

Qualification services for analytical chromatography instruments

Waters Empower CDS software platform



Help ensure the integrity of your results and become compliant

Qualification services verify and document that instruments and equipment have been installed and are operating and performing according to the manufacturer's specifications. Selecting the right compliance service provider to deliver your qualifications is essential to the success and efficiency of your regulated laboratory.

As an original equipment manufacturer (OEM) service provider for Thermo Scientific™ instruments, Unity™ Lab Services offers qualification services that help ensure your analytical instruments meet global standards, mitigating the risk of regulatory non-compliance. Our operational qualification (OQ) for chromatography instruments controlled by Waters™ Empower™ Chromatography Data System (CDS) software provides a full range of capabilities and benefits that include:

- Reduced instrument downtime
- Single-vendor convenience
- Dedicated, proven qualification protocols using the Empower CDS software
- A no charge requalification guarantee*
- Comprehensive documentation and reports

When you choose Unity Lab Services for your instrument qualification needs, you'll have peace of mind knowing you have a trusted partner to support your quality management systems, as well as traceability and audit readiness on your path to regulatory compliance and success.

Qualifications supported for Thermo Scientific chromatography instruments controlled by Empower CDS software



Benefits of Empower automated OQ

Our industry-proven, all-inclusive, consistent, and reliable approach to operational qualification for chromatography systems utilizes Empower CDS software. It's delivered by certified field service engineers who have been trained on applicable hardware and software, as well as agency regulations to help you meet instrument requirements. This will help ensure your ongoing compliance with the highest levels of data quality.

The automated qualification that uses this software is a project-based OQ. The methodology provides solid OQ protocols coupled with predefined sample sets, processing methods, and verified report calculations and evaluations to help you:



Maximize data integrity



Help maintain instrument compliance

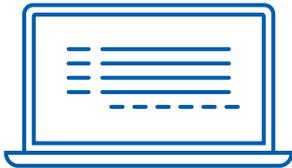


Pass inspections the first time



Stay on schedule with less downtime

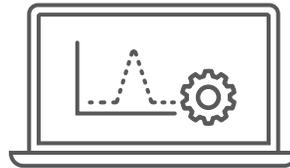
Empower qualification workflow



Build test methods
for system
configuration



Acquire OQ
parameter sample
set methods



Review and
process data



Report test results





What to expect with our IQ/OQ services

Instrument qualification is necessary after the installation of a new device, system relocation, or repairs, or when required by facility regulatory requirements. Unity Lab Services offers qualification services that support all major government regulations, e.g., FDA, cGMP, and international industry standards (ISO and pharmacopeial). These policies require verification and documentation that systems have been installed and are functioning according to the manufacturer's intended use. This includes certification, traceability, and monitoring.

Here's what you can expect with our Empower qualification services:

- Qualifications performed in accordance with the OEM's intended use of the system
- Services performed by experts trained on your instruments¹
- Designed protocols that comply with instrument testing methodology and specifications established by the European Directorate for the Quality of Medicines (EDQM)² and the United States Pharmacopeia (USP)³
- All testing protocols are available for pre-approval by your QA team
- Instruments installed to factory-defined specifications directly within the CDS software
- Scheduled PM and requalification* services according to your metrology program

System service recommendations

Full or partial qualification services are recommended in accordance with regulatory agency and facility requirements:

? When should I request service?

After system installation or relocation

After system repairs or other changes that alter the configuration depending upon the scope of repair or change

Annually or more frequently depending on system usage and regulatory requirements

Services**

IQ/OQ

OQ or requalification*

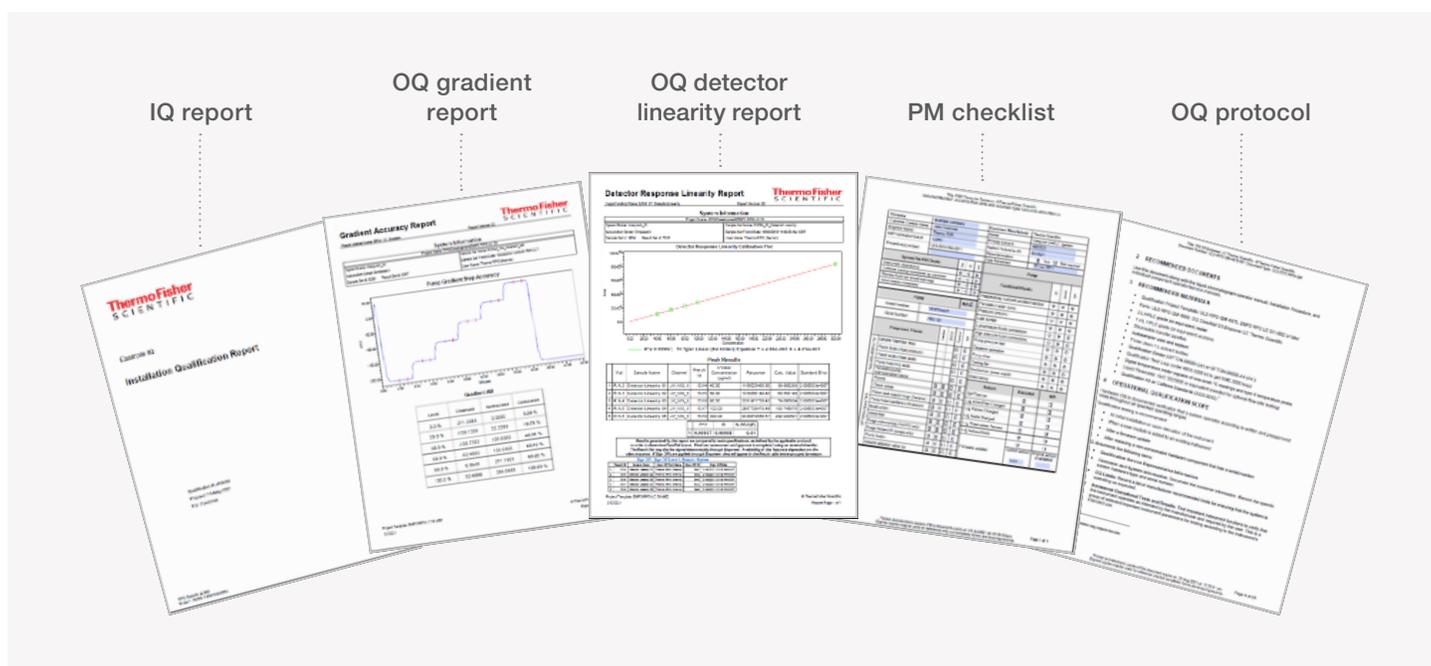
OQ

Inspection-ready documentation included



- A comprehensive qualification packet (provided as an eBinder or physical binder) that clearly identifies the instrumentation and tests performed, summarizes the results for all testing, and details any unexpected results and how they were resolved
- All relevant certificates, CDS printouts, and supporting documentation
- A full review of the completed qualification with your staff to make sure there are no concerns with the final documentation
- Support for any further quality questions that may arise

Sample qualification report documentation



All Empower-driven qualification activities contribute to compliance with GxP regulations and help ensure your system is ready for production use in a regulated environment.

For more information, contact [Technical Support](#) or reach out to your local Thermo Scientific sales representative to discuss a complete service solution that best suits your needs.

Find out more at unitylabservices.com/complianceservices

*Unity Lab Services is the only OEM service provider that offers a guarantee to requalify instruments if a key component fails while under a qualifying [instrument service plan or warranty](#). Requalification covers the requalification of the corrective maintenance repair at no additional charge. [Terms and conditions apply](#).

**Installation qualification (IQ), operational qualification (OQ)

Resources:

1. Video: [Operational Qualification \(OQ\) for Thermo Scientific HPLC Systems](#)
2. [General European OMCL Network \(GEON\) Quality Management Document: Qualification of Liquid Chromatography Equipment; PA/PH/OMCL \(11\) 04 R6](#)
3. U.S. Pharmacopeia (USP) General Chapter (1058) on Analytical Instrument Qualification (AIQ)

© 2021 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. Available services may differ by region. Please consult your local sales representative for details.

ThermoFisher
SCIENTIFIC