CHOOSE WATERS FOR YOUR COMPLIANCE NEEDS

Waters offers a variety of compliance services for UPLC, HPLC, and GC systems:

- Instrument and Software Qualification
- Informatics and CDS Validation
- Training
- Self-Directed Qualification Tools and Accessories

For more information about Empower SystemsQT and Waters Compliance Services, contact your Waters representative or visit us at [waters.com/compliance](https://www.waters.com/compliance).

WATERS GLOBAL SERVICES

Delivering world renowned services and support

Waters Service and Support offerings are tailored to optimize your laboratory productivity while addressing your budget realities. Our offerings help maintain system peak performance, minimize down time, address scientific application challenges, and support stringent compliance requirements. As your services and support provider, we are committed to the success of your laboratory and business.

Waters quality support and consultative services ensure your success wherever your laboratory is located in the world.



Waters has consecutively earned the ACE Award since 2001 for providing best-in-class technical knowledge, issue resolution, and process support.

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

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