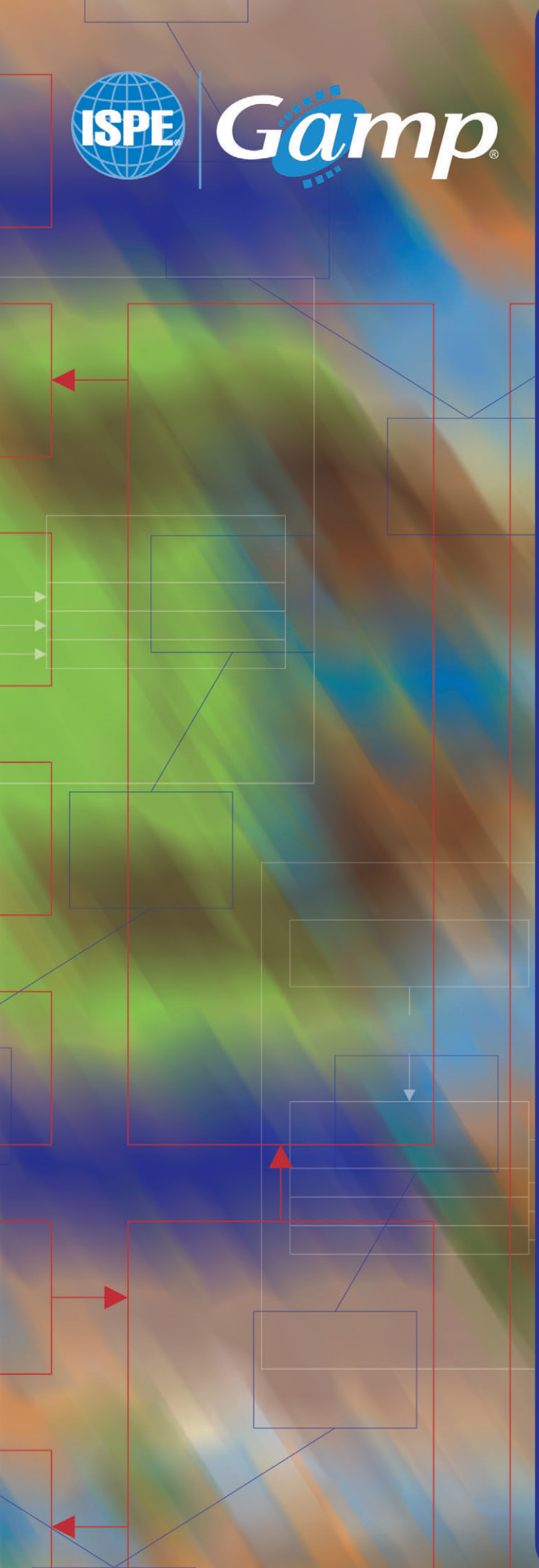

GAMP Good Practice Guide

A Risk-Based Approach to GxP Process Control Systems

Second Edition

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Disclaimer:
This Guide is meant to assist regulated companies in achieving and maintaining compliant process control systems that are fit for intended use. The International Society for Pharmaceutical Engineering (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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Preface

This GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems provides additional guidance and examples for the application of GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems to a range of GxP regulated process control systems.

This Guide also may be used in conjunction with the other ISPE guidance documents such as Good Practice Guides (GPGs) and Baseline® Guides.

This Guide has been produced by a GAMP® Community of Practice (COP) Task Team. This team included representatives from regulated companies and a wide range of suppliers, including OEMs, Integrators, and managing contractors.

Acknowledgements

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ISPE and GAMP COP Committees

Members of the ISPE GAMP COP Council and Steering Committees, along with the ISPE Guidance Documents Committees are thanked for their participation in the review of this Guide.

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1 Introduction

This Good Practice Guide (GPG) aims to achieve process control systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.

It provides recommended good practice based on a life cycle approach for the development and management of process control systems.

This Guide covers both regulated company and supplier Quality Management Systems, and is applicable across the full system life cycle from concept to retirement.

The Guide recognizes that Good Engineering Practice meets most of the applicable compliance requirements. The Guide also emphasizes that in order to be efficient, appropriate specification and verification activities should be an integral part of the normal system life cycle.

The Guide recognizes that many suppliers of systems now have mature quality management systems and system development, test, and support documentation. The Guide promotes the leveraging of supplier documentation and activities to avoid unnecessary duplication, cost, and waste.

Wherever possible, a range of examples across differing systems has been included to illustrate the approach and the scalability that may be applied. Examples are introduced in the body of the document, and expanded as appropriate in the Appendices.

The Guide applies science-based Quality Risk Management, as described in ICH Q9 (Reference 2, Appendix 13) and GAMP 5 (Reference 15, Appendix 13).

1.1 Rationale for this Revision

This revision has been significantly updated to align with the concepts and terminology of recent regulatory and industry developments including:

- International Conference on Harmonisation (ICH) Guidance setting out expectations for the application of science- and risk-based approaches to drug development and manufacture supported by pharmaceutical quality systems

- Product Quality Lifecycle Implementation® (PQLI®) – ISPE's global industry initiative for a practical approach to implementation of International Conference on Harmonisation (ICH) guidances Q8 (R2), Pharmaceutical Development, Q9, Quality Risk Management and Q10, Pharmaceutical Quality System (References 7, 1, 2, and 3, Appendix 13)

- FDA cGMPs for the 21st Century Initiative and associated guidance promoting science-based risk management (Reference 5, Appendix 13)

- Emerging industry standards such as those produced by the ASTM E55 Committee promoting process understanding, control and capability for drug development and manufacture (Reference 17, Appendix 13)

- ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment (under development at time of publication, Reference 13, Appendix 13)

Where the previous edition focused specifically on the validation of process control systems, this Guide has a wider scope. It describes good practice based on a complete life cycle approach for the development and management of compliant process control systems, reflecting the above developments.

1.2 Purpose

The purpose of this Guide is to provide a cost effective framework of good practice to ensure that process control systems are fit for intended use and compliant with applicable regulations. The framework aims to safeguard patient safety, product quality, and data integrity, while also delivering business benefit.

This Guide provides guidance and examples on the application of the principles and framework of GAMP 5 (Reference 15, Appendix 13) to a wide range of GxP regulated process control systems.

This Guide also provides suppliers to the life science industry with guidance on the development and maintenance of process control systems by following good practice.

This Guide also may be used in conjunction with the other ISPE publications such as Good Practice Guides (GPGs) and ISPE Baseline® Guides.

1.3 Scope

This Guide applies to process control systems used in GxP regulated activities, including development, manufacturing, and distribution of the product.

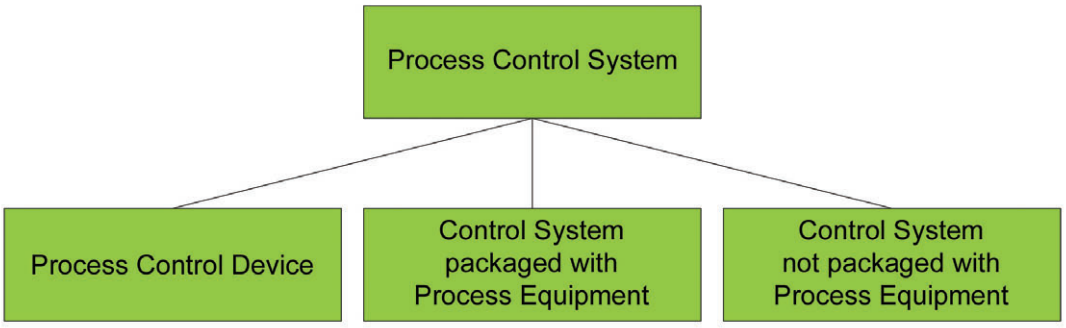
The scope covers a wide range, from basic instruments to large, complex, distributed control systems.

Process control systems may maintain electronic records and signatures subject to specific GxP regulations such as US FDA 21 CFR Part 11 (Reference 4, Appendix 13). Therefore, systems should be assessed to see if they fall within the scope of these or other applicable regulations. Detailed guidance can be found in the GAMP Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures (Reference 16, Appendix 13).

The overall IT infrastructure of the regulated company is outside the scope of this Guide. Analytical laboratory instruments are also outside the scope of this Guide. These topics are covered in separate GAMP Good Practice Guides.

This Guide distinguishes three types of process control systems. These are intended to be used in conjunction with GAMP categories to highlight system scale and complexity (often in terms of the range of suppliers involved), and to allow a common basis for presenting examples across a range of systems.

Figure 1.1: Types of Process Control Systems



Note that this division into “device,” “packaged with process equipment,” and “not packaged with process equipment” is independent of the GAMP category. Some examples are given below and more detail on categorization is given in Section 4.4 of this Guide.