

Waters Empower SystemsQT Qualification Tool for Empower Software

A streamlined, holistic way to achieve regulatory compliance

REDUCE THE RISK OF NON-COMPLIANCE THROUGH AUTOMATION, TRACEABILITY, AND ARCHIVAL

The United States Food and Drug Administration predicate rules for cGMP, Title 21 CFR 211.68 discuss the use of computers in the manufacture of drug products. It states that if such equipment is used, it shall be "routinely calibrated, inspected or checked, according to a written program designed to assure proper performance" and that written records of these checks shall be maintained. Similarly, the European Directorate for Quality Medicines guideline regarding the Validation of Computerized Systems for Official Medicines Control Laboratories discusses verification of software at installation and after updates or changes.

Waters™ can help you maintain your data system in compliance and aligned with these rules. Empower™ SystemsQT™ is a self-contained qualification tool built into your Empower Chromatography Data System (CDS).

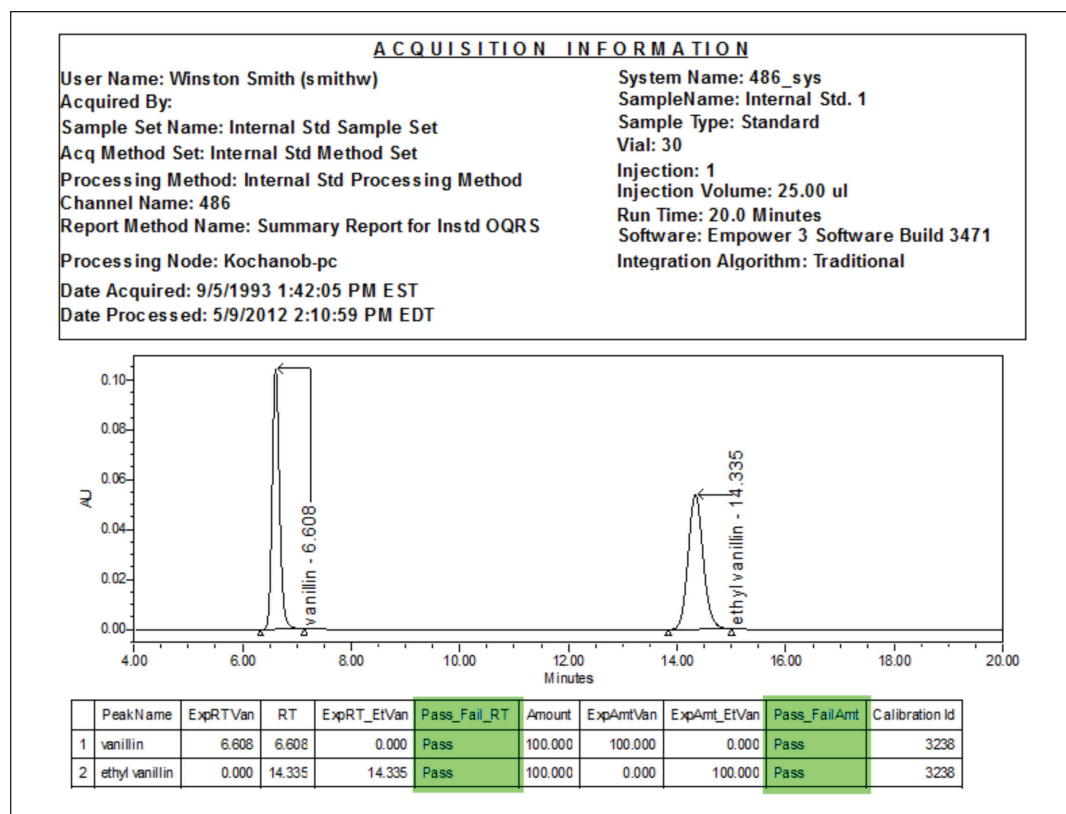
It facilitates compliance with:

- 21 CFR Part 11, electronic records and electronic signatures and EU GMP Annex 11 computerized systems compatible results that can be signed off either electronically or on paper
- 21 CFR Part 211.180(d) requirement for having an exact and true copy of the raw test data maintained
- 21 CFR Part 211.94(a) requirement for "complete data"
- Easily searchable data for audits

BASED ON A PATENTED WATERS TECHNOLOGY, EMPOWER SYSTEMSQT OFFERS THESE FEATURES:

- Workflow-based, automated qualification solution
- Simple wizard interface built into Empower Software
- Qualification data stored in the same database as your analytical results for complete data security, traceability, trending, and tracking capabilities
- Qualify multiple nodes simultaneously
- Simplified review and approval processes
- Easy integration into laboratory SOPs





Example of an Empower SystemsQT test results report.

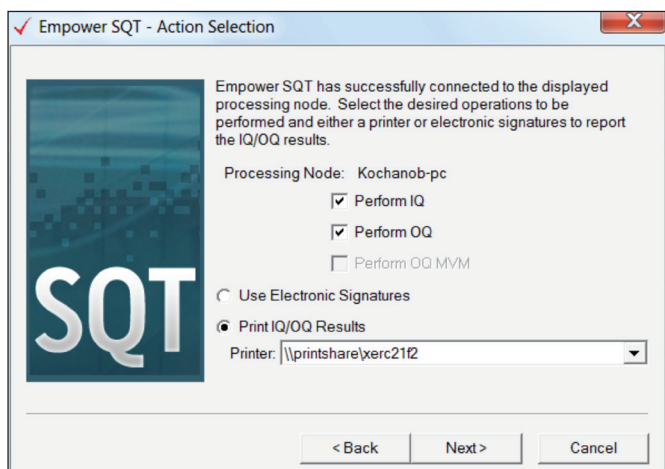
All too often, laboratory systems such as CDS are installed but not checked on any regular basis after installation or as part of a managed change control process, leaving users exposed during an audit. If you are one of the thousands of users who have chosen Waters Empower Software as your CDS of choice because of its capabilities to meet US 21 CFR Part 11 or EU GMP Annex 11 requirements, you should be aware that Empower also has an option that will help make regular testing of your CDS fast and easy.

Empower SystemsQT for Software provides an easy way to verify your software installation and document:

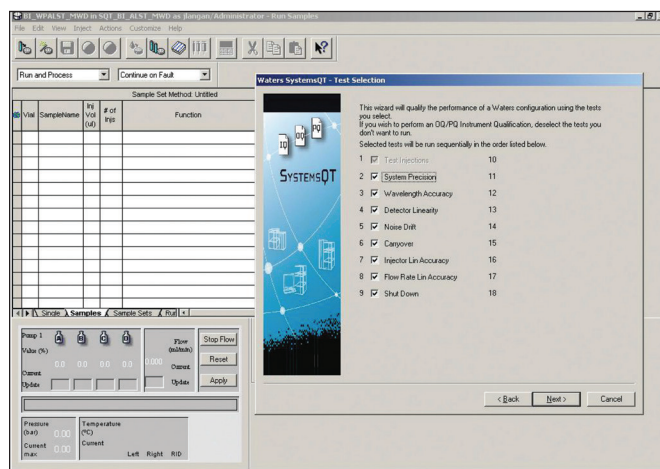
- The Empower Software has been loaded properly or is unchanged since last checked
- The system has the proper files loaded
- The checksums for the files are correct
- No critical files have been changed
- Any changes are identified so you can assess possible effects

Empower SystemsQT for Software also provides an easy way to verify and document the ability of your Empower Software to:

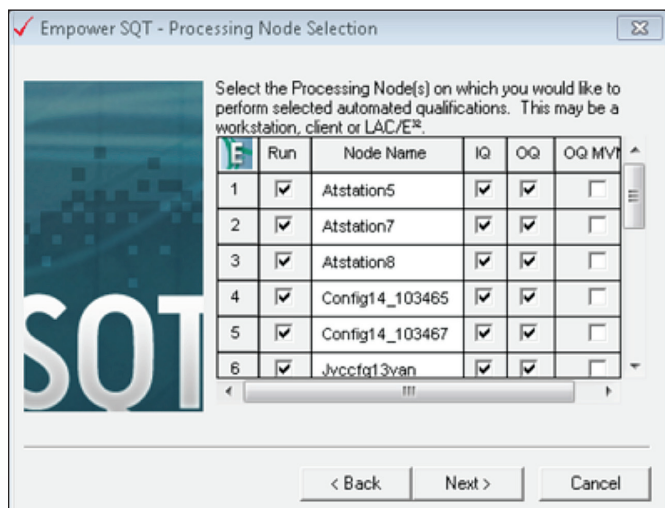
- Restore projects
- Process standards
- Process unknowns
- Perform peak integration (using both traditional and Apex Track algorithms)
- Perform calibration
- Perform quantification
- Calculate results accurately
- Print reports



Empower SystemsQT user selection screen for Operations to be performed.



Example of Empower SystemsQT Test Selection screen and Empower Run Samples.



Screen shows that you can select multiple nodes to be qualified at the same time, resulting in less system downtime.

Qualification using Empower SystemsQT for Software is provided as a service by more than 1000 Waters' trained and certified Compliance Specialists worldwide. Alternately, Waters offers Self-Directed Qualification Services, whereby we train and license you and/or your team to perform qualification on your own as the need arises to address changing software environments.

Leverage the power of your Empower Software for cost-effective, full regulatory compliance of your system. Contact your local Waters representative for additional details.

WATERS COMPUTER SYSTEM VALIDATION SERVICES

Computer Systems Validation (CSV) can be a time-consuming, complex activity requiring the time and effort of multiple domain experts. Waters offers comprehensive services for implementing systems and software into the regulated laboratory. Computer Systems Validation (CSV) services are available for Empower Software, as well as other Waters Enterprise software products. These services can significantly reduce the time needed to develop documentation, and perform various activities of the validation process.

Waters' Validation Consultants can work with you to develop customized tests that cover customer specific user/functional requirements, and provide documentation for traceability between requirements and test outcomes.

For more information about Empower SystemsQT and Compliance products in general, 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

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