UNIVERSAL DOCUMENTATION: AN INNOVATION IN LABORATORY COMPLIANCE

Sponsored By

PerkinElmer®
For the Better

Page 3
Increasing Demands, Increasing Paperwork

Page 4
Universal Documentation Simplifies Compliance Testing

Page 5
Resolving Pain Points with Universal Documentation

Page 6
Navigating Compliance for Electronic Documents and Signatures

IT challenges have met their match.

With OneSource® Lab Computing Services, your operation is assigned qualified OneSource lab computing analysts who build relationships with scientists and lab managers to identify IT issues proactively.

When issues arise, your OneSource computing analyst takes ownership from problem to resolution – collaborating with vendors, scientists, internal IT, and lab management organizations. So you can spend less time on the hassles and get back to science.

Learn more at
www.perkinelmer.com

PerkinElmer®
For the Better

INCREASING DEMANDS, INCREASING PAPERWORK

Due to increasing regulatory demands on the pharmaceutical, food, and chemical industries, researchers are spending more time making sure that their instruments are functioning within defined parameters to stay compliant. The time and resources needed to meet global requirements for regulatory inspections and avoid audits are at odds with laboratories' needs to increase productivity and reduce operating costs.

Common Compliance Areas

There are various types of compliance for laboratory instruments, including installation qualification (IQ), operational qualification (OQ), performance qualification (PQ), and preventative maintenance (PM). Each of these serves an important role in ensuring that pharmaceutical, food, and chemical laboratories manufacture reliable, safe products without excess waste due to process errors. However, each compliance area comes with its own set of paperwork and data to track over time.

IQ measures ensure that laboratory equipment installation follows manufacturer-approved specifications. Procedures related to the maintenance, cleaning, and calibration of the equipment are drawn up at installation time. To keep track of all equipment, researchers need the dates the equipment was purchased, received, and installed, the equipment location, and proof of the initial order, such as the purchase order number. All major equipment components should be physically inspected and tested upon installation. Researchers must keep track of references such as manuals for equipment operation and maintenance, test certificates, safety features, standard operating procedures (SOPs), and documentation relating to the successful installation of the equipment.

The time and resources needed to meet global requirements for regulatory inspections and avoid audits are at odds with laboratories' needs to increase productivity and reduce operating costs.

Researchers perform OQ to determine if their equipment consistently operates within specified parameters to produce uniform results. The tests employed differ depending on the instrument, but they all must thoroughly test the essential functions of the instrument. Multiple users should follow the designated protocols to test their instruments at different times to make sure that any deviation from the standard is not simply due to user error. Any deviations from the acceptable outcomes must be investigated and resolved before the equipment can be used again.

After OQ measures are taken, PQ determines how well instruments work when tested with real materials to make a final product. Any deviations in tests from the norm could result in a flawed final product, which would waste time and money if not immediately repaired.

Finally, researchers must perform PM by going through a checklist of maintenance steps to determine if an instrument requires periodic service to maintain proper function.

The Downsides of Keeping Compliant

Compliance testing is time-consuming and requires many steps. When performing qualification and maintenance tests and organizing paperwork falls on researchers' shoulders, it takes time away from experiments. If laboratories have instrument vendors perform the compliance testing, multiple people sent from each vender need to enter the laboratory at various times and take over the use of the equipment.

In addition to the loss of productivity due to researcher involvement and equipment downtime, laboratory staff must keep track of and organize extensive paper trails to stay compliant and prepare for regulatory audits. This information, whether on paper or electronic, needs to remain safe and secure to promote data integrity. When this task falls to scientists unfamiliar with data integrity risks or the newest regulatory requirements, laboratories risk the consequences of noncompliance.

New electronic documentation services, such as OneSource® Universal Documentation from PerkinElmer, aim to alleviate these struggles. With features designed to free scientists from the burdens of keeping compliant and manually managing their records, laboratories become more productive.

UNIVERSAL DOCUMENTATION SIMPLIFIES COMPLIANCE TESTING

Scientists need simple solutions to streamline laboratory equipment compliance testing and document organization. Electronic documentation provides a solution that saves time and resources; however, moving away from familiar paper-based documentation systems can be daunting. The PerkinElmer OneSource® Universal Documentation program works with laboratory instruments through an automated process using smart PDFs, streamlining the process of equipment compliance.

These clear reports speed up the review of the results, which allows compliant instruments to get back to their usual duties in the laboratory.

The Basics of Universal Documentation

The OneSource Universal Documentation suite streamlines documentation across all major models of laboratory instruments, regardless of manufacturer, enabling researchers to use the same documents across all brands of the same instrument type, such as high-performance liquid chromatography (HPLC) machines, gas chromatography machines, UV and IR spectrophotometers, polarimeters, balances, and analog converters. For example, the same document is used for compliance testing of all HPLC machines. This uniformity allows researchers to easily compare the performance of all of their instruments. Additionally, because the documents are the same, a single PerkinElmer service engineer can run tests on all instruments of a type at the same time, including overnight, which generates all reports at once and avoids equipment downtime.

OneSource Universal Documentation reports are smart PDFs that display test results. Where applicable, the PDFs have built-in, validated, automated calculations, which reduce error compared to manual or semi-manual calculations on calculators or spreadsheets. Researchers only need a simple PDF reader to view their reports, and all of the information from a round of compliance testing, including training certificates, test printouts, and raw data are found in the same document. These clear reports speed up the review of the results, which allows compliant instruments to get back to their usual duties in the laboratory. The final PDF reports can be digitally signed or printed as hard copies.

Universal Documentation to Suit Every Need

The OneSource program provides universal documentation for various types of compliance testing, including operational qualification (UOQ), performance verification (UPV), and preventative maintenance (UPM). The UOQ program for laboratory equipment is targeted to pharmaceutical laboratories. Its reports contain details such as raw data and automatic calculations. UOQ is fully compliant with current regulatory standards, including United States, European, and Japanese Pharmacopeia (USP, EP, and JP), Current Good Manufacturing Practices (cGMPs), and EU Commission Annex 11 and 21 CFR Part 11 for electronic records and signatures.

UPV is similar to UOQ, but made for the needs of non-pharmaceutical laboratories. The UPV electronic form contains fewer tests than UOQ, only displaying those that are necessary to assess the state of the tested equipment and determine if it is in good working condition.

UPM is a simple maintenance checklist sold with UOQ or UPV for the periodic assessment of laboratory equipment. The UPM reports do not contain test results, but the test data are transferred to their corresponding UOQ or UPV forms. Like UOQ and UPV, UPM offers a uniform approach to testing equipment of the same type, with identical steps no matter the make or model.

With these options, the OneSource Universal Documentation suite meets the needs of a variety of laboratories and promotes security and uniformity in regulatory compliance testing.

RESOLVING PAIN POINTS WITH UNIVERSAL DOCUMENTATION

The OneSource® Universal Documentation suite from PerkinElmer for operational qualification, performance verification, and preventive maintenance (OQ, PV, and PM) is a reliable way to replace the cumbersome paper trail with a simple digital one. The benefits of this system minimize the risk of noncompliance and regulatory audit and improve lab efficiency.

Compliance Testing Pain Points	OneSource Solutions
1. Instrument downtime due to compliance testing from multiple vendors	☑ One vendor runs tests on all instruments, even overnight. ☑ Document uniformity makes performance assessments quick and easy.
2. Lost time at the bench as researchers manage compliance testing and paperwork	☑ Electronic documents are simple to understand and track ☑ Documentation uses the same checklists for all brands and models of the same equipment type.
3. Data integrity and security are difficult to maintain	☑ Automated, built-in calculations eliminate data integrity risks associated with spreadsheets. ☑ 21 CFR Part 11 compliance ensures digitally-signed reports are not falsifiable.
4. Trouble keeping up-to-date with new regulatory requirements	☑ Smart PDFs are fully compliant to the latest regulations, including USP, EP, and JP.

PerkinElmer®
For the Better

NAVIGATING COMPLIANCE FOR ELECTRONIC DOCUMENTS AND SIGNATURES

While electronic documentation alleviates many compliance pain points, researchers must follow government regulations on electronic records and electronic signatures. In the United States, device manufacturers, drug developers, and other companies regulated by the Food and Drug Administration (FDA) must handle their electronic records and signatures used in quality system processes according to specific guidelines legally mandated by Part 11 of Title 21 in the Code of Federal Regulations, or 21 CFR Part 11.[1]

21 CFR Part 11 Tips

21 CFR Part 11 sets up standards that, when followed, make electronic records and electronic signatures trustworthy enough to be considered equivalent to paper records. This distinction is important to prevent falsification of records and ensure data security. To follow these standards, users must implement controls, such as audits, system validations, and precise documentation, to make sure the software and systems that process electronic data are following the FDA rules.

For many laboratories, adhering to these standards is challenging, confusing, and requires the time and resources of the laboratory staff. Luckily, there are strategies to navigate this process.

All users with access to electronic documents should follow best practice guidelines for data security and password protection. If laboratories keep track of their documentation internally, the electronic folders storing their files must have the appropriate permissions. To access these folders, different users need unique logins with strong passwords. Additionally, the system may be set up so that users are logged out after periods of inactivity or locked out after several failed password attempts. Record creation, modification, and deletion should be clearly tracked, and each event should be labeled with information including the username of the person making the change and the date and time.

21 CFR Part 11 sets up standards that, when followed, make electronic records and electronic signatures trustworthy enough to be considered equivalent to paper records.

21 CFR Part 11 also regulates electronic signatures on documents pertaining to FDA-regulated processes. Electronic signatures on compliance documents must be set up with additional information, such as the printed name of the signer, the intention of the signature, and the date the signature was produced. These signatures are unique to a person and can never be reassigned to a different individual.

Simplifying 21 CFR Part 11 Compliance

The OneSource® Universal Documentation smart PDFs for operational qualification, performance verification, and preventive maintenance (OQ, PV, and PM) produce secure, digitally-signed reports that are compliant with 21 CFR Part 11 and EU Commission Annex 11 (the corresponding European Union regulation for electronic records). The PDFs are not falsifiable, and data from the universal documents can be safely shared when undergoing regulatory audits. The OneSource service provides secure and encrypted reporting with digital certificate technology, which prevents document modification, deletion, or duplication to meet regulatory standards. With these safeguards in place, researchers can be assured that their documentation is secure and meets federal standards.

Reference

1) U.S. Food & Drug Administration, "CFR—Code of Federal Regulations Title 21," *U.S. Food & Drug Administration*, retrieved September 8, 2021.

PerkinElmer OneSource is a single integrated solution.

Now you can harmonize documents across all models of lab instruments, regardless of the manufacturer, for easy tracking.

The PerkinElmer OneSource® Universal Documentation program works with laboratory instruments through an automated process using smart PDFs, so you can increase productivity, improve instrument availability, maximize efficiencies, and reduce costs due to instrument downtime.

Learn more at
www.perkinelmer.com

PerkinElmer®
For the Better