Compliance services

# Ensuring equipment compliance: a comprehensive strategy for labs in regulated environments

## Introduction

Lab equipment is the backbone of research, clinical trials, drug discovery, and production across the pharmaceutical, food manufacturing, biotechnology, and healthcare industries. Given the stringent regulatory landscape, ensuring that lab equipment meets compliance standards is essential for maintaining research accuracy and safety. Partnering with a trusted service provider can ensure that equipment meets compliance standards, safeguarding research accuracy and reliability while protecting organizations from legal liability and reputational damage. This white paper discusses critical compliance requirements and the importance of a robust strategy to manage them effectively.

### The importance of compliance with good manufacturing practices

Good manufacturing practice (GMP) guidelines ensure that lab equipment is consistently produced and controlled according to quality standards. Compliance with GMP helps organizations achieve:

- **Reproducibility and traceability:** through good documentation practices (GDP)
- **Defined procedures:** minimizing human error and variability
- **Quality management systems (QMS):** essential for passing audits and maintaining compliance

Customizing GMP to the institution's specific needs, processes, and equipment is vital for successful implementation.

### Equipment life cycle compliance journey

The journey to lab equipment compliance comprises several critical stages:

1. **Identification of regulations:** Understanding the applicable laws and regulations for the equipment in the country of use.

2. **Risk evaluation:** Assessing the impact of equipment on product quality.
3. **Acceptance limits:** Setting performance criteria based on regulatory guidelines and quality risk assessment.
4. **Compliance services:** Implementing services like calibration, installation and operational qualification, preventive maintenance, and performance testing to ensure ongoing compliance.
5. **Requalification:** Reassessing equipment to ensure adherence to safety, regulatory, and performance standards after initial qualification.

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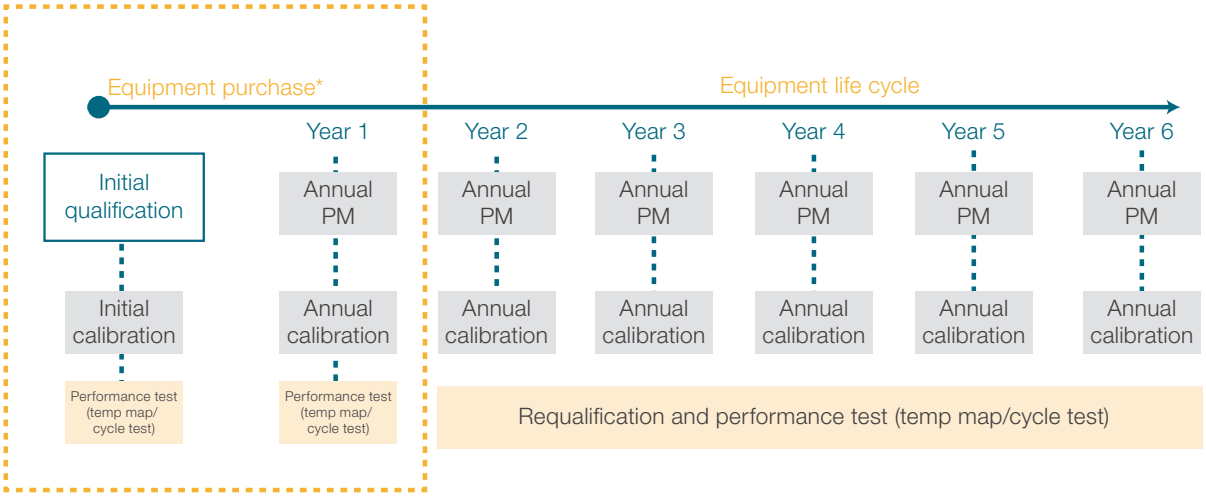


* This is our general recommendation for all lab equipment used in the current good practice (cGxP) environment. Customers can customize calibration, performance tests, and requalification after year 1 based on the recommendations of their quality team and the equipment's risk assessment.

At Thermo Fisher Scientific, we recommend performing a risk assessment with your quality team during the equipment life cycle to determine the frequency of compliance services for your lab equipment.

We generally recommend initial calibration, installation and operational qualification services, and applicable performance tests, at the time of purchase and installation. On an annual basis, you can arrange for preventive maintenance and calibration services. Based on your risk assessment and the role of lab equipment in a GxP environment, you can plan your next requalification and performance testing service on the equipment on a routine basis set by your quality team.

## Key considerations in choosing a compliance service provider

Selecting the right compliance service provider is a critical decision that can impact the quality, reliability, and cost-effectiveness of compliance solutions. When choosing a provider, organizations should consider:

- **Expertise and experience:** Choose a provider with a proven track record in the industry to ensure reliable results.
- **Comprehensive services:** Look for a provider that offers a complete range of compliance services, including calibration, installation qualification, operational qualification, performance testing, and requalification services. An ideal provider offers full equipment life cycle support and is a one-stop solution for all your compliance needs.
- **Quality assurance:** Ensure that the provider follows rigorous quality control processes and provides documented evidence of compliance. These are critical aspects of a high-quality service provider.
- **Timeliness and reliability:** It is crucial to select a provider that can meet deadlines and deliver accurate, reliable services.
- **Global presence:** Consider a provider with a worldwide network and deep understanding of various regional regulatory environments for unparalleled service reach, expertise, and post-service support if needed.

Thermo Fisher stands out as a provider that fulfills all these criteria, offering extensive expertise, comprehensive services, rigorous quality assurance, timely and reliable delivery, and a global presence.

## Compliance services offered by Thermo Fisher

We offer a comprehensive range of compliance services designed to support the entire life cycle of lab equipment and keep you audit-ready. These services include:

- **Calibration:** Periodic verification that equipment or remote monitoring solutions produce accurate results within specified limits compared to traceable standards. Our services are available to meet either ISO 9001 or ISO/IEC 17025 standards.
- **Installation qualification (IQ):** Documented verification that the equipment installation site and environment meet the manufacturer's specifications, user requirements, or both. Verifies that the equipment, manuals, supplies, and any other accessories arrived undamaged as specified in the sales order and are assembled and installed as per the manufacturer's specifications. Records configuration information for each system component.

- **Operational qualification (OQ):** Documented verification that equipment (as installed) is operating as intended according to the manufacturer's specifications. Verifies important equipment functions and ensures that the equipment operates as expected by the manufacturer and conforms to standards and requirements. Key tests: door ajar, power failure, and temperature alerts.
- **Performance testing (PT):** Custom tests to ensure equipment meets user specifications. Examples include temperature mapping for cold storage equipment like refrigerators and freezers, and cycle testing for centrifuges.
  - **Temperature mapping (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. Temperature measurements will be performed in the air or with simulated products loaded in a chamber, with a data collection interval configurable to customer needs. The collected data provide essential information, ensuring all materials are correctly stored within their labeled temperature range. TM service will include:
    - 1 open-door temperature recovery test
    - 1 power failure test
    - Min and max values along with averages
    - A temperature graph over time
    - Detailed reports that include raw probe data
  - **Cycle testing (CT):** Point-in-time test that monitors a unit and a specified rotor at predefined speed, time, and temperature (if applicable) set points. Testing demonstrates that a unit and specified rotor can meet the customer's specifications.
- **Requalification services (RQ):** Based on the customer's risk assessment, equipment may need requalification service and performance testing to ensure it continues to operate and perform as intended based on user specifications.

All services listed above are performed and delivered by a qualified Thermo Fisher engineer equipped with training certificates, a temperature mapping data log calibrated annually, and metrology certificates.

## Conclusion

Ensuring compliance of lab equipment is an ongoing process that requires careful planning, experienced support, and a commitment to quality. By partnering with a reliable compliance service provider like Thermo Fisher, organizations can safeguard their research, maintain regulatory compliance, stay audit-ready, and optimize the performance and lifespan of their equipment.

**Scan or click on the QR code to request a quote.**

Learn more at **thermofisher.com/unitylabservices**

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