Agilent CrossLab
From Insight to Outcome

Agilent Equipment Qualification Solutions

Qualify the Instruments in Your Laboratory
with a Harmonized, and Data Integrity Compliant Solution

Agilent

Instrument Qualification – A Regulatory Requirement

For your analytical results to be valid, your analytical instruments must be suitable for their intended use[1]. For regulated industries, such as those associated with pharmaceuticals, laboratories must demonstrate the suitability of instruments during audits and inspections. The best way to do this is through qualifying the instrument against user requirements, based on intended use and compliance with USP <1058>[2].

The USP is the only major pharmacopeia with a chapter dedicated to Analytical Instrument Qualification (<1058>)[3], giving it global regulatory significance. Agilent qualification services are designed to be compliant with USP <1058>.

This is because the Agilent Equipment Qualification Plan (EQP) can be configured[4] to ensure that the Operational Qualification (OQ) matches the range of use and the user requirement specification. This is an essential requirements for <1058> compliance[2]. The analytical instrument life cycle can be represented as a series of six stages. The Equipment Qualification Report (EQR) can be configured to meet your reporting needs[4].

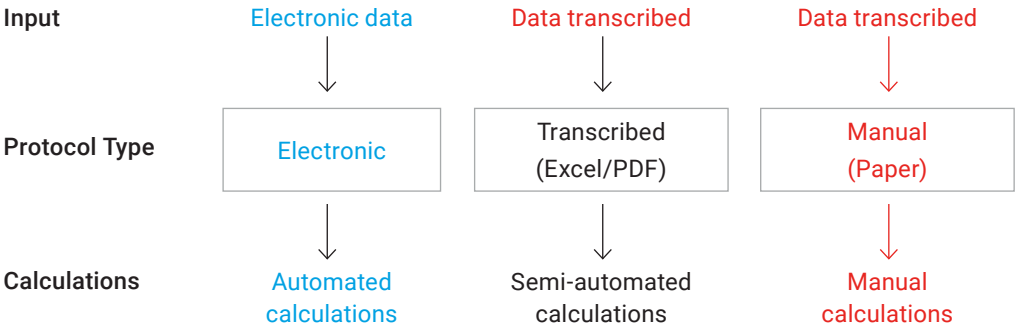
Assured Data Integrity Compliant Services - From the Industry Leader

Data Integrity has dominated regulatory audits and inspections in the pharmaceutical industry, but the audit findings have implications for all regulated and accredited laboratories. Regulators are looking in detail at all aspects of laboratory workflow, including the core Data Integrity of Analytical Instrument Qualification. The high number of Data Integrity guidance documents now available contributes to many laboratories being overloaded with information and struggling to implement compliant qualification solutions in a timely manner.

Agilent deliver harmonized qualification services all over the world using our Agilent Automated Compliance Engine (ACE) software. ACE uses electronic protocols and reports, ensuring qualification services are configurable to laboratory requirements in a compliant and efficient way. In response to evolving regulatory requirements, Agilent can now install Network Distributed ACE within your networked firewall to provide assured ALCOA+ Data Integrity compliance during Analytical Instrument Qualification[5]. Qualification services provided by Agilent are recognized globally as #1 in independent surveys[6].

Are Paper or Excel Protocols good enough?

The three most common protocol types used for equipment qualification are shown below:



Laboratories that rely on the use of paper or spreadsheet-based qualification protocols are creating additional data integrity risks[7].

However, frequently, many laboratories want an answer to the regulatory question:

- **Are Excel or Paper Qualification Protocols "good enough"?**

  It is not possible to answer this question without auditing the laboratory because Data Integrity risk assessments are dependent on the review of the full data life cycle, including transcriptions and manual calculations within the workflow. Three of the biggest risks with "Transcribed" or "Manual" qualification protocols are:

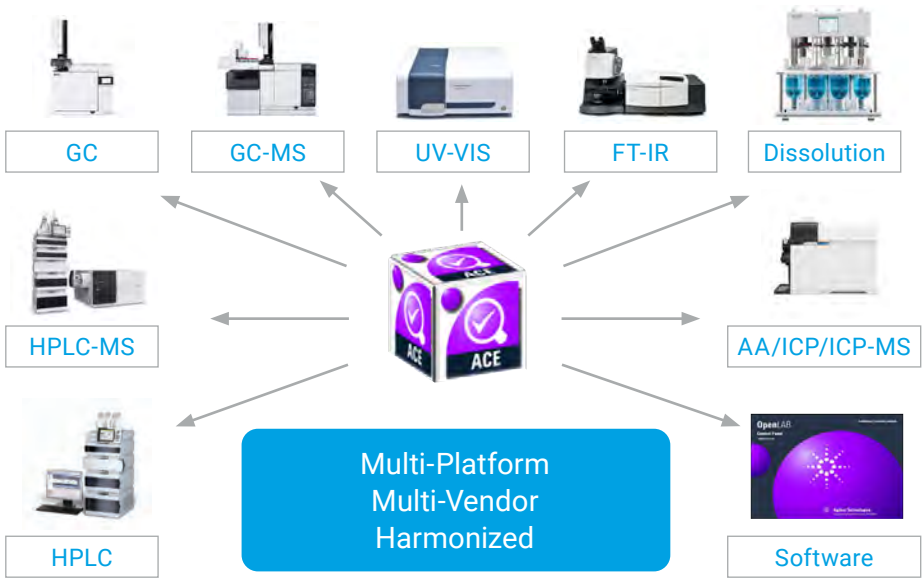
  - **Human Error**—transcription error and / or calculation error
  - **Manipulation of Results**—testing into compliance or hiding repeat work
  - **Subjectivity and Traceability**—of decision making

  Critical thinking highlights these three areas as **high risks** that need to be reduced. This is because procedural control is the only data integrity safeguard. Additionally, manual procedures need to be subject to additional risk assessment[8].

Widest range of Electronic Qualification Services in the industry

Agilent provides one of the widest ranges of electronic qualification services in the industry. These extend the benefits of secure, harmonized qualification services across Agilent and Non-Agilent instruments to include:

- Bioanalyzer
- Chromatography
  - HPLC and HPLC-MS
    1. Analytical
    2. Capillary
    3. Preparative
  - GC and GC-MS
  - CE
  - SFC
- Dissolution
- Elemental
- Sample Preparation
- Software
- Spectroscopy



Advantages of Agilent Qualification Services

Agilent has been providing analytical instrument qualification services for over 20 years. First introduced in 2007, use of the Agilent Automated Compliance Engine (ACE) software saw Agilent implement secure electronic qualification plans and reports many years before the global regulatory focus on Data Integrity.

The move to secure and audit-ready qualification protocols and reports contribute to Agilent being recognized as the leader in Analytical Instrument Qualification[6]. Key advantages of Agilent ACE Qualification services are:

- **Configurable Qualifications**—designed to support USP <1058>, by testing range of use and user requirements[2]
- **Data Integrity by Design**—qualification designed to satisfy ALCOA+ requirements[5]
- **Flexible Delivery**—by Agilent compliance engineers or your own staff through our Partner ACE program[10]
- **Harmonization of Qualification**—aligned with your instrument, laboratory, site or global compliance strategy
- **Multi-Vendor Ready**—with standardized structure, workflow, and layout, independent of the vendor or CDS
- **Reduces Audit Risk**—through our validated and audit-ready qualification processes
- **Save Time**—electronic protocols and reports save time on review and approval

Contact Agilent

To find out more about Agilent compliance and consultancy capabilities, and how they can help you achieve your laboratory compliance goals, contact your local Agilent representative.

References

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To know more, please visit:
www.agilent.com/chem/qualification

DE.3204513889

Published in the USA, July 02, 2020
5989-4440EN

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