



Compliance services

**Keep your lab
equipment compliant.
We've got your back.**

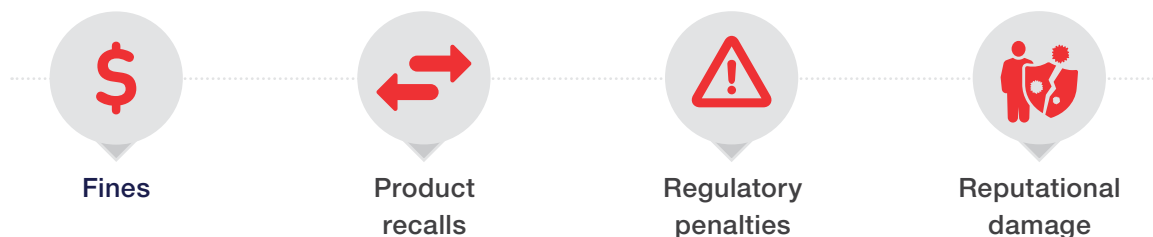
Partner with the Unity Lab Services team
to stay audit-ready

unitylab services

Navigating the complexities of compliance

Compliance standards are constantly evolving, and regulated industries must remain vigilant in meeting these requirements. Ensuring adherence to GxP compliance (GLP/GMP/GDP/GCP) and regulatory requirements from agencies like the FDA, EMA, and ICH involves documented verification that equipment and systems are installed and operating as intended by the manufacturer. Failure to meet compliance standards may have serious consequences.

✗ Potential consequences of noncompliance:



With the tightening of regulations across various industries, a proactive compliance strategy that is future-focused and adaptable can help prevent potential issues before they have an impact on your manufacturing and operations.

✓ Benefits of staying in compliance:



In a world where industries and regulations are continuously changing, having an experienced and dependable partner to guide you through compliance requirements is more important than ever.

The Unity™ Lab Services team understands the critical importance of regulatory compliance. Our comprehensive and customizable compliance services for lab equipment are designed to meet the unique needs of your lab, helping to ensure that you always have the audit-ready data required for regulatory adherence.

Choose a trusted service provider

When you partner with the Unity Lab Services team, you get access to a global network of more than 2,000 factory-trained field service engineers with a wealth of experience maintaining the equipment that we service. Our company has been serving customers around the world for more than 50 years.



Comprehensive compliance solutions

We are an all-in-one solution for your lab's compliance needs. From calibration to qualification and requalification, we offer a seamless experience to keep your equipment ahead of industry standards and regulations.

Original equipment manufacturer (OEM) advantage

As the OEM, we provide exceptional expertise using innovative tools to help keep your equipment compliant throughout its life cycle.

Customized programs, flexible approach

We understand that every lab is unique. That's why we design compliance programs tailored to your specific requirements. Our flexible approach helps ensure that we can meet your timelines and deliver solutions that align with your exact needs, including servicing third-party equipment.

No-charge requalification guarantee

The work done by our field service engineers is backed by a no-charge requalification guarantee.* If a key component fails while under a qualifying service plan or warranty, we will requalify your equipment at no charge to ensure it maintains compliance.

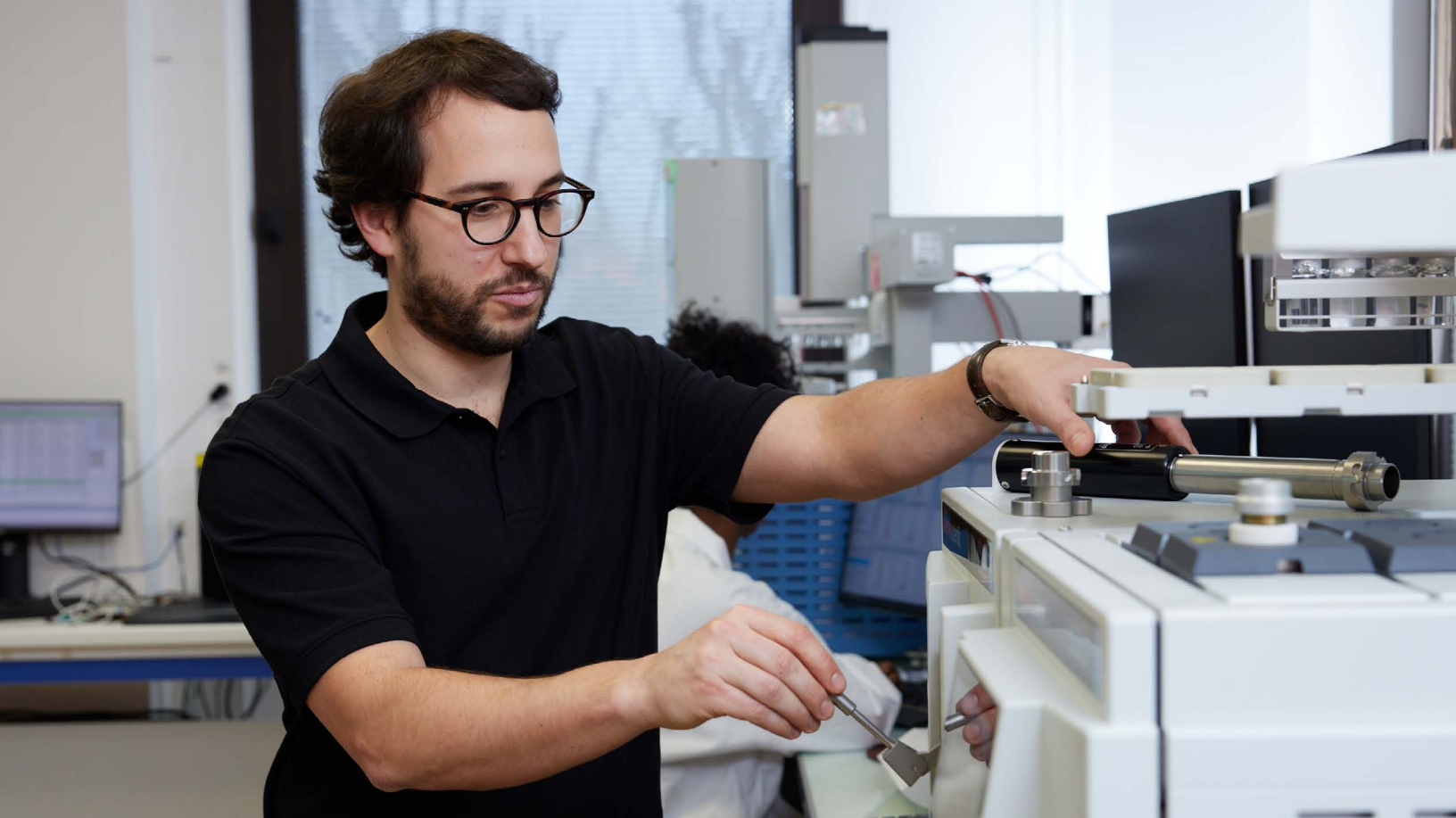
*Our no-charge requalification guarantee for laboratory equipment applies only to equipment under a qualifying Unity Lab Services equipment service plan or warranty and includes requalification on covered corrective maintenance repair at no additional charge. Terms and conditions apply.

Experience

When you tap into the Unity Lab Services team, you get the experience of field service engineers who have a thorough understanding of industry regulations and standards.

- We use rigorous quality control processes to deliver consistent, audit-ready documentation that helps you adhere to industry standards and quality benchmarks
- We take a consultative approach to understanding your needs
- We aim to give you peace of mind and confidence that your equipment is in compliance





Equipment we service

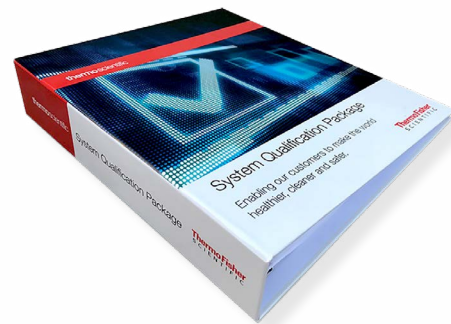
We provide comprehensive compliance services for a range of Thermo Scientific™ lab equipment. In some cases, we may also be able to provide compliance services for third-party lab equipment. Please speak with your local service representative for more information.

- Biological safety cabinets
- Centrifuges
- CO₂ incubators
- Cold storage (freezers, refrigerators, Thermo Scientific™ CryoMed™ Controlled-Rate Freezers)
- Environmental chambers
- Immersion coolers and circulators
- Microbiological incubators
- Ovens
- pH meters
- Recirculating chillers
- Remote monitoring products
- Shakers
- Water baths
- Water purification systems



Our compliance service offerings

Designed with you in mind, our comprehensive portfolio of compliance services offers a one-stop shopping experience. Our services are fully customizable to meet your specific needs and help ensure audit-ready data.



● Calibration

- Periodic verification that equipment and remote monitoring sensors produce accurate results within specified limits and maintain compliance with ISO 9001 or ISO/IEC 17025 standards.

● Preventive maintenance

- Routine inspections that use standard procedures to help ensure equipment performance is at or near the same level achieved at installation. Typical procedures include overall general inspection and cleanup, replacement of worn parts, general performance testing, and tuning.

Qualification

- **Installation qualification (IQ):** Documented verification that the equipment installation site and environment meet the manufacturer's specifications and user requirements. IQ verifies that the equipment, manuals, supplies, and any other accessories arrived undamaged and are properly assembled and installed. Configuration details for each system component are recorded.
- **Operational qualification (OQ):** Documented verification that the equipment (as installed) is operating as intended according to manufacturer's specifications. OQ verifies important equipment functions and ensures that the equipment operates as expected by the manufacturer, and that it conforms to standards and requirements. Key tests include door ajar, power failure, and temperature alerts.
- **Performance testing (PT):** Custom tests to help ensure that the equipment meets user specifications.
 - Examples include temperature mapping (TM) and cycle testing (CT) for centrifuges.
 - **TM:** A mapping study that establishes the temperature distribution within the chamber being mapped and locates hot and cold spots, which provides a view of the equipment's performance. TM includes one open door temperature recovery test, one power failure test, minimum and maximum average values, a temperature graph over time, and detailed reports that include raw probe data.
 - **CT:** A point-in-time test that monitors a unit and a specified rotor at predefined speed, time, and temperature (if applicable) set points. CT demonstrates that a unit and specified rotor can meet customer specifications.

● Requalification

Documented verification that equipment (as installed) continues to operate as expected by the manufacturer's specifications and conforms to standards and requirements throughout the equipment life cycle.

When services are needed

- = At equipment purchase
- = Annually
- = Based on customer risk assessment. We recommend at least once every 2–5 years.

Industries we serve



**Academic
institutions**



Biotechnology



**Diagnostics and
healthcare**



Government



Industrial



Pharmaceutical

Why calibrations matter

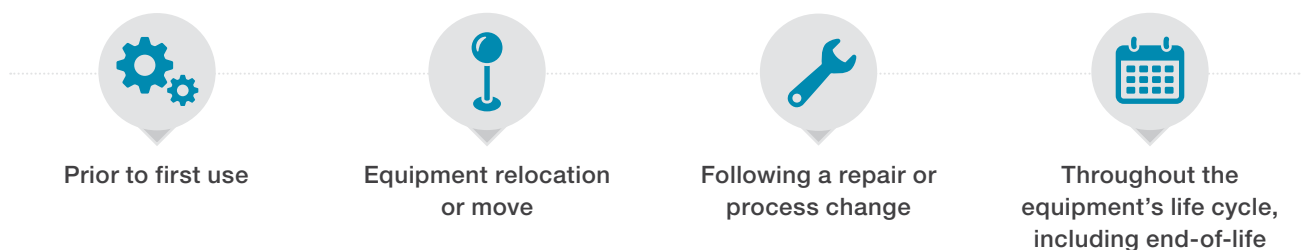
Regulated environments such as biotechnology, biobanks, pharma companies, and healthcare require periodic verification that equipment is producing accurate results within specified limits when compared to traceable standards of measurement. Without calibration, equipment can drift out of specifications, affecting accuracy, safety, quality, and equipment longevity.

All of our calibrations are performed with high-accuracy tools and provide traceability to the International System of Units (SI) and other regulatory agencies specific to your region. We utilize innovative software for calibration record management to help ensure that service records are easily accessible. The calibration management portal is accessible across multiple users and sites, helping to enable consolidation of calibration service records for equipment across an organization.

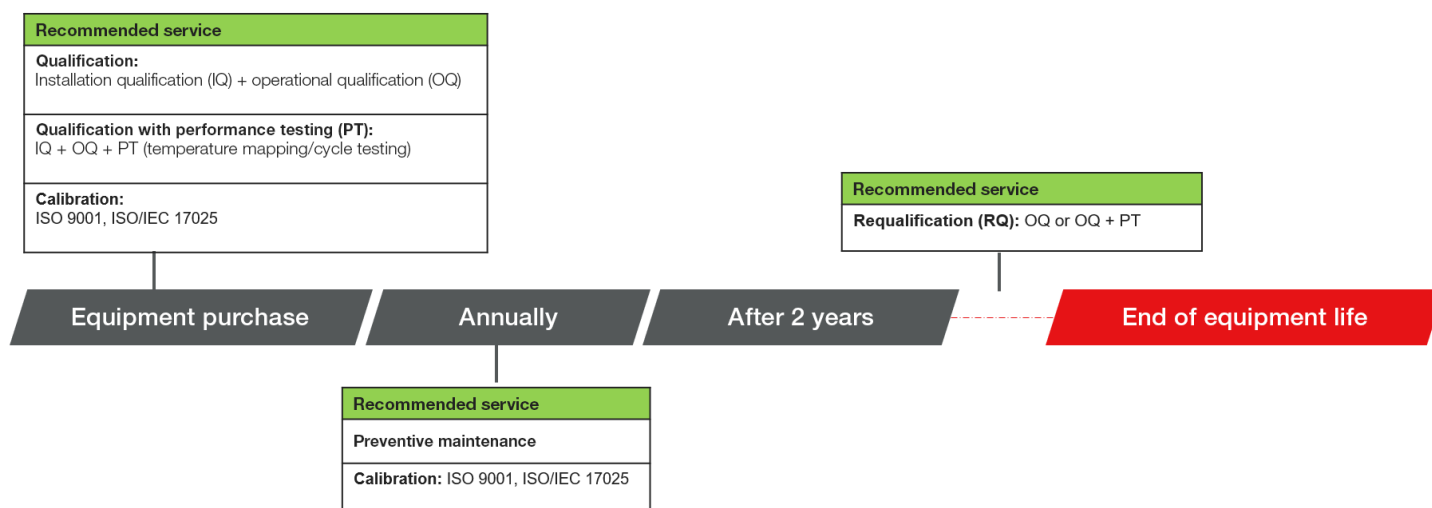
What's on a calibration certificate?

ISO standard	ISO/IEC 17025 Accredited certificate with data and uncertainties	ISO 9001 Certificate with before-and-after data
Regulatory requirements	Ideal for organizations in highly regulated environments where uncertainties are required to help assure compliance	Ideal for organizations needing to verify equipment performance to the manufacturer's specifications (uncertainties not required)
Included in service delivery	As found as left calibration data	As found as left calibration data
	TUR calculation	–
	Greater than 4:1 uncertainty ratio	–
	Detailed calibration label	Detailed calibration label
	If a unit is out of tolerance, an adjustment is performed	If a unit is out of tolerance, an adjustment is performed
Included on accredited certificate	Serial/asset number	Serial/asset number
	Measurement data	Measurement data
	Environmental conditions	Environmental conditions
	Reported uncertainties (K=2)	–
	Conformity assessment	Conformity assessment
	Reference equipment used	Reference equipment used

When are compliance services needed?

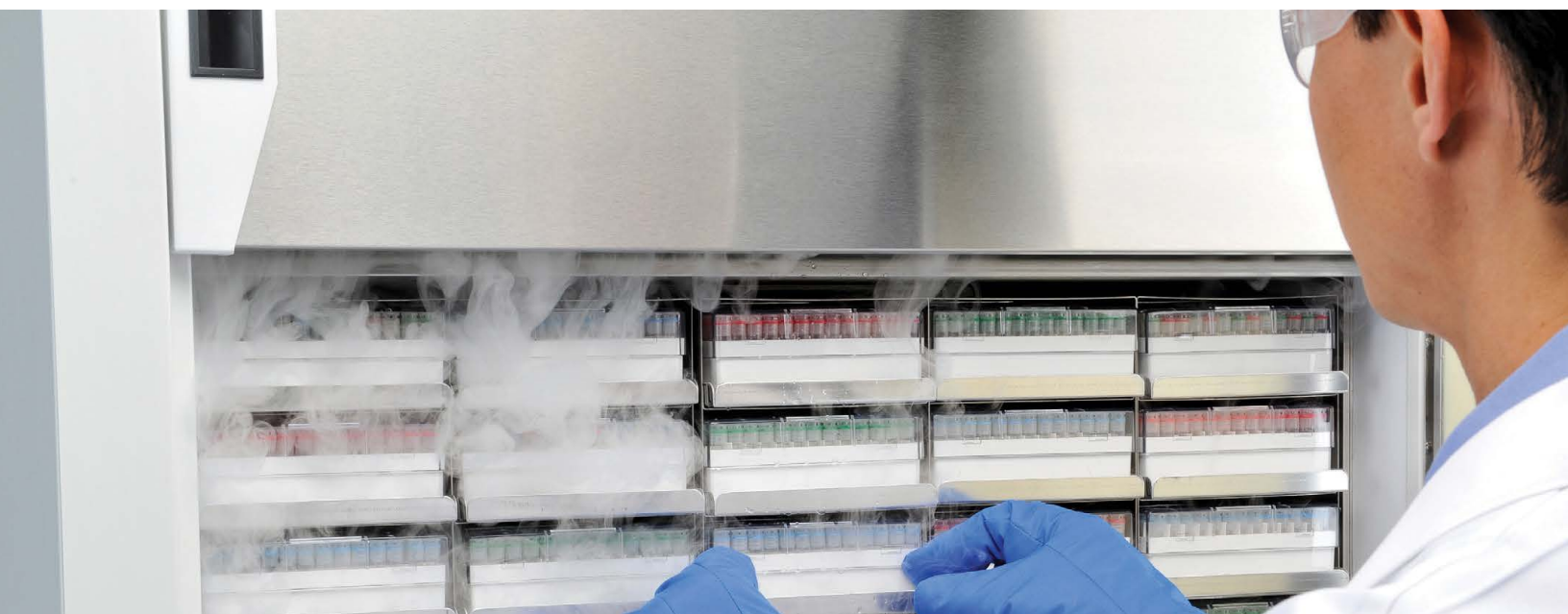


Our recommendations across the equipment life cycle



We offer compliance support for your lab equipment all throughout the equipment's life cycle. At the time of purchase and installation, we generally recommend calibration, installation and operational qualification, and applicable performance tests. You can opt for preventive maintenance (PM) and calibration services on an annual basis.

At the two-year mark, we recommend performing a risk assessment with your quality team to determine the appropriate frequency of all compliance services for your lab equipment. Based on your risk assessment and the role of lab equipment in a GxP-compliant environment, you can plan your next PM, calibration, requalification, and performance testing service for the equipment on a routine basis set by your quality team. Please note that installation and operational qualification, ideally along with PM and calibration, should be completed on lab equipment before requalification services can be performed.



Flexible purchasing options to meet your lab's needs

We offer two options to purchase our compliance services to fit your workflow, regulatory requirements, and budget: equipment service plans, which are annual contracts, and on-demand services.

Equipment service plans

For labs that want all-inclusive solutions, we offer Regulatory Assurance plans that package together compliance and other key services into one comprehensive service plan to help you with everything from getting started with your new equipment to maintenance and repair and staying in compliance.

Our Regulatory Assurance plans help assure full alignment with good laboratory practice (GLP) and good manufacturing practice (GMP), so your critical equipment is always audit-ready, regardless of where it is in the warranty period—new purchase, in warranty, or after warranty.

GLP service plan

New purchase	In warranty	After warranty	Additional benefits
- Start-up service - Calibration** - Preventive maintenance	- Calibration** - Preventive maintenance	- Calibration** - Preventive maintenance	- Priority on-site response commitment[†] - All-inclusive repair warranty and coverage - Spare parts - Unlimited access to eLearning courses

GMP service plan

New purchase	In warranty	After warranty	Additional benefits
- Start-up service - Calibration** - Preventive maintenance - Installation qualification - Operational qualification - Performance testing (temperature mapping/cycle testing) if applicable	- Calibration** - Preventive maintenance	- Calibration** - Preventive maintenance	- Priority on-site response commitment[†] - All-inclusive repair warranty and coverage - Spare parts - Unlimited access to eLearning courses - Dedicated account coordinator 1-hour consultation - Document customization support - Discount on remote monitoring solutions and optional add-ons

Optional add-ons: extra temperature mapping and requalification

**Calibrations will meet ISO 9001 standards, with an option to upgrade to ISO/IEC 17025 standards in selected locations. In the United States, NSF 49 certification will be provided for BSC equipment, while in Europe, verification will be conducted in accordance with EN 12469 standards instead of calibration.

[†]One business day response time for corrective maintenance is available in selected locations and excludes all biological safety cabinet (BSC) equipment in the United States. The response time begins once a service order ticket is created for the field service engineer (FSE). Where one-day response is unavailable, these service bundle packages remain available, and we will make every reasonable effort to provide a priority response based on FSE availability. Please speak with your sales representative about availability for your specific location.

On-demand services

For labs that want solutions as the need arises, we also offer à la carte, on-demand compliance services that give pay-as-you-go flexibility.

Please contact your sales representative for more information or to request a quote.

Learn more at thermofisher.com/unitylabservices

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