Agilent CrossLab
From Insight to Outcome

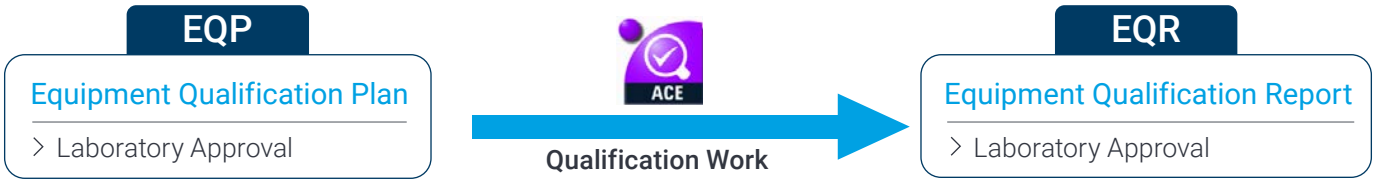
Advantages of Agilent Qualification Documents

- Equipment Qualification Plan (EQP)
- Equipment Qualification Report (EQR)

Agilent

Components of Agilent Qualification

The two cornerstone documents that are the foundation of Agilent's qualification services are the Equipment Qualification Plan (EQP) and the Equipment Qualification Report (EQR). These two secure electronic documents ensure the qualification work is compliant with regulatory and Data Integrity requirements. The EQP contains details of the qualification tests, set points and limits, while the EQR contains the electronic qualification results and meta data. Both require customer approval:



Equipment Qualification Plan (EQP)

The customer reviews and approves the EQP **before** the qualification work is performed. Documents can be wet ink or electronically locked and approved. The standard EQP contains the Agilent Recommended tests, set points and limits for the qualification work. Many customers approve the standard EQP.

Increasingly, customers are asking Agilent to configure (customize) the electronic EQP to ensure the Operational Qualification (OQ) matches the instrument range of use and add additional tests. Together, these two options mean the OQ satisfies laboratory user requirements for compliance with USP <1058>[1] and other regulatory requirements.

Equipment Qualification Report (EQR)

The EQR is provided to the customer for review and approval **after** the qualification work is complete. The secure electronic EQR includes traceable data, meta data and results from the automated pass/fail decisions. The EQR is a complete record of the qualification work performed, containing session log, OQ test counter, OQ test results (including any test failures), and associated support documentation essential to document compliance of the work performed.

The electronic EQR can be configured to match customer reporting requirements. Where required, a customer specific EQR template can be created for future use.

Advantages of Agilent EQP

- Compliant
- Configurable
- Electronic
- Harmonized
- Secure
- Test Description

Advantages of Agilent EQR

- Audit Ready / Complete
- Configurable
- Electronic
- Original Data + Meta Data
- Session Log
- Test Counter

EQP and EQR Workflow

PDF copies of Agilent standard EQP files are readily available[2]. Additionally, to assist customers in deeper understanding of the qualification work Agilent can provide an example EQR. The high level workflow for configuring an EQP is shown below:

- Customer
- Sales Rep /
- Engineer

Review EQP Approve or Request EQP Configuration → Engineer Uses EQP Electronic → Engineer Generates EQR Electronic → Review EQR Approve

Key Benefits of an Agilent Electronic EQP and EQR

Agilent implemented electronic qualification plans (EQPs) and qualification reports (EQRs) in 2007, with introduction of the Agilent Automated Compliance Engine (ACE). Agilent's move to electronic qualification protocols was many years before the current regulatory focus on Data Integrity during audits and inspections. Fundamentally, the Agilent approach of using EQPs and EQRs through the ACE software has a number of significant advantages over other options:

Audit Ready

EQRs are audit ready because they are a complete electronic record of the work performed, including electronic data, meta data, training records, certificates for reference materials and the calibrated tools used. We can even include copies of any customer SOPs the engineers must follow on site.

Configurable Electronic Protocols

Electronic Protocols used by ACE are independent of the ACE software platform and designed to be configurable. This satisfies customer reporting needs and helps ensure that the qualification matches user requirements and range of use, in line with USP <1058>[1] compliance. Because of the controlled flexibility of configurable protocols, we can align EQPs to satisfy user requirements of your instrument, laboratory, site or global compliance strategy.

Data Integrity Compliant

The validated workflows used within ACE ensure the approved EQP is followed by the engineer. With end-to-end electronic traceability, ACE is designed to be compliant with Data Integrity requirements such as ALCOA+[3].

Electronic Deviation

Electronic deviation reports are a standard part of the ACE workflow. If a qualification test fails, the engineer investigates the cause and must complete an electronic deviation report for inclusion in the EQR.

Faster Review

EQPs and EQRs are electronic, and consistent across all ACE platforms. They are designed to speed up review and approval, saving save time and resource.

Harmonized Qualification

The regulatory data integrity focus is driving a need for a consistent and harmonized qualification that satisfies data integrity requirements. ACE is designed to be independent of the instrument manufacturer and supports harmonized qualification, valid across multiple platforms with a harmonized structure, layout and workflow.

Independent of the CDS

The validated test calculation algorithms Agilent use are fully independent of the chromatography data system (CDS), therefore ensuring consistent qualification, independent of any limitations of the CDS used. Advanced features such as using first and second derivatives of the gradient pump response, provides unmatched accuracy and consistency of the gradient performance test. Agilent's qualification testing, provides additional independent assurance of the instrument performance.

Validated Software

Validated software remove the need to check qualification results, speeding up review and approval of EQRs, as well as removing the risks associated with paper, Excel or PDF-based qualification[4].

Customer Responsibilities and Workflow for EQP Configuration

Customer responsibilities are defined within each EQP, but specifically, the customer is responsible for review and approval of the EQP before the work is performed and timely review and approval of the EQR when the work is complete.

Agilent Recommended EQPs are available on the Agilent web site[2], or an Agilent representative can provide one for you. Review this against your instrument use and qualification requirements. If customized EQPs are already in use on-site, please advise your Agilent contact before installation of a new instrument, so that the appropriate configured EQP is used. If a new configured EQP is required, you can share your user requirement specification and / or contact your Agilent representative, who will arrange for someone to work with you to prepare your configured EQP.

Frequently Asked Questions (FAQ)

What is an Agilent EQP?
An Equipment Qualification Plan (EQP) lists the tests, setpoints, and limits that will be used during Agilent analytical instrument qualification (AIQ).

What is an Agilent EQR?
An Equipment Qualification Report (EQR) is the report provided to the customer when the qualification work is complete and contains raw data and metadata.

Can an Agilent EQP be configured / Customized?
Yes, the Agilent Recommended EQP can be configured to include set points and optional additional tests – to align the EQP with a range of use and user requirements. For example, for HPLC, the EQP should cover the flow, temperatures, and wavelength range used.

Why are there no instructions in an Agilent EQP?
ACE and the secure EQP files it uses are designed to support paperless electronic workflow. Protocol instructions are built into the ACE software, so they are not included in the EQP.

How does an Agilent EQP comply with USP <1058>[1]?
The ability to configure EQPs to match user requirements is required by USP <1058>[1]. Creating a User Requirement Specification (URS) is fundamental to <1058> compliance[1].

Can an EQR be configured / Customized?
Yes, like the EQP, the EQR can be configured to create templates for consistent reporting to satisfy customer requirements.

Should I Qualify at the Instrument Specification?
No, instrument specifications document what new instruments are capable of under ideal conditions, which can be different to your laboratory. They should not be used for user requirements[5]. For example, detector noise and drift limits are temperature sensitive. The Operational Qualification (OQ) should test user requirements.

Is ACE Validated?
Yes, the Agilent ACE software and associated protocols are managed under change control and follow an approved validation life cycle within Agilent's global ISO accredited QMS.

Is ACE compliant with 21 CFR Part 11?
Yes, details of how ACE complies with 21CFR Part 11 are available on request.

What does Agilent mean by Variance?
Variance is the parameter range, such as pump flow, that Agilent validates during the EQP development life cycle. A setpoint within variance is within the range Agilent has validated.

References

1. USP <1058> Analytical Instrument Qualification, USP 42-NF 37, Dec. 2019
2. **www.agilent.com/en-us/products/crosslab-instrument-services/compliance/qualification/inkapproval**
3. Agilent CrossLab Network Distributed ACE, How it Satisfies ALCOA+ Data Integrity Requirements, **5994-1660EN**, Feb. 2020.
4. Analytical Instrument Qualification, Comparison of qualification approaches across electronic, Excel, or paper-based protocols for HPLC. Technical Overview, **5994-0506EN**, Nov. 2019.
5. How to Comply with the 2017 Version of USP <1058>, **5991-9419EN**, Nov. 2019.

To find out more about Agilent's analytical instrument qualification services, contact your local Agilent representative.
www.agilent.com/chem/qualification

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