5 Things You Can Improve During Instrument Qualifications

Analytical instrument qualification is a crucial step in the field of scientific analysis, enabling researchers, scientists, and industry professionals to obtain accurate and reliable data from their instruments. The process involves a series of tests, verifications, and calibrations to establish whether the instrument performs within predefined parameters and meets the requirements of its intended use. To ensure the success of an instrument qualification, it is essential to follow best practices and adopt a systematic approach. In this white paper, we present five things you can improve when it comes to the instrument qualification.

1: Understanding What Is Required

Currently, there are no direct guidelines for the validation approach to analytical equipment. However, a few references are regularly cited when instrument qualification is discussed:

- **United States Pharmacopeia (USP) General Chapter <1058> Analytical Instrument Qualification**

  This This chapter is dedicated to the instrument categorization and qualification approach for each group of laboratory equipment. It is the best guidance that is currently available. However, an instrument can fall into multiple groups depending on the intended use.

- **United States Code of Federal Regulations (21 CFR Part 11)**

  This entry describes regulatory requirements for electronic records and signatures used for good practice (GxP) activities. Nowadays, almost all laboratory instruments generate electronic records. But, does that capability mean that all Part 11 requirements always must be fulfilled by the system? The answer is no.

- **GAMP5: A Risk-Based Approach to Compliant GxP Computerized Systems**

  This guideline can be followed when it comes to the qualification of instrument-controlling software. Equipment applications fall either into GAMP Category 3 (not configurable, off-the-shelf systems) or GAMP Category 4 (configurable systems). The biggest gap in GAMP5 for analytical instruments is in the guidelines for hardware qualification—there aren't any.

The lack of established standards or regulations tailored to instrument qualification can present difficulties. This can lead to uncertainty regarding the appropriate qualification approach, criteria for acceptance, and necessary documentation. However, by adapting existing guidelines or seeking collaboration with experts, it is possible to address and overcome this challenge.

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2: Defining the Intended Use

At first glance, stating the intended use of an analytical instrument doesn't sound too complicated. But as you start looking closely at the system capabilities, the requirements for qualification might change. To overcome this challenge, here are some useful questions to pose when defining the intended use:

- Will the system be used for data acquisition?
- Will the system be used for data processing?
- Will the system be used for data reporting?
- Will the system be used for data storage?
- Will the system be the true GxP data source?

If the analytical instrument is used simply for acquiring and reporting analytical data, then performing the vendor standard IQ and OQ protocols for the equipment hardware can be enough to release the system for GxP use.

It is a different story when the instrument and its applicable software are used as a true source of GxP electronic records. In this case, 21 CFR Part 11 requirements apply. In addition to the extensive validation, procedural controls must be implemented for periodic activities such as user audit, system configuration audit, and backup/restore verification.

Defining the intended use correctly will avoid unnecessary qualification deliverables and set a good foundation for a practical and compliant validation plan.

3: Determining the Vendor Role in Qualification

Most of the time, vendor documentation, services, and support are underused by laboratories, especially when it comes to instrument qualification. Knowing what to ask the vendor for might save organizations a lot of time and resources. Some of the focal points to question the vendor about include the following:

- **Instrument Selection**
  Vendors can assist in selecting the appropriate instrument for the specific customer needs. They can provide information about the instrument's features, capabilities, and suitability for the intended purpose. Vendors may also offer demonstrations or trials to help users make informed decisions.
- **Documentation and Compliance**
  Vendors typically provide documentation, such as, user manuals, specifications, and validation guides, to assist users in complying with regulatory requirements. They may also offer validation packages or templates that align with industry standards or regulatory guidelines.
- **Installation and Training**
  Vendors are responsible for the proper installation and setup of the instrument. They should ensure that the instrument is correctly calibrated and configured according to the user's requirements. Training programs, either on-site or remote, may be offered by vendors to familiarize users with the instrument's operation, maintenance, and troubleshooting procedures.
- **Performance Verification**
  Vendors often provide performance verification protocols or procedures to assess the instrument's accuracy, precision, sensitivity, and other relevant parameters. They may assist users in executing these protocols or provide guidance on conducting validation tests.

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- **Technical Support**
  Vendors offer technical support services to address any issues or challenges that users may encounter during the validation process. This includes troubleshooting, software updates, and maintenance services. Vendors should respond promptly to user queries and provide timely resolutions to ensure smooth validation activities.
- **Validation Assistance**
  In some cases, vendors may offer additional services such as validation consulting or on-site validation support. This can involve working closely with users to develop validation protocols, execute validation tests, analyze data, and generate validation reports.

4: Taking a Risk-based Approach

Often, a project team ignores the risk-based approach for instrument qualification. Although the risk-based approach in instrument qualification offers significant advantages such as resource optimization, reduction of unnecessary testing, and ensuring that the most critical aspects of instrument performance are thoroughly evaluated, implementation of the risk-based approach can be hindered by factors such as lack of awareness, time constraints, absence of guidance, and organizational culture.

Overcoming these challenges requires education, standardization, and regulatory support to ensure that project teams recognize the value of risk management and incorporate it effectively into the instrument qualification process. In addition, a risk-driven culture promotes a proactive and systematic approach to managing risks associated with instrument use, leading to improved data integrity, product quality, and consumer safety.

5: Making the Validation Plan

The validation plan is an important document that outlines the overall approach and strategy for instrument qualification. But, does there have to be a separate validation plan for each instrument? Depending on the overall qualification objective, a validation plan can be created for setting up a new laboratory with numerous instruments or for a group of instruments that have similar intended uses and complexities. Most of the time, the same qualification approach can be followed for many instruments. Reducing the number of validation plans doesn't compromise the quality of the verification, while it does save project time and resources.

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The improvements discussed here, with respect to five aspects of instrument qualification, can significantly enhance the effectiveness and reliability of your qualification process. CSols understands that navigating the complexities of instrument qualification can be challenging. That's where our consulting services come in.

Our team of experts can provide you with the guidance, expertise, and support you need to optimize your instrument qualification process. Whether you need assistance in developing customized acceptance criteria, designing test protocols tailored to your specific instruments, implementing a robust calibration and maintenance program, performing comprehensive risk assessments, or establishing a deviation management system, our consultants are here to help. Let us be your trusted partner in optimizing your instrument qualification process and achieving excellence in performance. **Contact Us Here:** **https://hubs.la/Q01Z-dBt0**

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