



Compliance Services

Delivering the tools you need to meet audit requirements

ThermoFisher
SCIENTIFIC



Simplify the complexities of compliance

As compliance standards shift and change shape over time, it's important for regulated industries to stay focused on requirements. In these environments, compliance with government and international standards requires documented verification that systems are installed and functioning according to the manufacturer's intended use.

Besides the obvious — protecting public health, ensuring accurate and reliable data, and strengthening business decisions — strict compliance standards are necessary due to tightening regulations in many industries. For example, pharmaceutical paradigms are shifting from traditional drugs to physiologically relevant and complex cell and gene therapies, which have a very fluid regulatory environment. When your industry is constantly changing, you need a knowledgeable, reliable partner to help you navigate requirements and maintain compliance.

Tap into audit-quality data

Depend on Unity™ Lab Services to verify that your instruments and laboratory equipment are working according to manufacturers' specifications. We offer qualification service packages that provide audit-quality data to show appropriate regulatory bodies that your facility is meeting necessary requirements.

For organizations within regulated environments that require documented verification of system installation and function, Unity Lab Services offers instrument qualification and calibration services that ensure support for all major guidelines (FDA, GMP, ISO, and pharmacopoeial), including certification, traceability, and monitoring.

Over a decade of regulatory expertise

Unity Lab Services is uniquely positioned to provide the transparency you seek for meeting audit standards.

Depend on Unity Lab Services for:

- **Proprietary knowledge and support:** As an original equipment manufacturer (OEM), we know the equipment, factory-designed specs, and service requirements for our instrumentation and equipment more intimately than anyone else.
 - Ensure that instruments and equipment are positioned to pass regulatory standards and stay in compliance.
 - Trust factory-trained technicians who have the instrument expertise to properly perform qualification services (plus proof of accuracy) with detailed documentation.
- **Convenient service delivery:** Partner with one trusted service provider for all your system maintenance.
 - Depend on single-vendor convenience and expertise for reduced testing time, consistent procedures and results, and qualification processes tailored to your specific needs.
 - Bundle preventive maintenance with qualification services to have confidence that your instruments are in top shape — **before** testing starts — to decrease the possibility of issues during the qualification service.
 - Take advantage of a full range of services to ensure proactive maintenance of instruments and equipment.
- **Global reach, local support:** Our dedicated workforce of technicians spans the globe, allowing for timely customer support regardless of location. Backed by a global network of technical, application, and factory support, our technicians have the know-how and resources to support customers like no other.

Visit unitylabservices.com/complianceservices for more details about our compliance offerings.

Why is qualification important?

- It provides documented evidence of performance
- It supports quality management systems and process validation
- It mitigates risk to research results
- It helps maintain sample integrity
- It produces evidence of suitability for use

Myths about process validation and qualification

- Validation/qualification of a process, equipment, or instrument is performed just once
- Process validation/qualification is only needed when subsequent verification is impossible
- Validation/qualification is burdensome
- My field service or planned maintenance report is adequate documentation of performance
- I don't need validation/qualification if I use QA/QC standards while analyzing samples

Open the door to confident compliance

Laboratory equipment services highlights

Selecting the right compliance services solution is a significant part of your quality system. As you rely on quality results from our extensive range of equipment, including everything from centrifuges and pipettes to cold storage and water purification systems, you also can trust Unity Lab Services to be the compliance partner that helps you meet your regulatory assurance and documentation needs (see Table 1).

Our compliance and calibration services support organizations that rely heavily on equipment for critical sample storage and growth, and our protocols deliver robust and efficient regulatory compliance coupled with the desired degree of confidence.

Benefits:

- **Industry-exclusive, no-charge requalification guarantee:** Unlike other OEM service providers who charge for requalification services, we are the only provider to offer a guarantee and promise to requalify your lab equipment at no charge if a key component fails while under the original factory warranty or a qualifying instrument service plan.*
- **OEM confidence:** We're trained in instrument compliance and maintenance, so we can fix audit issues that others can't.
- **Proven efficiency:** We help you **pass qualifications** the first time with our one-and-done best practices, which ultimately save resources and maintain operational uptime.
- **Audit-ready calibration:** We offer accredited and non-accredited calibration services. Our accredited services comply with ISO/IEC 17025 standards, giving you confidence that your results are both precise and accurate.
- **Global reach:** With service professionals located strategically across the globe in 23 countries, Unity Lab Services is better positioned to offer consistent and comprehensive support compared to smaller, local, third-party service providers.

Lab equipment compliance services

- **Installation Qualification (IQ):** Documented verification that equipment is installed to manufacturer's specifications and/or user requirements.
- **Operation Qualification (OQ):** Documented verification that equipment (as installed) is operating as intended according to manufacturer's specifications.
- **Requalification (RQ):** Operational tests performed after a corrective maintenance service or any other major change to the instrument. Depending on the type of repair/change, a full or partial OQ may be required.
- **Calibration:** Periodic verification that equipment is producing accurate results within specified limits compared to traceable standards of measurement; best suited for cold storage equipment, CO₂ incubators, centrifuges, water purification, and pipettes.
- **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.
- **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.



Laboratory Equipment: *When • Why • What*

Table 1

Application	Requirement	Recommended Services
Initial qualification of new instrument or change of service/status	I need my instrument qualified before I can use it	IQ/OQ Temperature mapping Calibration
Re-qualification	I need annual or periodic re-qualification	PM Temperature mapping Calibration OQ/RQ
Fleet programs	I have multiple units and I need service done throughout the year	PM Temperature mapping Calibration IQ/OQ OQ/RQ

Turn to the industry leader

Compared to smaller, third-party service providers, only Unity Lab Services can offer **truly comprehensive laboratory equipment solutions**, including ease of purchase, support for the entire installed base, OEM expertise, temperature mapping support for all chambers, a process that supports previous audits, local and global support, break/fix assistance, warranty benefits, and on-site calibration.

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

Analytical instrument services highlights

Analytical instrument systems (including LC, LCMS, GC/GCMS, IC, ICP, ICPMS, AA, NIR, Raman, and FT-IR) are vital to your scientific research, drug discovery and development, pharmaceutical quality control, food safety, environmental testing, climate research, and industrial process optimization. Maximize your investment with complete service and support solutions. Unity Lab Services offers qualification services that ensure your critical equipment meets global standards and mitigates the risk of regulatory non-compliances (see Table 2).

Qualification services for analytical instruments benefit a range of organizations that rely heavily on the operation of instrumentation according to manufacturers' specifications and standards. These services include robust documentation regarding service performed to support preparation for regulatory audits and are executed by factory-trained service engineers capable of resolving instrument issues with the highest level of complexity.

Benefits:

- **Industry-exclusive, no-charge requalification guarantee:** Unlike other OEM service providers who charge for requalification services, we are the only provider to offer a guarantee and promise to requalify your analytical instruments at no charge if a key component fails while under the original factory warranty or a qualifying instrument service plan.*
- **Trusted OEM services:** Our Field Service Engineers have access to a network of professionals and resources to ensure instrumentation is qualified according to specification. We know our products better than anyone in the industry and offer an impressive global reach alongside local support.
- **Detailed documentation:** Factory-trained technicians have the instrument knowledge to properly perform qualification services and can provide proof of accuracy. Our comprehensive documentation package for regulatory audits provides accurate and detailed information and ensures audit readiness for regulated environments.
- **Efficient service delivery:** Our engineers are trained on qualification and instrument maintenance to offer you quality instrument support throughout a unit's lifecycle. We also support many products from other manufacturers.

Analytical instruments compliance services

- **Installation Qualification (IQ):** Documented verification that equipment is installed to manufacturer's specifications and/or user requirements.
- **Operation Qualification (OQ):** Documented verification that equipment (as installed) is operating as intended according to manufacturer's specifications.
- **Requalification (RQ):** Operational tests performed after a corrective maintenance service or any other major change to the instrument. Depending on the type of repair/change, a full or partial OQ may be required.
- **Preventive Maintenance (PM):** While not technically a qualification service, PM is considered to be a maintenance procedure that brings instruments to "Day 1" condition or as close to it as possible. A typical PM procedure includes inspection, cleanup, replacement of worn parts, tuning, etc. Recommended before all OQ and RQ events to ensure all tests pass within OEM specs.



Analytical Instruments: *When • Why • What*

Table 2

Application	Requirement	Recommended Services
Initial qualification for new instrument or change of service/status	I need my instrument qualified before I can use it	IQ/OQ
Operational qualification at scheduled intervals	I need annual or periodic qualification	PM OQ
Re-qualification following corrective maintenance or major change to instrument	I need my instrument qualified to ensure it still operates within OEM specifications after a repair or configuration change	RQ

Your key to success

Follow the leader: Only Unity Lab Services offers **truly comprehensive analytical instrument solutions**, including flexible services plans, add-on preventive maintenance, factory-qualified expertise, quality documentation for audit-readiness, corrective maintenance, warranty benefits, and digitally enhanced technical support and service.

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

Unity Lab Services provides superior service and support that gets you up and running faster.



Service and support excellence

- Instrument issues are resolved remotely **35%** of the time
- Digital remote support capabilities help diagnose, repair, and increase first-time fixes
- Faster path to resolution — **50%** faster response time and **30%** reduction in downtime with a service plan
- Proactive preventive maintenance visits increase instrument uptime



OEM technical expertise

- Unparalleled knowledge and service expertise
- Direct access to more than **2,000** highly experienced and OEM-certified service professionals with an average of **18** years of experience maintaining scientific instruments



Proven track record

- Over **50** years serving science, delivering seamless service commitments and improving overall service experiences
- Preferred asset management advisor and trusted partner, improving lab operations
- One of the broadest and most comprehensive sets of service solutions in the industry



Global reach

- Consistent global execution with service professionals located strategically across the globe in **23** countries
- Committed to providing the fastest response possible, increasing lab productivity and uptime



Ensure your audit-readiness with our industry-exclusive, no-charge requalification guarantee

Unity Lab Services is the only original equipment manufacturer (OEM) service provider that offers a guarantee to re-qualify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying service plan.*

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

Find out more at
unitylabservices.com/complianceservices

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