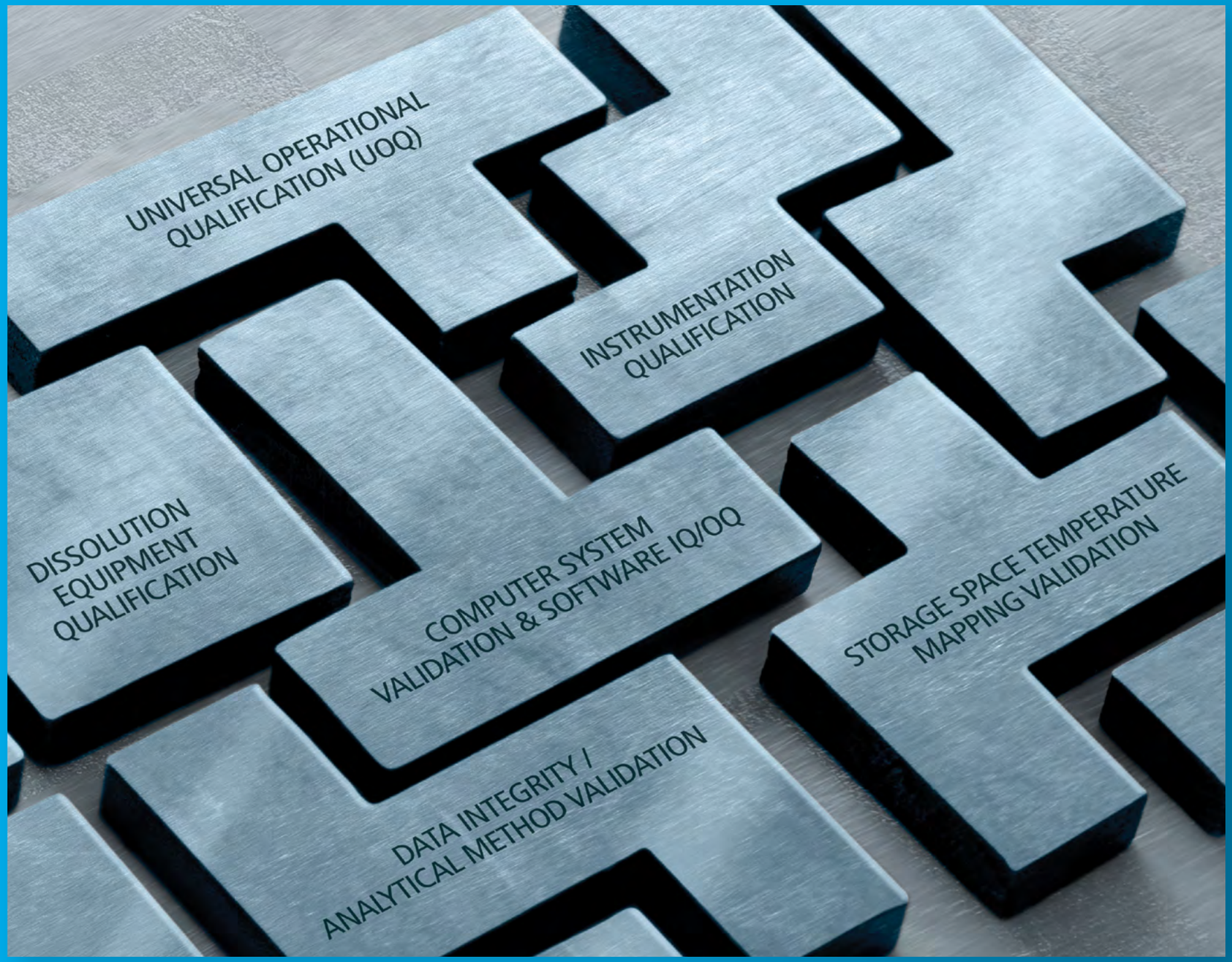

OneSource Laboratory Services

WHO SAYS COMPLIANCE NEEDS TO BE COMPLICATED?

PerkinElmer
For the Better

GREAT SCIENCE IS BUILT ON LABORATORY-WIDE COMPLIANCE

Navigating the complexities of global regulatory entities and requirements can be difficult, and the penalties of noncompliance – lost time, staff attrition, fines, recalls, or worse – can slow down productivity in even the best-run laboratories. With Compliance Services from OneSource, you can address your challenges head-on. You'll have access to a library of custom qualification documents and methods, and a trusted consultant with real expertise in qualification, requalification, risk management, and remediation. It's a multivendor approach that frees your scientists to concentrate on research and discovery, allowing you to meet business and regulatory objectives.

OneSource Compliance Services: This is compliance made simple.

Click on the various services to learn more about our offerings.

OneSource Laboratory Services

- Instrument Qualification
- Universal Operational Qualification (UOQ)
- Computer System Validation and Software IQ/OQ
- Data Integrity / Analytical Method Validation
- Dissolution Equipment Qualification
- Storage Space Temperature Mapping Validation
- Contact Us

www.perkinelmer.com/OneSource

INSTRUMENT QUALIFICATION
FROM TRADITIONAL TO ELECTRONIC

Instrument Qualification methods guide your lab through automated, secure electronic or traditional paper qualification procedures with standard OQ protocols customized to your specifications.

Qualification Approaches Customized for Your Lab

Automated Qualification

The Universal Operational Qualification (UOQ) process is designed to harmonize documentation across all manufacturers' laboratory instruments, delivering:

- Automated OQ with uniform reports
- Coordination with existing data acquisition systems
- Encrypted, secure reporting for a simplified and efficient review

Traditional Qualification

We offer a number of traditional application-based qualification protocols and services, ensuring consistent, reliable, accurate data with instrument qualification services that provide:

- Qualification protocols using calibration standards
- Applications-based custom protocol development
- Execution of customer-developed protocols
- IQ/OQ/PQ protocols library

Click here to see what's over the horizon for data integrity.

OneSource Laboratory Services

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The Next Big Thing in Compliance Software

OneSource Compliance Services is ensuring the highest levels of compliance with international regulations and guidelines with a move to the Universal Operational Qualification (UOQ) process.

UOQ enables a seamless, cross-platform approach to the documentation process, letting you gain immediate access to raw data from computer or database, for increased scientific productivity.

You also benefit from:

- Simplified reports with no hidden algorithms
- Electronic documentation with fewer errors for better audit preparation
- Better use of existing data acquisition systems
- Ultrasecure qualification reports

Benefits to Your Lab

UOQ was developed to heighten compliance to OQ technology by using smart PDFs that comply with 21CFR Part 11, a configurable protocol that increases security and streamlines the qualification process across multiple vendors.

The UOQ protocol:

- Utilizes software that's currently connected to your instruments
- Leverages data acquired by software or independent metrological equipment
- Applies to FTIR, UV/VIS, HPLC, UPLC, and GC systems, regardless of OEM
- Provides all documents/reports in PDF format, allowing for electronic signatures if needed

Return to Instrument Qualification

OneSource Laboratory Services

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A NEW DIRECTION IN COMPLIANCE

Our Universal Operational Qualification (UOQ) service gives the most advanced, efficient, and highly automated instrumentation qualification program available today. With UOQ, you benefit from accurate results as well as optimal uptime – and that means maximum productivity, along with the peace of mind that comes with ongoing regulatory compliance.

Compliance, Automated and Simplified

With our UOQ service, you can boost scientific productivity, increase instrument availability, reduce overall costs, and maximize overall organizational efficiency. That's because UOQ services streamline the qualification process for all lab instrumentation, allowing you to consolidate onto a single integrated solution. And for easy documentation tracking, it enables you to harmonize documents across all models of lab instruments, regardless of manufacturer. The service:

- Encompasses USP, EP, JP, and other pharmacopeial compliance standards, where applicable
- Accommodates existing data acquisition systems
- Provides secure, encrypted reporting using digital certificate technology to prevent duplication and tampering, meeting 21CFR Part 11 standards.

UOQ TIMELINE

UOQ is an innovative, harmonized, cross-platform approach that simplifies the qualification process:

BEFORE | DURING | AFTER

- The Review Protocol is user-configurable for all set points and limits and provides for full customization – for individual instruments to harmonize all instruments

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UOQ TIMELINE

UOQ is an innovative, harmonized, cross-platform approach that simplifies the qualification process:

BEFORE | DURING | AFTER

- Instrument testing allows service engineers to perform testing for multiple systems simultaneously, even after hours for maximum uptime
- An ultrasecure UOQ report is generated using built-in calculations and pass/fail determinations for reliability

OneSource Laboratory Services

A NEW DIRECTION IN COMPLIANCE

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UOQ TIMELINE

UOQ is an innovative, harmonized, cross-platform approach that simplifies the qualification process:

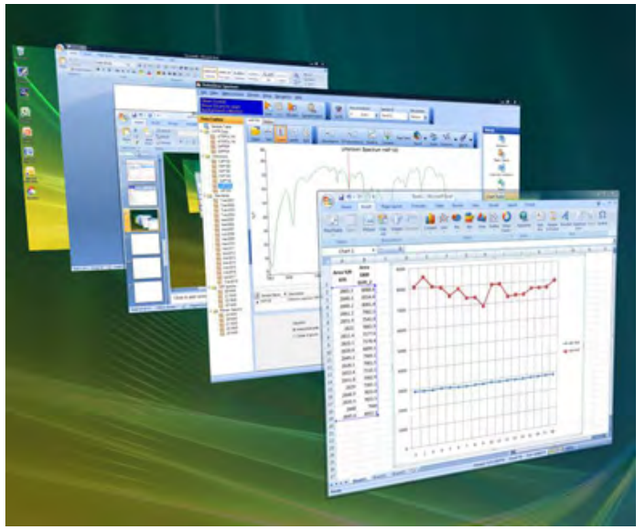
BEFORE | DURING | AFTER

- Compliant: UOQ meets the highest regulatory standards and international guidelines
- Simplified: Easy-to-read reports with no hidden algorithms
- Audit-ready: Digital archiving of data and records

OneSource Laboratory Services

VALIDATING SYSTEMS
WHILE MITIGATING RISK

Your lab needs to meet the most rigorous validation methodology to satisfy regulatory authorities. OneSource can help by providing a range of IQ/OQ offerings for computerized system validation, and the assurance that instrument data is complete, accurate, and consistent. These Computer System Validation (CSV) solutions streamline and supplement your validation projects and deliverables while meeting the requirements of data integrity.



Validated Connections Between IT and Instrumentation

Computer Systems Validation methods ensure your lab's computerized systems and software meet demanding regulatory requirements. These services employ the GAMP 5 V model, using a risk-based approach that's customized based on specific user requirements – from full validation for new systems or new intended use to change-control validation for existing standalone and enterprise systems.

At the same time, we provide a range of software IQ/OQ offerings, including enhanced security instrument software products such as WinLab 6 ES, NexION® ES, Spectrum® ES, and more. And there's special support available for Waters Empower® software.

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INTEGRITY AT THE HEART OF YOUR LAB

Highly regulated industries such as food, pharmaceuticals, biologics, cosmetics, and medical devices are now dependent on the ability of scientists to ensure the integrity of their data. Regulators are probing the ways in which data is generated, reported, and stored. Our OneSource solution is based on centralized monitoring and continual improvements that enable you to pursue science with integrity – and compliance.

OneSource works with you to develop a comprehensive data integrity governance program to ensure your lab is meeting all aspects of ALCOA and is inspection ready. The compliance team can also assist in remediations of corrective action plans for CSV and creation of procedures and policies that eliminate gaps in data integrity. Scalable services include:

- Assessment of systems, documents, policies, and environments
- Plans of corrective action
- Remediation and effectiveness checking

Analytical method requirements that span the full compliance lifecycle – from method development and validation to method transfer services – can be time-consuming to design and implement. Our OneSource team can streamline lab workflows to boost scientific productivity, with data integrity assessment and methods to establish quality control procedures that help ensure your data is both reliable and compliant. Services include:

- Method validation with USP <1225> and ICH Q2
- Metrology and calibration

Data Integrity is at the Heart of Laboratory Compliance

OneSource Laboratory Services

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It's a New Day in Data Integrity

Given today's evolving and increasingly complex regulatory environments, global agencies such as the US Food and Drug Administration (FDA), the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), and the European Medicines Agency (EMA) are bringing a whole new mindset to auditing, moving away from traditional instrument validation approaches and concentrating on the data lifecycle to detect gaps or fraud in product development and quality control.

Over the past few years, many regulatory agencies have determined that electronic data is more secure than "paper" documentation and less likely to be manipulated over the phases of a product's development lifecycle. Printed documentation is no longer considered an exact and complete record since it doesn't represent the raw data and metadata agencies are looking for.

But that doesn't mean electronic lab data is perfect: It must comply with a number of other stringent regulations, including the US's 21 CFR Part 11 and the EU's EDQM Annex 11. The Good Automated Manufacturing Practice (cGMP) guidelines are an essential tool for ferreting out common electronic data errors labs make, including access control, lack of permissions, lack of audit trails, no electronic signatures, improper (or no) backups, and lack of disaster recovery procedures – all of which better enable you to comply with regulators' expectations for data integrity.

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TAKING THE STRAIN OUT OF DISSOLUTION TESTING

Dissolution testing mimics the behavior of pharmaceuticals in the body and is an important part of quality control, determination as to whether drugs are performing to regulatory standards, and decisions around pharmaceutical excipients. It's a key concern for the FDA and other regulatory bodies, and can lead to out-of-spec (OOS) test results, an FDA Form 483 observation, or even a warning letter from the FDA.

Our OneSource service teams are staffed with engineers and consultants who know the ins and outs of dissolution testing. Our teams have contributed to the FDA/USP working group on vibration limit evaluations and settings. We offer mechanical qualification and chemical validation services that meet the very latest U.S. and E.U. guidelines, and deliver technologies that produce the clearest, most useful, and fully integrated reports available. Plus, we work with your lab managers to find the optimum testing level and frequency to fit your lab's compliance needs and budget. Services include:

- Basic preventative maintenance
- Corrective maintenance
- Mechanical qualification
- Performance verification

In addition, we can evaluate your testing regimen and advise on best practices for minimizing everyday operational problems.

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THE UPS AND DOWNS OF
TEMPERATURE-CONTROLLED STORAGE

The guidance is clear: All chemical reference standards, drug product samples, and tissue and blood samples must be stored in appropriate, controlled conditions, while incubators and storage cabinets used for accelerated stability studies must be monitored. So storage space temperature mapping has become a key component of validation.

Today, many labs have gaps in the validation records for temperature-controlled storage devices, with inadequate temperature mapping studies, no open-door restabilization studies, and missing temperature mapping data. Plus, labs don't want to invest in test equipment or risk performing validation on their own using inexperienced operators.

OneSource provides GLP/GMP-compliant thermal mapping studies, including open-door restabilization testing using test equipment calibrated to international standards. With OneSource, you get storage space temperature mapping validation done right – the *first* time. And fully automated reports and advanced techniques such as wireless temperature probes reduce human error and damage to instrumentation.

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Contact Us

PerkinElmer, Inc.
940 Winter Street
Waltham, MA 02451 USA
P: (800) 762-4000 or
(+1) 203-925-4602
www.perkinelmer.com

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For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

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