

OneSource Instrument GxP Compliance - One partner for all your instrument compliance needs, regardless of manufacturer.

Features

OneSource Instrument GxP Compliance Program manages all aspects of instrument compliance regardless of manufacturer.

Universal IQ, OQ, PQ template format ensures consistent documentation of results for all instruments.

Independent verification of components' functionality, operation, and conformity to manufacturer's specifications.

Pre-scheduled maintenance visits designed to reduce the total cost of ownership of your instrumentation and an important part of your performance qualification (PQ) program.

Coordinated IQ, OQ and PQ activities according to your laboratory's productivity requirements.

Only NIST and *vendor traceable* materials and equipment are used during testing.

One *partner* for all instrument GxP compliance requirements.

Benefits

Peace of mind in knowing that compliance experts are managing the entire process.

Easier to demonstrate compliance when all instruments have been qualified using a standard template.

Impartial results generated by factory trained, certified service engineers supports robust *quality* of data at time of audit.

Optimal productivity & cost savings through minimizing instrument downtime and allowing laboratory personnel to focus on core laboratory activities.

Implementation of the Instrument GxP Program is *controlled* according to *your* requirements.

Confidence in knowing that instrument validation is a repeatable and traceable process.

From high end analytical instruments to low end refrigeration, your equipment will be in *compliance*.

OneSource. One partner for audit-tested IQ, OQ, and PQ

Requirement	Applicability	Service
Standard Operating Procedure (SOP) Development	All instrumentation-related laboratory procedures	SOP development and documentation
Installation Qualification (IQ)	New instrument installation New hardware or software installation	Verification that equipment or Instrument move instrumentation (as installed or modified) complies with approved design, manufacturer's recommendations and/or user requirements.
Operational Qualification (OQ)	New instrument installation Instrument move Instrument repair New hardware or software installation	Verification that the equipment or systems (as installed or modified) perform as intended throughout the anticipated operating range
Performance Qualification (PQ)	Perform PQ routinely on all working instruments for which established test criteria should verify that instrument performance is within specifications. Supplement with scheduled preventative maintenance to ensure successful PQ testing and to avoid potential downtime.	Verification that equipment and integrated ancillary systems can perform effectively and reproducibly based on the approved process method and specifications.

OneSource from PerkinElmer — professional services to help your lab achieve its goals

OneSource is an outsourced asset and managed maintenance solution for *all* instruments *regardless of vendor*. OneSource services include onsite repair, managed maintenance, asset management, instrument GxP compliance, laboratory relocation and training.

Meet your lab's ever-increasing needs for more productivity and reduced costs with OneSource. We'll help you address these challenges with a combination of standard and customized solutions developed specifically to meet your needs. We *guarantee* a measurable impact on your laboratory operations.

For more information about PerkinElmer's OneSource Instrument GxP Compliance services or other OneSource programs, call **1 (800) 762-4000** or **e-mail us at onesource@perkinelmer.com**.

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Design Qualification (DQ)

Method Validation (MV)

Standard Operating Procedure (SOP) Development

Multi Vendor Instrument Qualification

GxP Training

OneSource® Instrument GxP Compliance



One partner for your entire compliance process – and *all* your lab's instruments





Qualification and validation services

for *all* laboratory equipment – regardless of manufacturer



With **OneSource® Instrument GxP Compliance**, you work with *one* knowledgeable partner specifically focused on addressing your instrument compliance needs. Focus on the science and leave the rest to us.

Ensure all of your instruments are adequately designed, validated, maintained and calibrated. Maintain an audit-proof documentation system. Be confident that your lab personnel have the knowledge and skills to comply with regulatory requirements.

For more information about PerkinElmer's OneSource Instrument GxP Compliance services or other OneSource programs, call 1 (800) 762-4000 or e-mail us at onesource@perkinelmer.com.

One knowledgeable source so you're always in compliance

Avoid multiple vendors' interpretations of what you need for instrument compliance. With **OneSource Instrument GxP Compliance**, the benefit is a single, standardized approach for instrument qualification that is audit-proven and continuously updated to meet the latest quality standards. And applicable to all of your instrumentation—regardless of manufacturer.

With OneSource Instrument GxP Compliance, you get the help you need to meet your specific compliance requirements. We'll help you develop standard operating procedures and a unified documentation approach that will help you get through the auditing process with relative ease.

Tackle every complex compliance challenge head-on

Interpreting and executing compliance requirements is not a simple task. Many regulated laboratories face complex compliance challenges including:

- **Diverse range of instrumentation from multiple manufacturers**, all requiring qualification—from high end analytical instruments to low end refrigerators
- **Heavily customized equipment or integrated systems** that include components from different manufacturers

- **Missing or incomplete qualification protocols** from manufacturers, especially when special laboratory-specific requirements need to be accommodated
- **Lack of experience, protocols, time or resources** to execute necessary validation tests internally
- **Complex regulatory compliance requirements**, sometimes subject to varied interpretation

One partner to manage your entire instrument compliance needs...

Extend the benefits of OneSource Instrument GxP Compliance beyond instrument qualification. We partner with your Quality Control (QC), Quality Assurance (QA), and Engineering groups to support every aspect of your compliance needs. We handle the careful planning and communication necessary to coordinate the efforts of multiple departments, while keeping expenses within budget. In short, OneSource Instrument GxP Compliance manages the entire compliance process for you.

OneSource offers on-site IQ, OQ and PQ services for a wide range of analytical instruments and equipment, including HPLC, LC/MS, GC, GC/MS, FPLC™, UV-Vis/FTIR spectrophotometers, incubators, environmental chambers and freezers from any vendor. We also provide 21 CFR Part 11 verification services.

Qualification is conducted by compliance experts using exacting protocols

Our compliance experts have extensive hands-on experience in the design and operation of modern analytical laboratory equipment regardless of vendor. They are experts in the design and execution of custom instrument qualification and can audit current supporting internal processes for optimization.

- All tools and devices used for our compliance program are NIST or vendor-traceable
- Calibration for thermocouples, data loggers, CO₂ and humidity sensors, tachometers, flow meters, light sensors and other tools are based on strict internal SOPs
- A certificate of calibration for each measuring device accompanies validation documentation

GxP training to ensure your personnel are knowledgeable and prepared

Labs often overlook the importance of staff training even though training deficiencies are frequently the cause of FDA 483 warnings. OneSource provides on-site training for personnel who need to understand GxP requirements and how they relate to their job functions. Customized e-Learning options are also available.

Examples of testing conducted during a OneSource Operational Qualification (OQ)

HPLC & LC/MS Systems (PerkinElmer, HP/Agilent, Waters, Varian, Shimadzu®, Gilson, other brands)

- Temperature accuracy and stability of column heater/cooler
- Detector lamp intensity, wavelength accuracy, noise, and drift
- Pump flow rate accuracy and repeatability
- Injector precision
- Detector linearity and sample-to-sample carryover
- Injector linearity
- Gradient composition
- Mass accuracy and sensitivity

GC & GC/MS Systems (PerkinElmer, HP/Agilent, Varian, other brands)

- Temperature accuracy, stability, and uniformity of column oven
- Detector (FID, NPD, ECD, TCD, MS) temperature accuracy, noise, and drift
- Gas flow rate accuracy and split flow ratio (air, hydrogen, nitrogen, helium, argon/methane)
- Injector precision and temperature accuracy
- Detector response linearity and sample-to-sample carryover
- Injector linearity
- Auto tune and mass accuracy tests

Incubators, Freezers, Refrigerators & Stability Chambers

- Temperature, CO₂ and humidity calibration
- Recovery mapping
- Load testing
- Short-term and long-term monitoring
- Light intensity measurements
- Statistical analysis
- Facility, Process & Instrument Qualification
- 21 CFR Part 11 Implementation

