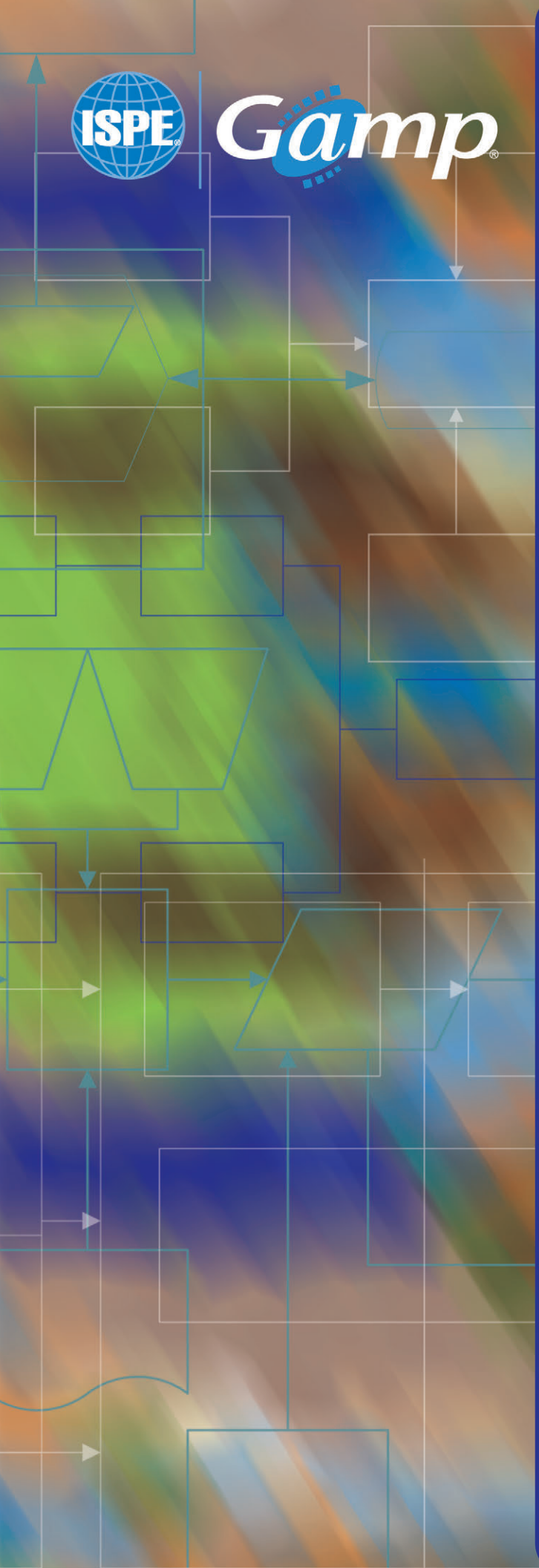

GAMP Good Practice Guide

A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems

Second Edition

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GAMP Good Practice Guide

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Second Edition

Disclaimer:
This Guide aims to provide a risk-based approach for defining a rational, scalable process to ensure that laboratory computerized systems are fit for intended use and compliant with applicable regulations. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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ISBN 978-1-936379-49-1

Preface

The ISPE GAMP® Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems represents a revision of the first edition, ISPE GAMP Good Practice Guide: Validation of Laboratory Computerized Systems and is intended as a supplement to ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems. This Guide provides an overview of the life cycle of laboratory computerized systems, from concept to retirement. It has been updated to align with the concepts and terminology of GAMP® 5 and regulatory and industry developments which focus attention on patient safety, product quality, and data integrity.

This revision:

- Describes a flexible categorization approach consistent with GAMP® 5, based on risks associated with the use of the system to support the relevant business process
- Applies the GAMP® 5 specification and verification approach to laboratory computerized systems
- Emphasizes the importance of leveraging supplier documentation and knowledge to avoid unnecessary duplication of efforts

This Guide provides direction for identifying, securing, and managing critical electronic records involved in regulated business decisions, consistent with recent regulatory guidance.

This Guide has been designed so that it may be used in conjunction with GAMP® 5 and other ISPE publications, such as the ISPE Baseline® Guides.

Appendices to this revision include examples for:

- Simple systems (e.g., pH meter, balance)
- Medium systems (e.g., HPLC)
- Complex systems

Additional appendices address concerns related to:

- Data integrity
- Defining electronic records and raw data
- Security management
- System interfacing considerations
- Robotics systems

The ISPE GAMP Community of Practice (COP) Laboratory Systems Special Interest Group (SIG) was asked to revise this Guide. The team consisted of representatives from regulated companies, Contract Research Organizations (CROs), suppliers of laboratory computerized systems, and independent consultants.

Acknowledgements

The production of the ISPE GAMP Good Practice Guide: Risk-Based Approach to GxP Compliant Laboratory Computerized Systems was initiated by the Laboratory Systems SIG at the request of the GAMP Council.

The following members of the GAMP COP Laboratory Systems SIG worked on one or more sections of this Guide and volunteered countless hours to attend meetings and review the many drafts, which were produced over a two year period. It has been informative and satisfying to work with such a dedicated group of professionals on this project.

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The GAMP Laboratory Systems SIG would like to acknowledge the support of their direct management and companies in this endeavor.

The GAMP Laboratory Systems SIG would like to express their thanks to the following who facilitated alignment of this Guide with USP <1058>, through valuable discussion, advice, and review comments:

Christopher Burgess	Burgess Analytical Consultancy Limited	United Kingdom
Horacio Pappa, PhD	US Pharmacopeial Convention	USA

The GAMP Laboratory Systems SIG would like to express their thanks to the following for their contributions:

Frank Behnisch	CSL Behring GmbH and GAMP DACH	Germany
Shelley Gutt	Covance, Inc.	USA
Heather Longden	Waters Corporation	United Kingdom
Rene Schuermann	Mettler Toledo	Switzerland
Marcus Zeitz	Novartis Pharma AG	Switzerland

Particular thanks go to the GAMP COP Editorial Review Board for their review and comment:

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Gail Evans	ISPE	United Kingdom
Colin Jones	Conformity Limited	United Kingdom
Randy Perez	Novartis Pharmaceuticals	USA
Sion Wyn	Conformity Limited	United Kingdom

The Leaders of the GAMP Laboratory Systems SIG wish to thank GAMP Council, GAMP Americas Steering Committee, and the Guidance Documents Executive Committee (GDEC) for their contributions and commitment throughout the production of this Guide.

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Table of Contents

1 Introduction

This Guide is a revision of the first edition of the ISPE GAMP Good Practice Guide (GPG) on this topic: GAMP GPG: Validation of Laboratory Computerized Systems. It has been updated to align with the concepts and terminology of GAMP® 5 [1], and recent regulatory and industry developments. These developments focus attention on patient safety, product quality, and data integrity.

GAMP® 5 and associated GPGs aim to provide guidance to achieve computerized systems that are fit for intended use and meet current GxP regulatory requirements by building upon existing industry good practice in an efficient and effective manner.

The approach and terminology is also harmonized with the following industry guidance:

- International Conference on Harmonization (ICH) Guidance including Q8, Q9, and Q10 [2, 3, 4]
- American Society for Testing and Materials (ASTM) Standard E2500, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment [5]

The approach is intended to align with the proposed update to United States Pharmacopoeia General Chapter, <1058> Analytical Instrument Qualification underway at time of publication [6].

For brevity, throughout this Guide, the term “system” refers to “laboratory computerized system” unless otherwise indicated.

GAMP is an ISPE Community of Practice. For further information, see www.ispe.org [7].

1.1 Rationale

The automation of laboratory testing and data management operations is increasing in sophistication and complexity. Widespread reliance on these technologies, along with their potential impact on data integrity, has brought an increased focus on the importance of appropriate selection, implementation, control, and maintenance of laboratory computerized systems.

Due to the wide diversity of systems, a single prescriptive approach would be neither practical nor cost-effective. For example, a High Performance Liquid Chromatograph (HPLC) with a Photo Diode Array (PDA) detector is much more complex than a pH meter, and will require a correspondingly more detailed and complex implementation, control, and maintenance approach.

The aim is to achieve compliance, efficiency, and effectiveness – within a reasonable budget and timeline – for a wide variety of systems. It is recognized that many laboratory computerized systems are now based on configurable packages, many of them networked.

Poor management of laboratory computerized system acquisition, implementation, and operation may result in:

- Failing to meet process and user requirements
- Unacceptable cost or time overruns
- Risk of non-compliance
- Data integrity issues

This Guide seeks to develop a rational approach to laboratory computerized system specification, verification, and implementation by:

- Examining the system life cycle and its applicability for most laboratory computerized systems
- Identifying characteristics that distinguish various types of laboratory computerized systems
- Developing a rationale for scaling activities and effort based upon risk, complexity, and novelty
- Defining a strategy for supplier assessments, and the effective leveraging of supplier knowledge, experience, and documentation
- Appling the GAMP® 5 [1] Quality Risk Management (QRM) approach
- Defining necessary operational and maintenance activities
- Recommending an approach to system retirement
- Leveraging deliverables and activities for very similar or identical systems

This flexible approach is aligned with industry trends and drivers and supports rapid implementation of low risk and less complex systems. The approach requires better knowledge of the business process and intended system use, but results in greater efficiency and productivity, and a focus on the most critical activities. As a Subject Matter Expert (SME), the laboratory scientist needs to understand the business process and the risks to the integrity of their data based upon intended use.

1.2 New and Revised Material

The previous edition of this Good Practice Guide classified laboratory computerized systems into discrete sub-categories based upon a set of criteria, such as configuration, interfaces, data processing, and data storage. This revision describes a flexible categorization approach consistent with GAMP® 5 [1], and based on the risks associated with the use of the system to support the relevant business process.

This revision applies the GAMP® 5 [1] specification and verification approach to laboratory computerized systems.

This revision emphasizes the importance of leveraging supplier documentation and knowledge, whenever possible, to avoid unnecessary duplication of efforts.

1.3 Purpose

As a Good Practice Guide supporting GAMP® 5 [1] this Guide provides a harmonized overview of the life cycle of laboratory computerized systems, from concept to retirement.

This Guide is intended for use by regulated organizations, suppliers, and regulators. The intended audience for this Guide includes laboratory, quality, and computer validation professionals responsible for defining and managing laboratory computerized systems in regulated life science industries. Information Technology (IT) support personnel, management, and laboratory systems users (who are an integral part of the process), software developers, and suppliers of laboratory computerized systems are also expected to find benefit in using this Guide. Suppliers include providers of software, hardware, analytical instrumentation, system integration services, and IT support services, both internal and external to the regulated organization.

This Guide builds upon the framework presented in GAMP® 5 [1] to provide a risk-based approach for defining a rational, scalable approach to ensure that laboratory computerized systems are fit for intended use and compliant with applicable regulations. The focus throughout is on *data integrity, product quality, and patient safety.*

GAMP documents are guides and not standards. It is the responsibility of regulated organizations to establish policies and procedures to meet applicable regulatory requirements. Consequently, it is inappropriate for suppliers of products to claim that they are GAMP certified, approved, or compliant.

It is recognized that there are acceptable approaches other than those described in this Guide. *The Guide is not intended to place any constraints on innovation and development of new concepts and technologies.*

1.4 Scope

This Guide addresses laboratory computerized systems used within the regulated life science industries, including pharmaceutical, biological, and medical devices that are subject to:

1. Good Manufacturing Practice (GMP)
2. Good Laboratory Practice (GLP)
3. Good Clinical Practice (GCP)
4. Medical Device Regulations (with the exception of software embedded within medical devices)

These are collectively known as GxP regulations.

For the purposes of this Guide, the term *laboratory computerized system* refers to systems supporting a wide range of laboratory processes, including analysis of drug products, in-process materials, Active Pharmaceutical Ingredient (API), excipients, environmental samples, clinical samples, or toxicology samples. These may include:

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

Systems within the scope of this 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.

Not all the activities defined in this Guide will apply to every system. The scalable approach enables regulated organizations to select the appropriate life cycle activities based upon risk.

IT systems, such as Laboratory Information Management Systems (LIMS), are not specifically addressed since the approach described in GAMP® 5 [1] is directly applicable. Equipment interfaced to such systems is; however, addressed (see Appendix 9). This Guide does not cover infrastructure aspects, except in reference to specific issues related to laboratory systems.

1.5 Business Benefits

There are major business benefits in having a defined process that delivers systems that are fit for intended use, on time, and within budget. Systems that are well defined and specified are easier to support and maintain, resulting in less downtime and lower maintenance costs.

Specific benefits to both regulated organizations and suppliers include:

- Reduction of cost and time taken to achieve and maintain compliance
- Early defect identification and resolution leading to reduced impact on cost and schedule
- Cost effective operation and maintenance
- Effective change management and process for continual improvement
- Enabling of innovation and adoption of new technology
- Providing frameworks for user/supplier co-operation
- Assisting suppliers to produce required documentation
- Promotion of common, consistent, system life cycle, language, and terminology
- Providing practical guidelines and examples
- Promoting pragmatic interpretation of regulations

1.6 Structure

1.6.1 Overview of GAMP Documentation Structure

This Good Practice Guide forms part of a family of documents that together provide a powerful and comprehensive body of knowledge covering all aspects of computerized systems good practice and compliance.