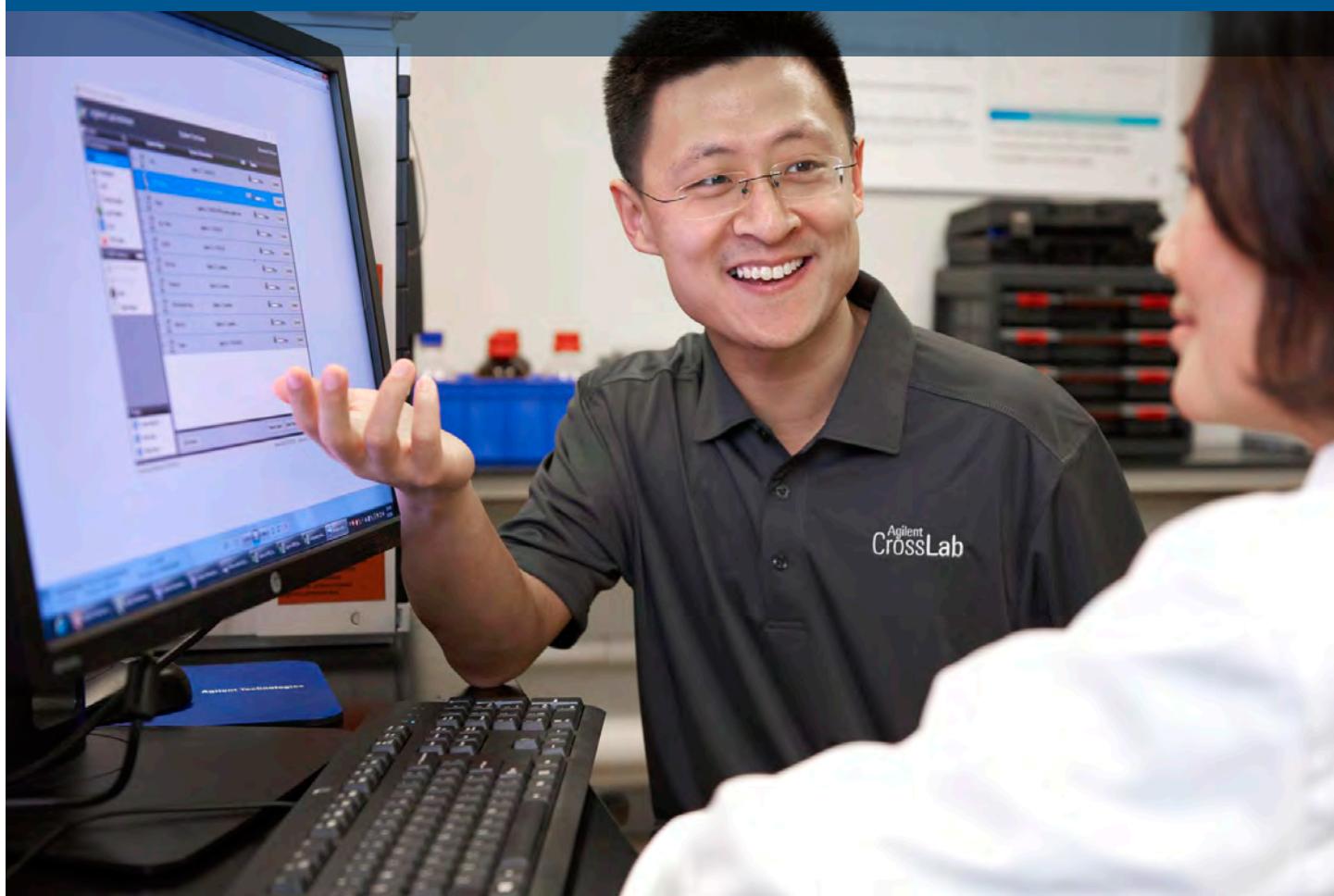


Why Laboratory Compliance is Essential to Valid Analytical Results

Reduce Regulatory Risk with Industry Best Practice



Confidence in Analytical Results

All analytical testing is performed to satisfy regulatory requirements or business needs. However, regulatory requirements are not the same all over the world. For example, GxP regulations and pharmacopeia requirements associated with the pharmaceutical industry are not harmonized and require interpretation by the laboratory. Additionally, there are differences in how accreditation bodies interpret evidence for ISO accreditation.

Fundamentally, this all means that laboratory compliance requirements must satisfy regulations in three areas:

- **Company Quality Management System**—for the supplier or service provider
- **Development Location**—where the product or service is developed
- **Sales or Export**—where the products or services are sold or exported to

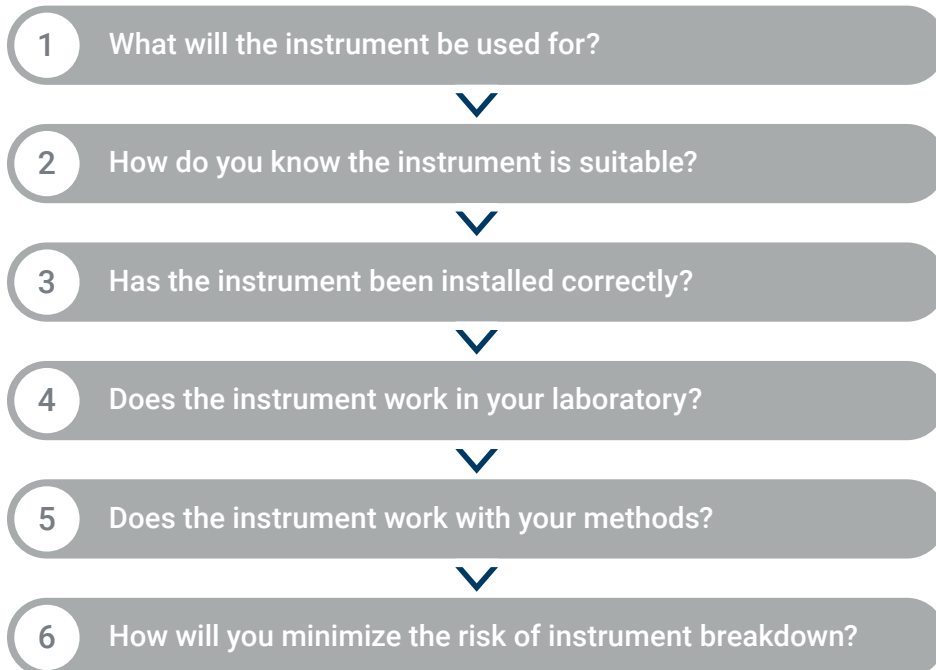
Overall, the two basic needs that must be satisfied for fundamental confidence in the analytical results (and scientific or regulatory validity) are the suitability of the:

- **Analytical Method** (used to test the samples)
- **Analytical Instrument** (used to run the analytical method)

The suitability of analytical methods is established by testing (validating) the method performance against acceptance criteria that are pre-approved and appropriate to the kind of analysis being performed.

Suitability of the Analytical Instrument

To establish the suitability of analytical instruments, six key questions must be answered, or the analytical results may not be valid:



The way answers to these questions are implemented, influences return on investment, peace of mind during audits and laboratory productivity.

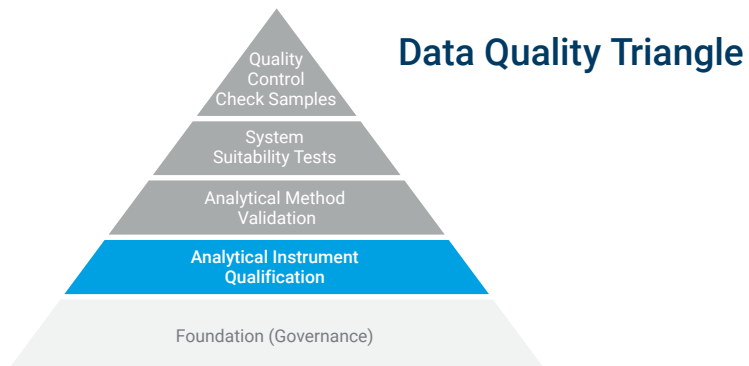
Defending Your Results in an Audit

During any laboratory audit or inspection, you will be asked to provide answers to a variety of questions. Some may be specific (e.g. to clarifying facts and information), while others will be more general, such as the one below, which without audit preparation, can be difficult to answer:

How do you know your analytical results are valid?

This question relates to the layers and information in the data quality triangle, which are universally applicable to laboratories in all industries because it represents good science. However, to answer this question during an audit, all aspects of laboratory compliance need to be considered and included:

- Analyst Training
- Suitable Reference Materials
- Method System Suitability Criteria
- Analytical Method Validation
- Software Validation
- Instrument Compliance / Qualification
- Data Integrity / Governance



Instrument Life Cycle

Instrument compliance is the analytical foundation of the data quality triangle and essential for valid results. Some laboratories may use names such as calibration or verification for instrument compliance. However, for pharmaceutical and other regulated industries, the term qualification is more typically used¹. For analytical instrument qualification, the six key numbered questions are directly related to specific stages of the qualification life cycle:

- Laboratory Responsibility
- **Agilent Service**

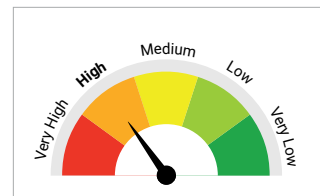


Agilent has developed and validated qualification services that are designed to satisfy regulatory requirements². To help laboratories make informed decisions about qualification, Agilent has written a series of Four detailed White Papers³.



Agilent Resources to Help Laboratories Comply with Regulations

The links below provide a rich source of laboratory compliance information and resources. Use these links to gain a deeper understanding of key laboratory compliance subjects such as analytical instrument qualification, requirements of USP <1058>, and computer software validation. Laboratories that are new to laboratory compliance can use the Agilent risk assessment guide to better evaluate potential compliance risks.



Analytical Instrument Qualification

Find out about the range of Qualification Services Agilent can provide for Agilent and Non-Agilent Laboratory Instruments. For example, how do you ensure the instrument range of use is tested during qualification?



Are You Compliant With USP <1058>?

Read about the impact of changes to USP general chapter <1058> (Analytical Instrument Qualification). This will help you understand some of the changes you may need to make to your instrument qualification.



Software CSV

Validation of laboratory software can be a daunting challenge. However, Agilent's validation starter kits and experienced consultants can speed up your Computer System Validation (CSV) program, which saves time and money on CSV projects.



Laboratory Risk Guide

Use Agilent's free risk assessment guide to better understand your potential compliance risks, such as the additional data integrity risks associated with the use of paper or spreadsheet / Excel-based protocols⁴.



Contact Agilent

Contact your local Agilent representative to find out more about Agilent's range of laboratory compliance services.

References

1. USP <1058> Analytical Instrument Qualification, USP 42-NF 37, Dec. 2019.
2. Agilent Equipment Quantification Solutions Brochure, [5989-4440EN](#), June 2020.
3. USP White Paper Compendium [5994-1134EN](#).
4. Analytical Instrument Qualification, Comparison of Qualification Approaches Across Electronic, Excel, or Paper-Based protocols for HPLC. Technical Overview, [5994-0506EN](#), Nov. 2019.

To know more, please visit:

www.agilent.com/chem/crosslab-compliance

DE.3439351852

This information is subject to change without notice.

© Agilent Technologies, Inc. 2020
Published in the USA, June 24, 2020
5994-2148EN