

Qualification Services for Analytical Instruments and Laboratory Equipment

Gain confidence with our requalification guarantee and reduce your risk of non-compliant instruments.

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

As an original equipment manufacturer (OEM) service provider for Thermo Fisher Scientific, Unity™ Lab Services offers qualification services that ensure your analytical instruments and laboratory equipment meet global standards and mitigate the risk of regulatory non-compliance.

With our services, you'll receive a full range of qualification capabilities that provide improved productivity, single-vendor convenience, a no-charge requalification guarantee*, and comprehensive documentation reports. You'll have peace of mind knowing we're supporting your quality management systems, traceability, and audit readiness.



STAY COMPLIANT with our industry-exclusive, no-charge requalification guarantee*

With Unity Lab Services qualification services, you'll be confident that your instruments maintain compliance should an unexpected audit arise. Unlike other OEM service providers who charge for requalification services, **we are the only provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under a qualifying instrument service plan or warranty.**



PASS AUDITS THE FIRST TIME with our robust and easy-to-understand OEM qualification protocols and harmonized documentation

Our factory-developed qualification protocols are written to support accepted industry standards and regulatory requirements. Our qualification services provide consistent, audit-ready documentation that meets pre-determined and/or user specifications. In addition, our harmonization of qualification protocols and documentation across all instruments saves you administrative work, review time, and complicated approval processes, helping to ensure the best audit outcome.



STAY ON SCHEDULE with our full-range, single-source support from experienced engineers

Unity Lab Services provides a full-service solution for installing, repairing, qualifying, and mitigating risks so your instruments (including other manufacturers' units) get up and running faster and your research stays on schedule. Our factory-certified validation engineers are product experts with experience in regulated environments, ensuring your qualifications are delivered efficiently and effectively to industry standards.



Industry-Exclusive, No-Charge Requalification Guarantee*

Unity Lab Services is the only OEM service provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under a qualifying instrument service plan or warranty.*

Unity Lab Services Compliance Services Portfolio

| Qualification/Service | Description |
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| Installation Qualification (IQ) | Documented verification that instrument or equipment is installed to manufacturer's recommendations and/or user requirements |
| Operation Qualification (OQ) | Documented verification that instrument or equipment (as installed) is operating as intended and to anticipated specifications |
| Performance Qualification (PQ) | Documented verification that instrument or equipment is performing effectively and reproducibly based on approved user-specific specifications; best suited for cold storage and incubation equipment, centrifuges, water purification, and pipettes |
| Requalification (RQ) | Operational tests performed after a corrective maintenance repair or any other major change to the instrument; depending on the type of repair or change, a full or partial OQ may be required <ul style="list-style-type: none">• Performed one year after an initial IQ, OQ, or PQ has been completed, after a corrective maintenance repair or major change to the instrument, or according to SOP requirements |
| Preventive Maintenance (PM) | A standard set of procedures intended to ensure instrument performance is at or near the same levels achieved at the time of installation <ul style="list-style-type: none">• A typical PM procedure includes inspection, cleanup, replacement of worn parts, tuning, etc.• A PM is recommended before all OQ and RQ service events to ensure all tests pass within OEM specifications |
| Calibration | Periodic verification that equipment is producing accurate results within specified limits compared to traceable standards of measurement; best suited for cold storage equipment, CO ₂ incubators, centrifuges, water purification, and pipettes |
| Temperature Mapping (TM) | Provides data measured at different temperatures and locations, door opening recovery tests, backup system testing, and a variety of checkpoints; best suited for cold storage and incubation equipment |

Guidelines for Instrument Qualifications

- After installation of new instruments or equipment or relocation of an existing unit
- Following additions, changes, or upgrades to a unit
- After preventive maintenance (PM) and critical repairs
- When required by facility regulatory requirements

Visit unitylabservices.com/complianceservices to request a quote for service or to learn more.

* Our no-charge requalification guarantee applies only to instruments under a qualifying Unity Lab Services instrument service plan or warranty and covers requalification on the corrective maintenance repair at no additional charge. [Terms and conditions apply.](#)