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ASIA EDITION

How to Comply with the 2017 Version of USP?

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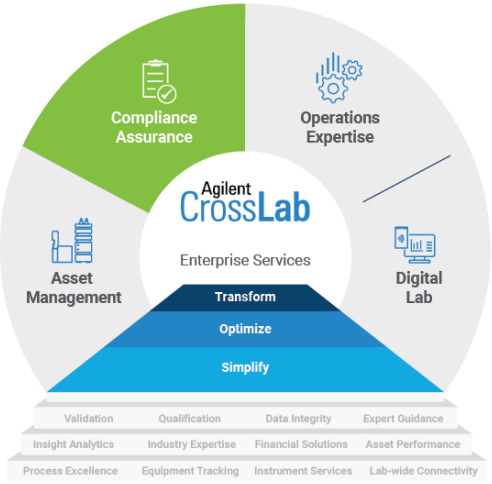
Regulated laboratories must demonstrate that the analytical instruments they use are suitable for their intendeduse. Analytical Instrument Qualification (AIQ) is fundamental to the success of all analytical work performed, including method development and validation, as well as the application of a validated method to the analysis of samples.



It is important to ensure that analytical instruments are qualified and configured to ensure data integrity during intended use, rather than using default software settings and configurations that were applied during initial installation.

Performing thorough instrument qualification and software validation ensures that the method and analysis are reliable, and there is lower exposure to possible regulatory action. if the instrument is not qualified and any software is not validated, the method validation and sample analysis will not be effective and can compromise data integrity.

The US Pharmacopeia (USP) general chapter <1058> on Analytical Instrument qualification (AIQ) was first implemented in 2008 and remained unchanged for nine years. During 2017, the USP implemented two updates to <1058>.

These updates have a significant impact on AIQ, and as the only major pharmacopeia with a chapter dedicated to AIQ, changes to USP <1058> are of global significance.

USP is the only major pharmacopoeia to have a general chapter on Analytical Instrument Qualification (AIQ), so many companies use the approach as a basis for qualifying their analytical instruments. The USP general chapter <1058> on AIQ is an important document as it is the only risk-based regulatory guidance on the subject.

To help regulated laboratories fully comply with 2017 <1058> requirements, Agilent has produced four White Papers with compliance consultant Bob McDowall, has been closely involved with the development of <1058>.

The four White Papers include:

What Has Changed with the 2017 Version of USP <1058>?

Many of the core components that are part of the USP <1058> AIQ framework are included in both the 2008 and 2017 versions. These consist of the Data Quality Triangle, 4Q qualification phases, and the classification of instruments into Groups A, B, and C.

The first White Paper in this series (What Has Changed with the 2017 Version of USP <1058>?) concentrated on explaining the changes to USP <1058>. To understand the impact of these changes more deeply, and recognise how to comply with the 2017 <1058>, it is necessary to review <1058> in greater detail.

How to Comply with the 2017 Version of USP <1058>?

The second White Paper in this series provides deeper insights into the significance of the changes and offers practical information about compliance.

Because so much of the new version of <1058> looks familiar to the 2008 version (for example, data quality triangle, groups A, B, and C, and so on), there is a danger that laboratories underestimate the significance of the changes and risk noncompliance.

The key issue is that each laboratory must review and, where appropriate, update their Analytical Instrument Qualifications (AIQs), associated SOPs, and related policy documents. It is essential to update the 4Qs (DQ, IQ, OQ and PQ) life cycle to reflect the 2017 version of USP <1058>, otherwise a laboratory does not meet compliance. The key stages of the 4Qs include User requirements specification (URS) • Design qualification (DQ) • Purchase order (PO) and supplier quotation • Installation qualification (IQ) • Operational qualification (OQ).

Each of these stages is discussed in more detail in this White Paper. The White Paper also highlights the importance of performing a preliminary risk assessment based on

the anticipated use of the instrument. This will determine which USP <1058> group the instrument belongs. This is a requirement, and helps the laboratory justify their decisions about <1058> groups (A, B, and C).

Role of Analytical Instrument Qualification in Data Integrity with 2017 USP <1058>

The third White Paper highlights the importance of AIQ as a component of data integrity and discusses what a laboratory must do to ensure that qualified analytical instruments and validated computerized systems are set up and configured to help ensure data integrity.

Data integrity is an increasing area of concern for laboratories. In many regulated industries, laboratories must demonstrate and document the suitability of analytical instruments and software for their intended use. This focus on compliance extends to how the instrument and software performance are evaluated.

The 2017 version of USP <1058> brings an integrated approach to AIQ and Computerized System Validation (CSV). This integrated approach closely aligns USP <1058> with GAMP. CSV is a requirement of many regulatory agencies around the globe. There are many different guidance documents on data integrity, and we have listed them in the reference section of this White Paper. The appendix of this White Paper includes a Table of example laboratory data integrity

nonconformances.

What Does Performance Qualification Really Mean?

The fourth White Paper in this series highlights the impact of the changes in 2017 version of USP <1058> on the least understood phase of the 4Qs model: Performance Qualification (PQ). PQ ensures that the instrument continues to perform as expected against its intended use or the URS.

The changes to USP <1058> in the 2017 version are significant and require laboratories to fundamentally re-evaluate their AIQ processes, or risk regulatory non-compliance. The 2017 version contains many similarities to the 2008 version, and there is a risk that laboratories make the following erroneous interpretation: “The changes appear to be small and evolutionary in nature; we already complied with <1058>, so the changes have minimal impact on our laboratory.”

The 2017 USP also brings an integrated approach to AIQ and software validation. It is no longer a case of USP versus Good Automated Manufacturing Practice (GAMP), but is an integrated approach of qualification and validation. Computerised System Validation (CSV), is a requirement of many regulatory bodies around the globe.

To help your lab comply with USP <1058> requirements, Agilent has developed four White Papers. Through our Compliance Consulting Services, we can also help you implement cost-effective electronic qualification and align your SOPs to comply with USP <1058>.

For more information, watch our Compliance webinars : On demand webinar