

Minimizing Qualification Risks

Ginny Halfpenny, Senior Product Manager of Compliance Services

Lisa Michaud, Service Commercialization Manager

Waters Corporation, Milford, MA, USA



Gain insight into industry qualification trends and learn how to leverage Empower™ SystemsQT™ Software to meet regulatory requirements and reduce qualification costs.

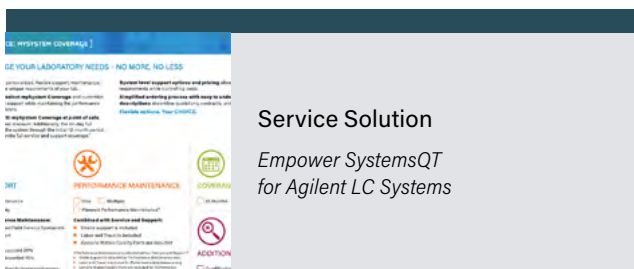
OVERVIEW

With over 60 years of experience in chromatography, mass spectrometry, and thermal analysis, scientists across the world have grown to rely on the partnership offered by Waters Corporation in helping customers minimize qualification risks by understanding and navigating the complexities associated with regulatory requirements.

In this article, we explain the critical nature of liquid chromatography (LC) system qualification and offer insight into industry qualification trends, data management, and ways to reduce qualification costs.

TRENDS IN INSTRUMENT QUALIFICATION

As regulatory requirements continue to evolve, a more holistic approach to instrument qualification is being adopted across the industry. Of specific interest is understanding how to embed analytical instrument qualification (AIQ) into a lifecycle approach, as described in the [Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management](#) guidelines. These guidelines are part of the International



Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH Q12). At the center of this approach is system-level qualification testing, which is becoming an industry best practice, primarily because the system gets tested in the way it is intended to be used and therefore more closely aligns with the quality attributes required. System-level testing can reduce the need for metrology-based testing; it is also simpler to automate, and it saves time and reduces errors.

There have also been many warning letters issued by the FDA related to electronic records and signature controls not being applied to AIQ data. There is a requirement to have complete data derived from all tests available as laboratory records, which means any results captured in paper form must have the required electronic meta-data to back them up.

QUALIFYING LC SYSTEMS

Companies that qualify their LC systems in regulated environments must show they are complying with local data-quality regulations. A foundational element of data quality is system and software qualification, which includes testing the system or software at a specific moment in time to verify, with documented evidence, that it meets predefined specifications.

“With Empower SQT, there is complete data security, traceability, trending, and tracking capabilities from the very start, helping to minimize risk and costs without the need for additional software.”

To qualify systems and software, Waters offers Empower™ SystemsQT™ (SQT). SQT is integrated into Empower Software and supports the collection, processing, and reporting of results used in system and software qualification. With Empower SQT, there is complete data security, traceability,

trending, and tracking capabilities from the very start, helping to minimize risk and costs without the need for additional software. Qualification results can be printed or signed-off electronically and conveniently stored directly in Empower Software.

While other vendors' qualification tools may collect data using Empower, the data may be subsequently exported into external applications to process the qualification results. The additional transferring of data adds an otherwise unnecessary level of manual work, which creates a potential data-integrity risk. Unlike other tools, SQT utilizes an automated whole-system testing approach for a more accurate indication of overall system-level compliance and eliminates most manual testing requirements by testing the system in the way it will be used.

Another benefit of SQT is its ability to increase laboratory productivity by allowing multiple systems to be qualified at the same time, quickly getting them back online in hours versus days.

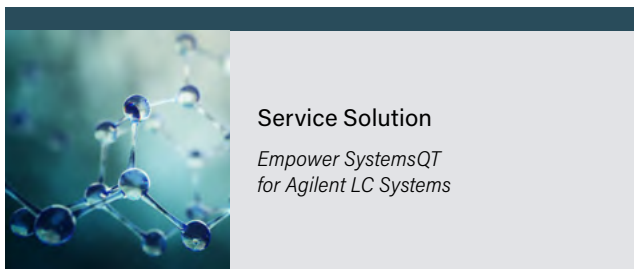
“The end result is a more robust compliance process that helps ensure regulatory compliance, increase laboratory uptime, and save time and money.”

REDUCE COMPLIANCE TEST TIME

Waters' portfolio of qualification services is designed to be advantageous to the broader scientific community and cover other vendors' instruments, including Agilent LC and GC systems. Waters qualification services provide users with access to a series of benefits, including:

- Faster, more robust instrument qualification
- Automated qualification of Empower Software
- Best-in-class expert technical knowledge for quick resolution of system issues
- Remote and proactive support to maximize instrument availability and minimize downtime

The suite of services offered allows customers to consolidate compliance and repair services for Waters and Agilent systems with a single service provider. Customers benefit from the fixed cost of ownership for their business-critical instruments and minimize the administrative burden.



IN-HOUSE SERVICE AND METROLOGY TEAMS

Companies that leverage their own in-house service or metrology teams have the option of using Self-Directed Empower SQT. Using Self-Directed Empower SQT can lower compliance-related costs. Waters can train a lab's in-house metrology group to utilize SQT for its instruments and software. This allows the user to maximize system uptime by enabling in-house service resources to immediately perform the re-qualification required after major repairs or upgrades. Using Self-Directed Empower SQT also lowers system downtime by scheduling system qualification during regular metrology/in-house service maintenance. Productivity is increased, as simultaneous qualification of multiple systems can be completed.

Another benefit to using the Self-Directed Empower SQT option is its ability to optimize the productivity of a laboratory's systems and in-house service resources by allowing the Empower Software to manage the entire data process. The end result is a more robust compliance process that helps ensure regulatory compliance, increase laboratory uptime, and save time and money.

ADD AUTOMATED QUALIFICATION TO YOUR LAB

Waters compliance experts frequently contribute and provide training and guidance document reviews to national regulatory authorities around the world. When choosing a compliance service provider, it is especially important to select a partner with knowledge of regulations, systems, and technology. Of equal importance is considering the level of expertise and quality of the services provided by its partners and the ability to save time and money by streamlining the qualification process to increase laboratory uptime.

By choosing Waters, you have a dedicated partner that can address these needs and is truly focused on your success.

For more information about Empower SQT and Waters' compliance services, contact your local services representative or visit www.waters.com/compliance.

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Waters Corporation
34 Maple Street
Milford, MA 01757 U.S.A.
T: 1 508 478 2000
F: 1 508 872 1990
waters.com

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