

Continuous Customer Support

Quality Measuring Devices

PerkinElmer understands the traceability requirements of quality measuring devices and ensures that:

- All tools and measurement devices used for our compliance program are traceable to appropriate national standards
- A certificate of calibration is provided for each measuring device and is included in the validation documentation provided to the customer.

Quality with Trained Qualification Specialists

PerkinElmer continues to invest heavily in systems, processes and people to sustain continued growth and development of its OneSource Multi-Vendor program. To support training, PerkinElmer has developed state-of-the-art training facilities across the world which are equipped with Multi-Vendor instruments, from a range of instrument manufacturers.

Our Multi-Vendor training program is managed, designed and implemented to the same exacting standards as the training our engineers receive on PerkinElmer products. Our training programs also focus on regulatory compliance applications, safety and computer operating system issues such as 21CFR part 11. These are backed up by state of the art Learning Management System (LMS) to centralise training activities, providing an all inclusive training solution for technical and non-technical content as well as instructor led and web-based training delivery.

Quality Multi-Vendor Protocols

Our robust Multi-Vendor protocols are audit-proven and cover a wide variety of instruments. Consistent IQ, OQ, PQ documentation across all your laboratory equipment.



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OneSource®

Enhance your Laboratory Compliance



One Contract, One Contact, One Solution



Enhance your Laboratory Compliance

OneSource, One Contract, One Contact, One Solution.

Regulatory audits, such as FDA inspections, will always include a focus on your analytical laboratory. One compliance slip, however small, and you will have to respond to a **483** observation letter, or, worse still, a **WARNING LETTER** with global implications.

Rely on the secure safety net of PerkinElmer OneSource Multi-Vendor services to secure your Laboratory Compliance:

- Global Leader in Multi-Vendor Services from a cutting edge instrument manufacturer
- OneSource will Repair, Service and Re-qualify your equipment
- Robust, audit-proven qualification and maintenance services
- Consistent IQ, OQ, PQ protocols designed to fit your laboratory needs
- Integrated solutions designed to reduce compliance risk

Expert Multi-Vendor Validation support and consultancy, working with you to improve compliance, reduce risk and save money.

“PerkinElmer engineers have demonstrated a high level of professionalism on supporting our multi vendor lab equipment from call login through to technical and analytical problem resolution and reporting. They understand our needs to increase throughput and reduce instrument downtime especially with our LC/MS systems. With their rapid response and ability to fix any instrument, our lab productivity is improving, leaving us to take care of the science”

Bioanalysis Department in Nerviano Medical Sciences, Nerviano (MI), Italy

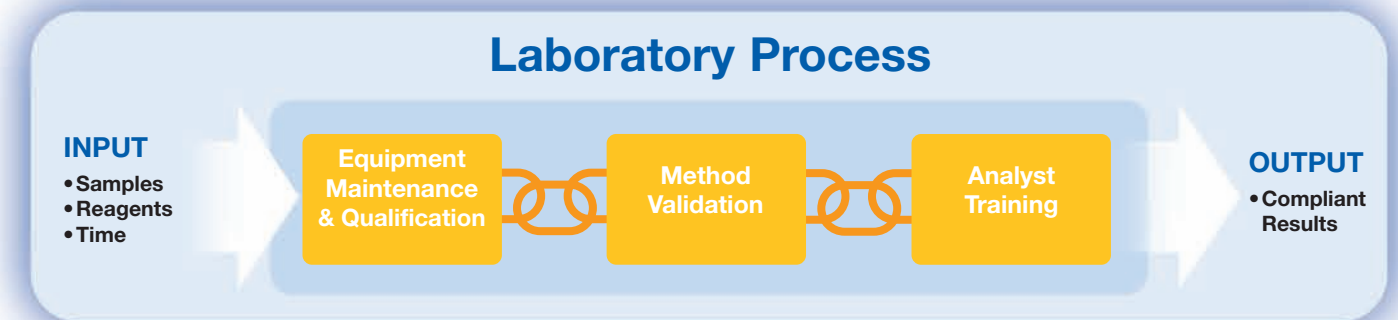
Identifying the Weakest link

Regulatory inspections concentrate on looking for deficiencies in your laboratory systems, workflow, procedures and ways of working. They look for problems you may not even know you have.

“One area that is frequently cited in FDA 483 observation reports is the failure to calibrate and maintain laboratory equipment”

Henry Avallone, Laboratory Controls and Compliance, in “Analytical Chemistry in a GMP Environment”, Ed J. B. Miller and J. B. Crowther, ISBN 0-471-31431-5

Don't let your instrument qualification and maintenance be the weakest link in your compliant results!



“Our relationship with the PerkinElmer service team is great. Together we have developed and standardized a protocol for all our HPLC systems. They have even customized the validation protocols ready for inspections. These inspections have been straight forward and we have had no validation issues”

INTENDIS MANUFACTURING S.P.A, QUALITY CONTROL LAB D.ssa Lavinia Baldan/Mr.Roberto Maggia, Italy

OneSource an Integrated Qualification Solution

Perkin Elmer OneSource qualification solutions present a harmonised qualification process for all your Laboratory Equipment and Apparatus. Consider, for example, different options available for qualification of an LC-MS system, where modules of the system come from different suppliers:



Customer Choices Available

OEM

- Different OEM approach for each component (Vendor 1-3)
- Customer co-ordinates each OEM
- LC-MS Not tested as a whole
- High Cost (no competition)

OR

Do It Yourself

- Inflexible labour resource
- Specialist expertise
- Availability of protocol & Tools ?
- High internal overheads
- Not core business

OR

Multi-Vendor Services

- Proven expertise
- Mixed systems from different vendors
- Standardised approach
- Integrated protocols
- System Tested as a whole
- More flexible, lower cost

OEM = Original Equipment Manufacturer

OneSource Solutions

- Consistent Approach
- Single Integrated Protocol
- One Phone Call
- Lower Costs

- Flexible Implementation
- Expert Engineers
- Audit Proven Protocols
- Project Managed Solution
- Core Business

- HPLC Module Qualification
- HPLC System Qualification
- MS Qualification
- Qualification of WHOLE LC/MS system
- Streamlined, Comprehensive, Consistent, Compliant

Analytical Instrument Qualification

“Quality cannot be tested in...”

Dr Scott Gottlieb, FDA Deputy Commissioner for Medical and Scientific Affairs, at 30th International GMP Conference, University of Georgia, 14th March 2006.

This fundamental principle - that quality must be designed into a system and cannot be “added on” later - equally applies to your laboratory. From method development to Quality Control, GMP to GLP, for Assured Compliance, quality must be designed in and qualification of your instrumentation is the foundation cornerstone of this.

Build a Solid Foundation for the Quality of Your Compliant Laboratory Results

Validation investment provides assurance of equipment design/use and prevents high costs of poor compliance.

Free your scientists from burdensome tasks, enabling them to focus more on the science.



“Analytical instrument qualification helps justify the continued use of equipment...”
Qualification of Analytical Instruments for Use in the Pharmaceutical Industry: A Scientific Approach [Ref:- AAPS PharmSciTech 2004; 5 - used as a starting template for USP General Chapter <1058>]



Widest range of Instrumentation Supported

Interpreting and executing compliance requirements in a safe and secure manner is a difficult task. Many regulated laboratories face complex compliance challenges due to:

- **Diverse Range of Instruments** from Multiple Manufacturers - from high-end hyphenated techniques such as LC/MS through to low-end refrigerated storage
- **Heavily Customised Systems** that include components from different manufacturers
- **Missing or Incomplete Qualification** histories or protocols
- **Lack of Expertise**, protocols or time
- **Complex Regulatory Requirements**

With OneSource Multi-Vendor qualification and maintenance solutions, you avoid the complexity and risks of having to explain and defend different vendors validation interpretation in an audit.

OneSource is part of the Life and Analytical Sciences, division of PerkinElmer, a company which understands instrumentation - because it designs, engineers, builds and supports instruments across its expansive range of different Instrumentation Platforms. This integral expertise is coupled with over 7 years front line Multi-Vendor validation and maintenance support experience. This makes us a global leader in Multi-Vendor validation.

Our front line experience means we have extensive expertise in working in True Partnership with laboratories from different industries and organisations. OneSource provides flexible services which range from development of customised qualification protocols; through to deploying and customising a full quality management system with defined responsibilities, ways of working, change control and agreed notification and communication processes.

IQ, OQ, PQ

The range of the instruments we support with IQ, OQ, PQ Multi-Vendor Qualification and Maintenance is extensive and includes, but is not limited to:

- | | |
|---------------|---------------------|
| • HPLC | • ICP |
| • LC/MS | • ICP-MS |
| • LC/MS/MS | • Dissolution |
| • GC | • KF |
| • GC/MS | • pH Meter |
| • FTIR | • Melting Pt. |
| • UV/Vis | • Stability Chamber |
| • Polarimetry | • Storage Facility |
| • TOC | • And more... |
| • AA | |

Qualification Life Cycle Management

Historically, instrument qualification was considered a burdensome “One Off” activity necessary for using instruments in regulated environments. The regulatory landscape has changed. Compliance regulations now require an instrument to be qualified throughout its working life. The risks and consequences for instrument qualification are becoming increasingly complex.

PerkinElmer Multi-Vendor OneSource engineers understand qualification life cycle management. Following our customer specific Quality Manual, they:

- Report trends in instrument performance
- Work to agreed and defined responsibilities
- Follow secure and proven change control processes
- Support responsive customer investigations into unplanned events (e.g. **OOS - Out of Specification**)

We don't “ship” exchange modules with the same serial number for you to arrange installation. In our opinion, this represents poor customer support and increases compliance risks. Exchanging a defective module does not help identify the underlying root cause of the failure or support the necessary customer impact assessment of instrument failure.

The “hands on” approach of our experienced and skilled engineers help identify the root cause of instrument failure and therefore supports detailed customer impact assessment. Failure to identify Corrective And Preventative Actions [CAPA - 21CFR Part 100] are frequently referenced in **FDA 483** warning letters.

Typical 4Q Qualification Life Cycle

