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Harmonizing USP <1058> and GAMP for Analytical Instrument Qualification

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This article presents a framework for harmonization of the approaches presented by the GAMP GPG on Compliant Laboratory Computerized Systems with the revised USP <1058>.

Recent years have seen an increase in the sophistication and complexity of computerized systems and software used for the automation of laboratory testing and data management operations. Widespread reliance on these new technologies and their potential impact on data integrity have increased the importance of the appropriate selection, implementation, control and maintenance of laboratory computerized systems. As any analytical instrument or computerized laboratory system used in a regulated GxP environment must be fit for its intended use,[1-6] there are various approaches to fulfill this requirement depending on the risk posed by the item, the use of the instrument, decisions to be made on the data obtained and complexity of the process it automates.

The challenge with implementing analytical instruments and computerized systems in a regulated laboratory is developing a quality approach to encompass the wide variety and complexity of systems. Two of the primary sources of guidance for the verification of analytical instruments and computerized systems in regulated laboratories are:

- The recently published ISPE GAMP® Good Practice Guide (GPG) Risk-Based Approach to GxP Compliant Laboratory Computerized Systems,[7] replacing the previous 2005 version.[8]
- United States Pharmacopoeia (USP) general chapter <1058> on analytical instrument qualification or AIQ.[9] Although this general chapter is currently under revision, the initial drafters of the revision are two authors of this article who were also actively involved with the writing of the GAMP Laboratory GPG above.

In addition, the warning letters issued by the Food and Drug Administration (FDA) provide an indication of how these guidance documents are interpreted by the inspectorate.

Both publications[7,9] strive for control of analytical instruments and laboratory computerized systems, but from different historical perspectives. The GAMP® 5 approach looks at the necessary controls for instruments and systems from the perspective of software; in contrast, USP <1058> controls instruments and systems from the perspective of instrument hardware.

This article will review the starting positions of the ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (GAMP® 5)[6] and the second edition of the Laboratory GPG[7] and USP <1058>[9] for the control of laboratory computerized systems before looking at the approaches to harmonization. To define a computerized system, the following PIC/S *Good Practices for Computerised Systems in Regulated "GXP" Environments* definition will be used:[5]

> *A computerized system consists of the hardware, software, and network components, together with the*

controlled functions and associated documentation.

For the purpose of this article, the term laboratory computerized system refers to systems operating in a regulated GxP laboratory environment and may include:

- Configured and non-configured software products
- Custom additions to configurable software products
- Analytical instruments, i.e., devices used to carry out a measurement

Systems such as Laboratory Information Management Systems (LIMS) are not specifically addressed within the Lab Guide as the approach described in GAMP® 5 is directly applicable to those systems.

ISPE GAMP® GPG: A Risk-Based Approach to Compliant GxP Computerized Systems

ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems[6] presents four software categories in Appendix M4 to help focus effort where risk is greatest and to help select the appropriate system life cycle activities and deliverables. Using the GAMP® 5 software categorization, laboratory computerized systems fit into software categories 3 and 4 and to some degree Category 5, although it needs to be noted that Categories 3 to 5 are effectively a continuum with no absolute boundaries.[10] The categories are defined as follows:

- **Category 3** – Non-Configured Commercial Products: this category includes off-the-shelf products used for business purposes. It includes both systems that cannot be configured to conform to business processes and systems that are configurable but for which only the default configuration is used;
- **Category 4** – Configured Commercial Products: configurable software products provide standard interfaces and functions that enable configuration of user specific business processes;
- **Category 5** – Custom Applications: these systems or subsystems are developed to meet the specific needs of the regulated company. The risk inherent with custom software is high. The life cycle approach and scaling decisions should take into account this increased risk, because there is no user experience or system reliability information available.

The recently published second edition of the GAMP® GPG for laboratory systems is aligned with the concepts and terminology of GAMP® 5 as well as recent regulatory and industry developments. The GPG builds upon the framework presented in GAMP® 5 to define a rational, scalable, risk-based approach to ensure that laboratory computerized systems are fit for intended use, meet current GxP regulatory requirements, are operated in a controlled manner and produce correct and accurate results.

The Laboratory GPG addresses laboratory computerized systems used within the regulated life science industries, including pharmaceutical, biological, and medical devices. Systems within the scope of the Guide support a wide range of processes, including but not limited to analysis of drug products, in-process materials, Active Pharmaceutical Ingredient (API), excipients, environmental samples, clinical samples, or toxicology samples used within the regulated life science industries, including pharmaceutical, biological, and medical devices.

Owing to the wide diversity of laboratory systems and how those systems are used, a single prescriptive approach would be neither practical nor cost-effective. The revision of the Guide presents a continuum of activities based upon risks incurred when operating a laboratory computerized system in the business environment, rather than discreet subcategories with prescribed activities, as in the first version. The aim is to achieve compliance, efficiency, and effectiveness – within a reasonable budget and timeline – for a wide variety of systems. The scalable, risk-based approach is aligned with industry trends and enables regulated companies to select the appropriate life cycle activities.

This approach requires thorough knowledge of the business process and intended system use, and focuses on the most critical activities to use resources more effectively. As a Subject Matter Expert (SME), the laboratory scientist must understand the business process and the risks to the integrity of their data based upon intended use. The revision emphasizes the leveraging of supplier documentation and knowledge, whenever possible, to avoid unnecessary duplication of efforts.

GAMP® 5 and the Laboratory GPG are aligned with the ASTM E2500 life cycle approach.[11] The life cycle approach defines and performs activities in a systematic way from concept, through development, operational use, to retirement.

Many laboratory computerized systems are now configurable products consisting of closely integrated hardware and software that are best verified as an integrated unit. For Category 3 (Non-Configured Product) systems, the amount of information available at the time of the initial risk assessment may be sufficient for all relevant risks to be identified, assessed and controlled without the need for further assessments. For Category 4 (Configured Product), it may be necessary to carry out additional detailed risk assessments on the specific configuration to support the business process. Controls should be traceable to relevant risks and verified. Verification should demonstrate that the controls achieve the expected risk mitigation. Furthermore, the software associated with an instrument can vary from basic firmware to

servers, workstations and configurable software for multi-user networked data systems.

United States Pharmacopoeia <1058> on AIQ

The USP General Chapter <1058> on Analytical Instrument Qualification became effective in August 2008.[9] Analytical Instrument Qualification (AIQ) describes the framework and general activities necessary to ensure the suitability of an analytical instrument for its intended use.

Before looking at the contents, it is important to understand the general chapter numbering of the USP. Analytical general chapters between <1> and <999> are mandatory (i.e., enforceable) and general chapters numbered between <1000> and <1999> are informational (i.e., strong guidance).[12] However, in the current USP revision cycle (2010 – 2015), USP plans to revise the majority of general chapters into two chapters per analytical technique: one mandatory and one informational. Each mandatory general chapter will contain a section on the analytical parameters to verify and the corresponding informational general chapter will offer guidance. The stimuli to the revision process and drafts of the general chapters are published in Pharmacopoeial Forum, available on the usp.org web site.

Therefore the proposed revision of USP <1058> needs to be seen in the context of the overall picture of updating the USP general chapters. The revised USP <1058> will contain the general principles for qualification and validation of analytical instruments and laboratory computerized systems under which the mandatory chapters will operate. Therefore, it is important for harmonization between USP <1058> and the GAMP GPG for laboratory computerized systems to provide a consistent message to analytical scientists working in regulated GxP laboratories.

USP <1058> manages risk in the AIQ process by classifying laboratory items into one of three general groups as follows:

- **Group A** – standard laboratory apparatus with no measurement capability or usual requirement for calibration.
- **Group B** – standard instruments providing measured values as well as equipment controlling physical parameters (such as temperature, pressure, or flow) that need calibration.
- **Group C** – computerized laboratory systems that typically consist of an analytical instrument that is controlled by a separate workstation running instrument control and data acquisition, and processing software.

The actual group that a laboratory items are assigned to is dependent on its intended use; however, one of the limitations of <1058> is that it only provides general guidance.

In Group A, there is no validation impact as there is no software in this group; therefore, this group will not be discussed further.

Group B software is firmware used to control the instrument with little data storage capability. It corresponds to the GAMP® 5 software Categories 3, 4, or even 5, depending upon the nature of the embedded software. However, the scope of Group B instruments ranges from firmware control only, firmware with the ability to perform calculations that are required to be verified and firmware with the capability for users to write their own programs using a language developed by the supplier. The breadth of this firmware category highlights the need for a structured approach to categorization based on use and consideration of sub-categories. The current USP approach is to qualify the instrument for the expected operating range, thereby implicitly verifying the firmware. This is an acceptable approach for firmware for instrument control, but verifying calculations and controlling user defined programs are not mentioned in USP <1058>.

In Group C, the software can vary from GAMP® 5 Category 3 to 4, sometimes with the ability to write custom modules (Category 4 plus Category 5 modules), e.g., macros or have additional code added to enhance functionality of the laboratory computerized system. However, USP <1058> assumes that the vendor has done all of the validation work and all the laboratory needs to do is to leverage this work, which can leave a laboratory exposed with the more complex software systems if they follow this approach.

USP <1058> introduces a quality triangle which highlights the critical components involved in the generation of quality data. The current data quality triangle consists of four layers: AIQ, method validation, system suitability and quality control checks. However, in the revised general chapter, the proposed data quality triangle is reduced to three layers and expanded in scope as shown in Figure 1. The fundamental principles of this triangle apply to all laboratories as it did in the current general chapter. The foundation layer is analytical instrument qualification which is instrument centric. The other two layers of the data quality triangle are method validation and holistic tests including system suitability tests and process performance verification tests. What has been added is the role of the manufacturer/supplier which was not included in the current version and the expansion of the AIQ layer into the component parts of the 4Qs model. In the AIQ layer and supplier addition, the roles of each are made more explicit. Both method validation and holistic tests are based on a specific analytical method. This reinforces the fact that effective AIQ is vital for ensuring fitness for purpose because if the instrument is not fit for purpose the rest of the effort in the triangle is wasted.

USP <1058> uses a single system life cycle, in both the current and proposed update, that is based upon the 4Q's model:

- **Design Qualification (DQ):** defines the functional and operational specifications of the instrument and is the responsibility of the manufacturers and developers.
- **Installation Qualification (IQ):** establishes that an instrument is properly installed and that the environment is suitable for the instrument.
- **Operational Qualification (OQ):** documents that the system functions according to its operational specification in the user's environment after installation or major repairs. The system is released for regulated use after the successful completion of the OQ.
- **Performance Qualification (PQ):** demonstrates that an instrument in operational use consistently performs according to the specifications defined by the user using established practices to address operation, calibration, maintenance and change control.

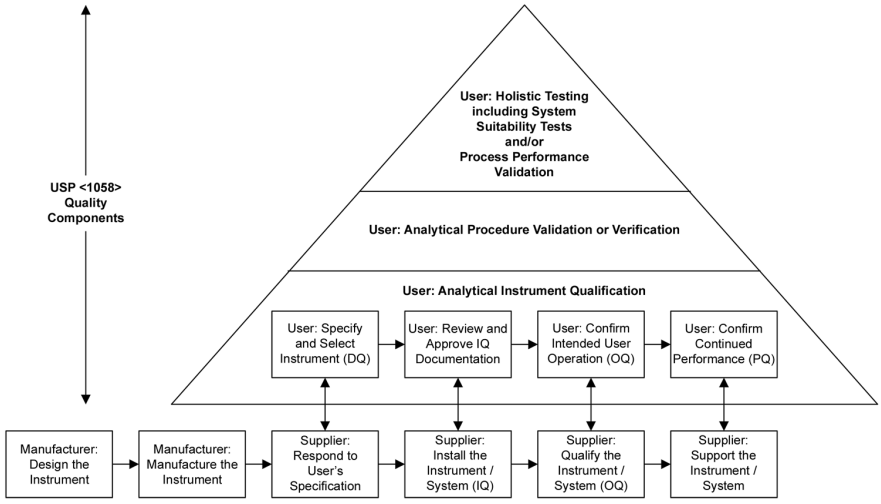

Figure 1. The Proposed USP <1058> Data Quality Triangle.

In the proposed draft, the data quality triangle is expanded to include more detail and the responsibilities of the user with respect to the 4Qs model plus also the responsibility of the instrument manufacturer and supplier - *Figure 1*.

Comparison between GAMP® 5 and USP <1058>

Both the GAMP® 5/Laboratory GPG and USP<1058> present a risk-based approach (using categorization) for compliant laboratory computerized systems (one based on software and one on hardware) and are designed to ensure that laboratory computerized systems are fit for purpose and operated in a controlled manner to produce the expected results.

While different terminology is used in the two publications, both aim to control computerized instruments and systems used in a regulated laboratory. Therefore, it is possible to map the two to determine the activities and approach to documentation as shown in Figure 2. Note that the sub division of instruments and systems shown in the figure will be discussed in more detail below under the section dealing with the revision of USP <1058>.

It is important to note key points from Figure 2 that establish the scope of harmonizing the USP and GAMP® 5 approaches.

1. GAMP® 5 exercises control of laboratory computerized systems through verification (software-driven) in contrast to USP <1058> which exercises control by qualification (hardware-driven).
2. Comparison between GAMP® 5 categories and USP <1058> groups are for illustrative purposes and it must be remembered that the GAMP® 5 categories represent a continuum.

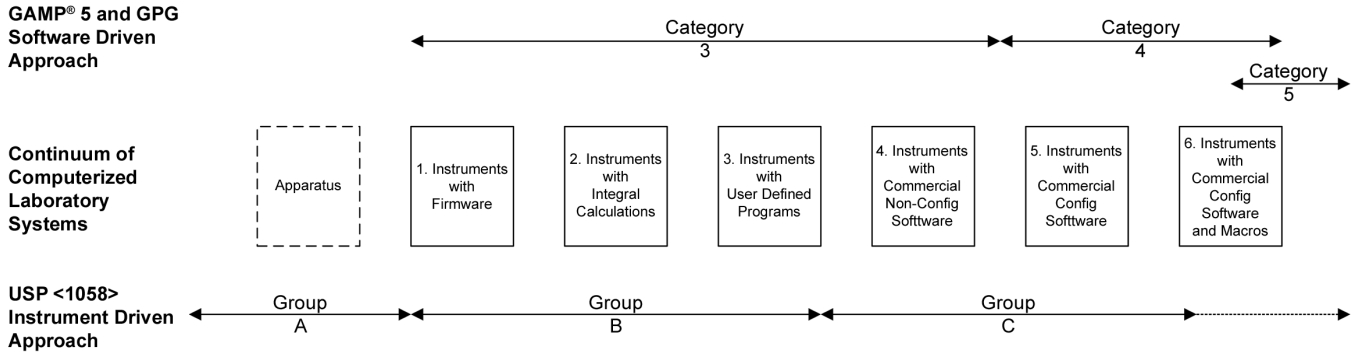

Figure 2. Mapping USP <1058> Instrument Groups and GAMP® 5 Software Categories.

3. USP<1058> Group A apparatus is not represented with the GAMP® 5 software categories as there is no software component nor any calibration requirement for these items.
4. USP <1058> groups B instruments and group C systems overlap with GAMP® 5 software Categories 3 and 4. However, USP<1058> does not include configurable and custom software elements described in GAMP® 5 Categories 4 and 5.
5. USP <1058> Group B items are essentially instruments controlled by firmware. GAMP® 5 Category 3 software covers a wide variety of instruments and systems, e.g., pH meters and analytical balances to chromatography and spectrometry data systems and consequently, requires a very efficient risk-based approach to identify the proposed use of the system, criticality of the records generated and the nature of the software used in the system to avoid wasting validation resources.
6. USP <1058> refers to the FDA guidance, General Principles of Software Validation13 for guidance on configurable and custom software elements. However, this guide is written principally for medical devices which are not customized (e.g., additional software code is written) or configured so that the business process automated remains the same. Therefore, there is a lack of guidance in USP <1058> for more complex software with or without custom modules.
7. The current USP <1058> recommends the use of qualification phases for analytical instruments while GAMP® 5 refers to specification and verification activities as described in ASTM E2500.[11] Though this represents a difference in terminology, the required activities are equivalent with the same outcome of demonstrating fitness for intended use against written specifications.

USP <1058> Term	Description	GAMP® 5 Verification Activity
Design Qualification	Documented Verification that the proposed design of system (specifications) and equipment is suitable for the intended purpose.	The Design Review is the assessment of this information to determine if the selected system matches their user requirements.
Installation Qualification	Documented verification that a system is installed according to written and pre-approved specifications.	Checking, testing, or other verification to demonstrate correct: • installation of software and hardware • configuration of software and hardware (See GAMP® 5 Appendix D5 for details)
Operational Qualification	Documented verification that a system operates according to written and pre-approved specifications throughout specified operating ranges.	Testing or other verification of the system against specifications to demonstrate correct operation of functionality that supports the specific business process throughout all specified operating ranges. (See GAMP® 5 Appendix D5 for details) Testing or other verification of the system to demonstrate fitness for intended use and to allow acceptance of the system against specified requirements. (See GAMP® 5 Appendix D5 for details)
Operational Release of Instrument of Laboratory Computerised System		
Performance Qualification	Documented verification that a system is capable of performing the activities of the processes it is required to perform, according to written and pre-approved specifications, within the scope of the business process and operating environment.	Operational controls Periodic reviews

Table A. Comparison of the USP <1058> 4Qs model versus GAMP verification activities.

A more detailed comparison of the two approaches can be seen in Table A which demonstrates equivalent activities of USP <1058> and GAMP® 5. It is presented from USP <1058> 4Qs model with the GAMP verification activities mapped. Note that under USP <1058> the operational qualification phase is equivalent to user acceptance testing and performance qualification is an activity when the system is operational compared with the traditional performance qualification for validation of laboratory computerized systems which equates to user acceptance testing. Therefore, a row in Table A indicating operational release of the instrument or system has been added to demonstrate equivalence between the two approaches.

An Integrated and Harmonized Approach – GAMP® Laboratory GPG and USP <1058>

In parallel to the second edition of the Laboratory Good Practice Guide, a stimulus to the revision process for USP <1058> chapter was submitted. The roots of this stimulus process can be traced back to the "round table discussion" on USP <1058> that took place

at the New Orleans AAPS meeting in November 2010. The authors of the <1058> stimulus paper were also invited to participate in the development of the GPG, creating the possibility of stronger alignment and harmonization of approach. The proposed <1058> stimulus paper included a new risk assessment and accompanying flow chart that is comprised of 16 questions, aligning the chapter with the principles of GAMP® 5.[14] This proposal is to provide a means of:

1. Differentiating Group A apparatus and Group B instruments based on their functionality and intended use
2. Incorporating risk assessment of the software elements contained in Group B instruments and Group C systems by identifying sub groups within groups B and C

The proposed risk assessment model[14] has been updated and published recently.[15] The risk assessment subdivides USP <1058> Groups B and C into the 3 categories each allowing greater granularity and flexibility in the approach to overall verification of function as shown below:

USP <1058> AIQ Inst Group	GAMP® 5 SW Category	Computerised Laboratory System Description	Verification Approach for Instrument	Verification Approach for Software
B	3	1. Instrument with firmware	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Implicitly validate the software functions of the instrument during instrument qualification
		2. Firmware instrument with in-built calculations	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Identify calculations used and input and output ranges • Implicitly validate the software functions of the instrument during instrument qualification • Check accuracy of the calculations during qualification
		3. Firmware instrument with ability for users to define routines	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Implicitly validate the software functions of the instrument during instrument qualification • Control user defined routines by SOP including specification of the routine, review of written code and testing against specification before release • Place under change control
C	4	4. Instrument controlled by non-configurable software	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Define user functions • Install and qualify software • Test whole system and software against user requirements • Place under change control
		5. Instrument controlled by configurable software	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Define user functions • Install and qualify software • Configure software • Test whole system and software against user requirements • Place under change control
	4+5	6. Instrument controlled by configurable software with custom additions	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Define user functions • Install and qualify software • Configure software • Specify, code and test custom elements • Integrate with application software • Test whole system and software user requirements • Place under change control

Table B. Harmonization of approach between GAMP® 5 and USP <1058>.

- Group A (apparatus) – no qualification impact (the risk assessment model also identifies instruments and systems with no GXP impact).
- Group B (instruments)
  1. Type 1 – Instrument firmware – requiring instrument qualification
  2. Type 2 – Instrument with software containing calculations – qualification required and calculations verified
  3. Type 3 – Instrument with software that is capable of end-user programs – qualification required plus control of user defined programs
- Group C (systems)
  1. Type 1 – Instrument with non-configurable software
  2. Type 2 – Instrument with configurable software
  3. Type 3 – Instrument with configurable software and customized macros

The reduced validation suggested by the stimulus paper is based on a risk-based approach for category 3 software using a single document to accomplish the complete validation.[16, 17]

Therefore, to harmonize the approach between GAMP® 5 and USP <1058>, there must be a mapping of GAMP® 5 software categories 3 to 5 with the proposed sub groups contained within Groups B and C. This is shown in Table B where the first two columns are the USP <1058> groups and the GAMP® 5 software categories respectively. The types of laboratory computerized systems possible are presented in the third column and the proposed verification approach that should be taken (contingent on the outcome of a risk assessment on the use of the system, process automated and the risk posed) is presented in the two right columns. These are split into instrument and software components of system. It is important to include two columns as the focus of GAMP® 5 is on software, but the analytical instrument functionality also must be tested.

Conclusion

Historically, there has been a tendency for people to align strongly with either USP <1058> or the GAMP® 5 Good Practice Guide. The different perspectives and approach of these two documents contributed toward this, but belied a commonality of intent and approach that may not have always been fully appreciated. Both publications strive to provide a guidance framework to support the activities necessary to ensure laboratory computerized systems are suitable for their intended use in GxP regulated environment, including the integrity of the data generated. Taking this commonality of approach further and mapping high level GAMP® 5 activities against USP <1058> provides a framework for understanding the inherent harmonization which already exists.

The updated ISPE GAMP® Good Practice Guide (GPG) Risk-Based Approach to GxP Compliant Laboratory Computerized Systems[7] has already been published. At the time the GPG was being finalized for publication, a stimulus to the revision process for USP <1058> chapter had been submitted, indicating the start of a revision cycle to <1058>. Prior to publication, expansion of the special interest group supporting the GPG development occurred, to include the authors of the <1058> stimulus paper which resulted in additional rich collaboration which contributed toward the development of the GPG.

“Taking this commonality of approach further and mapping high level GAMP® 5 activities against USP <1058> provides a framework for understanding the inherent harmonization which already exists.

The <1058> revision process will ultimately result in changes in its content and because of this, for pragmatic reasons, there were limits to how much information could be included in the GPG about <1058> at the time of publication (because of uncertainty over the extent to which it would change). The proposed expansion of <1058> defined in the stimulus paper and summarized in this document provides a further mechanism for even stronger harmonization of approach between USP <1058> and the GPG. The harmonization of these two approaches is important as they provide a consistent message and consistent guidance to users of computer laboratory systems in the GxP regulated environment. This reduces complexity and ultimately, well implemented harmonization can reduce compliance risks (because it reduces the diversity of approach/interpretation) and importantly in the current economic climate, reduce overall costs. As a comparison example, where pharmaceutical manufacturing validation has focused on reducing the cost of validation, the single biggest cost saving, approximately 30%, came from adopting standardized practices.[18]

The revision process for <1058> is on-going and changes will be made to the content of <1058> before the updated chapter is finalized and published. However, the sub categories contained in the current draft are based on practical experience of applying <1058>. Although the content of <1058> may change in the final version, the information contained within the draft and represented in this publication is of fundamental interest to achieving a harmonized

approach between GAMP and <1058>. Additionally, members of the GAMP community and readers of *Pharmaceutical Engineering* are encouraged to participate in the review process, when the proposed draft is published in Pharmacopeial Forum. This will help drive greater alignment.

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