Why you should mind your "P's and Q's"

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Abstract

Whether responding to recent requirements intended for accreditation bodies, or confirming that your laboratory quality system meets the requirements of ISO 17025 or USP, programs should be in place for Proficiency Testing and Analytical Instrument Qualifications.

Laboratories need consistent, reliable and accurate data. The data generated from laboratory equipment, instruments and computerized systems must be suitable for intended use. Acceptable performance must be demonstrated prior to accreditation. This is why proficiency testing and instrument qualification is mandatory for accredited laboratories.

This presentation will discuss how proficiency testing and analytical instrument qualification will assist laboratories in their pursuit to qualify and validate instruments and operators.

Proficiency Testing Introduction

Proficiency testing (PT) is one of the key tools used to assess laboratory competence. A proficiency testing plan assists the laboratory by revealing problems in testing methodologies, instrument or analyst's performance. The laboratory results need to accurately represent the true value and offer objective evidence of laboratory competence. For these reasons it is important that the laboratory obtains the right answers. Obtaining the right answer supports consumer confidence that this data is what it states.

PT techniques differ depending on the type of the test item, the method being utilized, and the number of laboratories contributing. PT can assist in recognizing any trends that suggest unreliable data is being generated. Customers have a greater level of confidence in a laboratory when they have the ability to carry out a test method in a manner that produces valid results when proficiency testing is employed.

What is a Proficiency Test?

A proficiency test (PT) is a method that is used to validate ***a particular measurement process***. The reference value is not known by the participating laboratory at the time of the test. The PT samples must be stable and homogeneous.

A PT supplier distributes the samples to the participant with instructions. The participant then evaluates both the PT sample and their sample. Results are submitted to the PT supplier for statistical analysis. The participant is then supplied a report that allows them to compare their performance with other participants. The performance of the individual laboratories is only known by the participant laboratory. The PT may be either from a commercial provider, developed internally or completed through a cooperative effort. The PT must meet the applicable requirements of the accreditation body, such as ISO 17043.

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Why have Proficiency Testing?

- The laboratory will meet the requirements of ISO 17025 in the area of PT and comply with regulations and standards by other accredited bodies.
- PT aids the laboratory in accreditation and demonstrates compliance.
- Analytical competence is demonstrated by PT. The laboratory will have assurance of suitable performance and capabilities of the analytical staff.
- The laboratory staff gains confidence in their abilities and knowledge of their capabilities.

Why do laboratories need a Proficiency Plan?

PT is required for certification and accreditation bodies. PT is a way of validating analytical method measurements. PT also provides proof about the labs competence to management and customers. PT offers and insight into understanding the quality issues in the method or test.

PT programs should be properly designed and statistically robust so it can gauge participants performance is properly conducted and the participants can monitor trends and identify gaps in their performance for corrective actions and improvements.

Most accreditation bodies require accredited labs to participate every year in some form of PT or reasonable alternative if none is available. The maximum cycle time is 4 years.

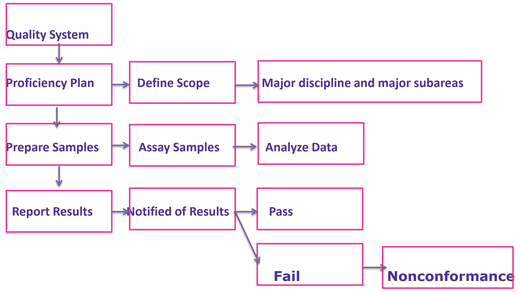
Limitations of Proficiency Testing

- PT cannot be used as a substitute for routine internal quality control.
- PT is not a means for training individual analysts or the participating laboratory.
- PT provides an indication of problems if they are present. It does not provide any diagnostics to help solve the problem.
- Success in PT for one analyte does not indicate that a laboratory is equally competent in determining an unrelated analyte.

Conclusion

- PT requirements must be understood from the accreditation body.
- A complete ISO 9001 Quality Management System will address PT criteria.
- A developed PT plan will allow the laboratory to meet accreditation requirements, establish quality, and verify the measurement processes.

Proficiency Test Summary



Instrument Validation Introduction

Qualification of analytical instruments and validation of systems is required by many national and international regulations, quality standards such as ISO 17025 and company policies. There are many products being manufactured on a daily basis. With certain products, especially those going into the medical, drug, and food industry, certain guidelines must be in place before products can be sold to the public. Instrument validation helps to improve instrument uptime and avoid out-of-specification situations (OOS) in laboratories.

What is Instrument Validation?

Instrument validation is a documented process that all users of an instrument must follow. These guidelines are written in a very clear, easy to follow way so anyone can apply them. Consistency is of the utmost importance when performing the validation of an instrument. The goal of the established guidelines is to make sure that all equipment is up to spec before any work is done.

Why is Instrument Validation Necessary?

Analytical instruments are used for a specific analysis. Regular performance verifications are made to ensure that the instrument to be used is suitable for its intended application. All equipment used in the production of products shall be properly validated and calibrated **"to demonstrate that it is suitable for its intended purpose".**

In I.Q, the setups of the unit connections are confirmed that they are correct. Any problems identified in I.Q must be investigated and appropriate actions must be taken. All such actions must be documented and approved by higher authority.

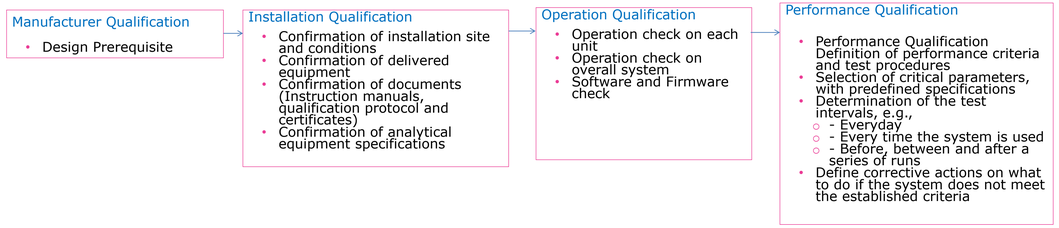
O.Q includes procedures and documentation of the analytical instrument. When all procedures are executed and all items pass the inspection, it is verified that the system operates to satisfy the intended purpose.

The PQ represents the final qualification of equipment or system. This incorporates a range of testing to simulate your production process options and provide assurance that systems and operating documentation are capable of subsequent process validation activities

Conclusion

Analytical Instrument Qualification establishes practices to maintain and calibrate instruments. Each assessment will depend on whether the instrument will be used according to GLP/GPC/GMP/ISO regulations. Each maintenance and calibration activity should be documented.

Analytical Instrument Qualification Flow Chart



References:

1. ISO 9001:2008, Quality management systems-requirements, 2008
2. ISO/IEC 17025, General Requirements for the competence of testing and calibration laboratories, 2005.
3. ISO/IEC 17043, Conformity assessment – general requirements for proficiency testing, 2010
4. USP 37 1058 Analytical Instrument Qualification