Agilent CrossLab
From Insight to Outcome

Move Your Analytical Instrument Qualification to Agilent ACE

Agilent

Continued regulatory focus on data integrity

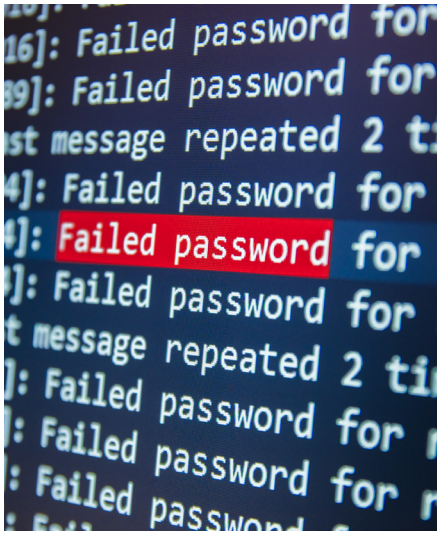
Audits by the FDA and other agencies continue to identify fundamental data integrity problems in laboratories. These findings drive the sustained regulatory focus on the data integrity of all aspects of laboratory work.

Regulatory audits and analytical instrument qualification

Instrument qualification is now the highest area of laboratory concern (after data integrity)[1]. Documenting instrument suitability is good science for all laboratories, but a requirement for pharma, biopharma and other regulated companies[2].

Any regulatory authority (e.g. FDA, PIC/S member or other) may challenge instrument qualification from two very different perspectives:

- **Compliance:** of the instrument qualification
- **Data Integrity:** of the qualification work



Because of this, "defending" instrument qualification against regulatory expectations is increasingly challenging. You must satisfy compliance of the instrument qualification, such as testing range of use, and data integrity of how it was approved, performed, reported, and reviewed[3]. Additionally, the tests, set points and limits used must be based on scientific principles and satisfy user requirements[4]:

"The first activity is the generation of a user requirements specification (URS)".

Agilent have created a starter kit, to help laboratories document critical elements of the USP <1058> instrument qualification life-cycle[5].

Impact of complex qualification workflow

Complex workflows, manual calculations or transcriptions into LIMS, EXCEL, other software or protocol, create multiple points of potential data integrity failure. Therefore, manually re-entering data, and/or performing manual "measurements" on chromatograms, means increased data integrity risk[6].

Move your instrument qualification to the Agilent Automated Compliance Engine **(ACE)** to reduce instrument down time and costs[7].

Companies are locking down access to USB or CD Rom drives. If your instrument qualification uses these, contact Agilent to find out about moving to **Network ACE**.

Reduce risks by moving to electronic qualification workflows

Many data integrity failures can be traced to weak data integrity governance[8]. Companies who rely on PDF forms, Excel, or paper-based protocols are reliant on procedural control for the data integrity of their instrument qualification.

Agilent ACE – Why it is the qualification solution of choice

Agilent created ACE to enable harmonized electronic qualification workflows for HPLC, GC and across a wide range of other complex computerized systems[9].

Designed for analytical instrument qualification, ACE development follows a standard life-cycle process within Agilent. When compared with other common qualification options, the limitations, and constraints of these approaches are evident. Some have data integrity risks; can't test the range of use or don't support a harmonized approach:

Qualification Requirement and Features (using chromatography as an example)		Qualification Protocol Type			
		Network ACE	CDS Based	Excel or PDF	Paper
Qualification Data Usage	Calculations use electronic raw data (e.g. HPLC)	✓✓✓	✓✓✓	×	×
	Electronic data and deviation reporting workflow	✓✓✓	✓✓	✓	×
	Electronic metrology data (used in HPLC and GC)	✓✓✓	×	×	×
Regulatory Compliance	ALCOA+ data integrity compliant	✓✓✓	✓✓✓	✓	×
	USP <1058> compliant++ (and GAMP® 5 aligned)	✓✓✓	✓	✓✓	✓✓
	21 CFR Part 11/Annex 11 compliant	✓✓✓	✓✓✓	×	×
Security	Data and reports fully protected*	✓✓✓	✓✓✓	×	×
	End to end data traceability (audit trail)	✓✓✓	✓✓✓	×	✓
Validation Life Cycle	Developed under global QMS/ISO accreditation	✓✓✓	✓✓✓	✓	×
	Full validation life cycle and revision history	✓✓✓	✓✓✓	✓	✓
Archiving	Conforms to IT policies and control	✓✓✓	✓✓✓	✓	×
Cloud	Designed to be cloud compatible	✓✓✓	✓✓✓	×	×
Harmonized Qualification	Designed to qualify multivendor instruments#	✓✓✓	✓	✓✓	✓
	Harmonized over multiple analytical techniques#	✓✓✓	×	✓✓	✓✓
Protocol Design	Can test range of use/match user requirements	✓✓✓	×	✓✓	✓✓
	Electronically configurable protocol and report	✓✓✓	×	✓✓	✓
Qualification Protocol (EQP)	Automated full range gradient testing (HPLC)	✓✓✓	×	×	×
	Minimizes additional qualification work++	✓✓✓	×	✓✓	✓✓
	Responsibilities defined in the protocol	✓✓✓	✓✓	✓✓	✓✓
Qualification Reporting (EQR)	Complete secure report of the qualification work	✓✓✓	✓	✓	×
	Failed test results automatically reported	✓✓✓	✓	×	×
	Test report status summary – to speed up review	✓✓✓	✓	✓	×
Attachments	Certificates (training, tools, materials, SOP's)	✓✓✓	✓	✓✓	✓

Key: Level of alignment with criteria: ✓✓✓= Very Strong, ✓✓= Strong, ✓=weak, ×= does not comply,
* Checksummed and Encrypted[10], # Not limited by Chromatography Data System (CDS), ++ Testing range of use

ACE, the instrument qualification of choice

Through development and validation of ACE, Agilent implemented electronic qualification workflows in 2007, years ahead of the regulatory focus on data integrity.

The two electronic templates used within ACE are:

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

The EQP and EQR are designed to be configured[11]. The qualification work defined in the EQP can be digitally aligned with your user requirements to ensure that the instrument range of use is tested, while the contents of the EQR can be matched to your reporting needs.

The advantages of this approach are:

- **Alignment:** with USP <1058> requirements
- **Compliance:** with ALCOA + data integrity
- **Configurable:** qualification and reporting
- **Harmonized Qualification:** across the lab
- **Multivendor:** compliant qualification
- **Reduced Audit Risk:** through audit-ready qualification
- **Solution of Choice:** for data integrity and <1058>

The electronic workflow, controlled flexibility, and advantages of ACE over other qualification options, make it the solution of choice in regulated laboratories, and recognized as the market leader in independent surveys[1].

To understand more about analytical instrument compliance requirements and the design strengths of ACE, see references 2 and 3.

References

1. Preferences and Trends in Qualification Practices in Regulated Labs, **5994-5126EN**.
2. AIQ **Requirements for Instrument Qualification**.
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8. PIC/S Data Integrity Guidance, PI 041-1, July **2021**.
9. Agilent Equipment Qualification Solutions, **5989-4440EN**.
10. ACE Secure Data Store, **5994-5138EN**.
11. Advantages of Agilent Qualification Documents, **5994-2147EN**.

Contact Agilent

Contact your local Agilent representative to find out more about Agilent **qualification services**.

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