Agilent CrossLab
From Insight to Outcome

Move Your Analytical Instrument Qualification to Agilent ACE

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Laboratory audits and inspections continue to identify data integrity problems and risks in the pharmaceutical industry all over the world.

The new USP general chapter <1058> on Analytical Instrument Qualification (AIQ) published in 2017[1] includes many additional AIQ requirements that were not present in the 2008 revision of <1058>. These new requirements include:

- User Requirement Specification (URS) – need to define for each instrument
- Risk Assessment – is now a core part of the AIQ process
- Clarification of OQ and PQ requirements, etc.[2]

At a time when laboratories are focusing on reducing costs, increasing productivity and maximizing return on investment, they need to be ready to address fundamental questions about the compliance of their AIQ during laboratory audits and inspections.

Compliance with Pharmaceutical Regulations

There are two different perspectives a regulator may question analytical instrument qualification from:

- **Data Integrity** – of how the analytical instrument qualification work was performed and documented
- **Compliance** - of the qualification (for example, does it comply with USP <1058> requirements / framework)

In a data integrity focussed audit, the emphasis is on "proving" the data is not fraudulent, rather than scientific justification of the information, which significantly changes audit preparation and "defence" requirements[3]. The qualification must be founded on scientific principles and include a balance of holistic and metrology based instrument testing, "right-sized" to laboratory requirements. Changes to USP <1058> mean that there is an increased risk of non-compliance if laboratories do not align their AIQ with new <1058> requirements, such as ensuring the operational qualification aligns with the URS and testing the range of use of the instrument[2].

Because of these two focus areas, many laboratories are reviewing their analytical instrument qualification to reduce potential data integrity audit risks. The requirement for regulated laboratories to demonstrate that instruments are suitable for their intended use has not changed, but the focus of questions that need to be "defended" during an audit has.

1. Electronic Protocol

- Software / CDS*
- Electronic Chromatographic data used#

2. Transcribed Protocol

- PDF Forms / Excel
- Chromatographic data manually transcribed#

3. Manual Protocol

- Paper Protocol
- Manual calculations#

* CDS = Chromatography Data System
\# Attributes of the three approaches

"Laboratories need to address compliance and data integrity requirements of AIQ and Agilent ACE has been designed to meet this need."

Options for Performing Analytical Instrument Qualification

The three general approaches used for performing analytical instrument qualification are:

- **Electronic Protocol** – software focussed solution, with electronic signatures and electronic data
- **Transcribed Protocol** – template focussed solution with manual data entry
- **Manual Protocol** – with manual calculations and recording of information.

The potential data integrity risks associated with these three options increases from 1 to 3, with option 1 (electronic protocols) having the lowest intrinsic data integrity risk and option 3 (manual protocols) the highest risk. With electronic protocols (option 1), technical controls are "built into" the software based approach, while other options are dependent on procedural control.

However, because regulators are prioritizing technical controls over procedural controls[4], there is a general requirement to move away from procedurally controlled compliance towards electronic solutions. Therefore, in parallel with many laboratory operational activities, there is a strong interest in moving from manual protocols, towards option 1, fully electronic qualification solutions with secure electronic end-to-end data traceability.

Agilent ACE - Why It's the Qualification Solution of Choice

Qualification Requirement	Qualification Protocol Type			
	Agilent ACE (NDA)	CDS Based	Excel or PDF	Paper
Chromatographic Data Entry	Electronic		Manual	
Data Integrity Compliant	✓✓✓	✓✓✓	✓✓	✓
Configurable to URS Requirements	✓✓✓	×	✓✓	✓
Covers Range of Use	✓✓✓	×	✓✓	✓
Minimum User Qualification	✓✓✓	✓	✓	✓
Automated Data Entry	✓✓✓	✓✓✓	×	×
ALCOA - aligned approval and review	✓✓✓	✓✓✓	✓	×
Electronic Qualification Reports	✓✓✓	✓✓	✓	×
End to End Data Traceability	✓✓✓	✓✓✓	×	×
Validated Life Cycle	✓✓✓	✓✓✓	✓	×
Electronic Test Management	✓✓✓	✓	×	×
Conforms to IT Policies / Control	✓✓✓	✓✓✓	✓	×
Full HPLC Gradient Testing	✓✓✓	×	×	×
Not Limited by CDS	✓✓✓	×	✓✓✓	✓✓✓
Multi-Vendor Approach	✓✓✓	×	✓✓✓	✓✓✓
Harmonized Across Analytical Techniques	✓✓✓	✓	✓✓	✓

Key: Level of alignment with criteria: ✓✓✓ = Very Strong, ✓✓ = Strong, ✓ = weak, × = does not comply

Agilent ACE has significant advantages over all the other options shown. The global focus on data integrity is driving laboratories to move towards harmonized qualification approaches which are not limited to a particular instrument manufacturers or software, so that a consistent qualification strategy can be implemented across a wide range of analytical instruments and technologies.

Conclusion

Agilent Technologies have designed and validated a comprehensive portfolio of qualification services for analytical laboratories using the Agilent ACE software platform. This is the result of investment in ongoing research and development programs that have been running for over 15 years. The advantages of this continued Agilent investment in ACE for analytical instrument qualification are:

- Compliant with data integrity requirements
- Configurable to match user requirements specification (URS)
- Designed to fulfil GMP / GLP requirements
- Includes Agilent and non-Agilent (multi-vendor) instruments
- Wide portfolio of analytical technologies supported by ACE

Agilent designed and implemented Network Distributed ACE (NDA) to simplify compliance with data integrity requirements[5], while providing a harmonized and cost-effective approach, based on a scientific risk assessment throughout a thorough understanding of the underlying predicate rules.

To help laboratories understand and reduce their audit risks, Agilent has created a number of web sites to provide additional information, such as white papers and reference data[6, 7].

Move to Agilent ACE today, contact your Agilent office to arrange for a dedicated Agilent compliance specialist to discuss your AIQ and laboratory compliance requirements.

References

1. USP <1058>, USP 40-NF 35, through 2nd Supplement, December 2017
2. "Impact of USP <1058>, Regulatory Spotlight on Analytical Instrument Qualification", Agilent Technical Note, 5991-8463EN, October 2017
3. "Data Integrity in the Analytical Laboratory", Pharmaceutical Technology, May 2014
4. "Data Integrity in Pharmaceutical Quality Control Laboratories: What You Need to Know", Agilent Whitepaper, 5991-6827EN, June 2016
5. "Agilent CrossLab Qualification Services, Flexible Use Cases for Instrument Qualification Services", Agilent Publication 5991-7404EN, November 2016
6. https://www.agilent.com/chem/compliance-1058
7. https://www.agilent.com/chem/assured-data-integrity

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