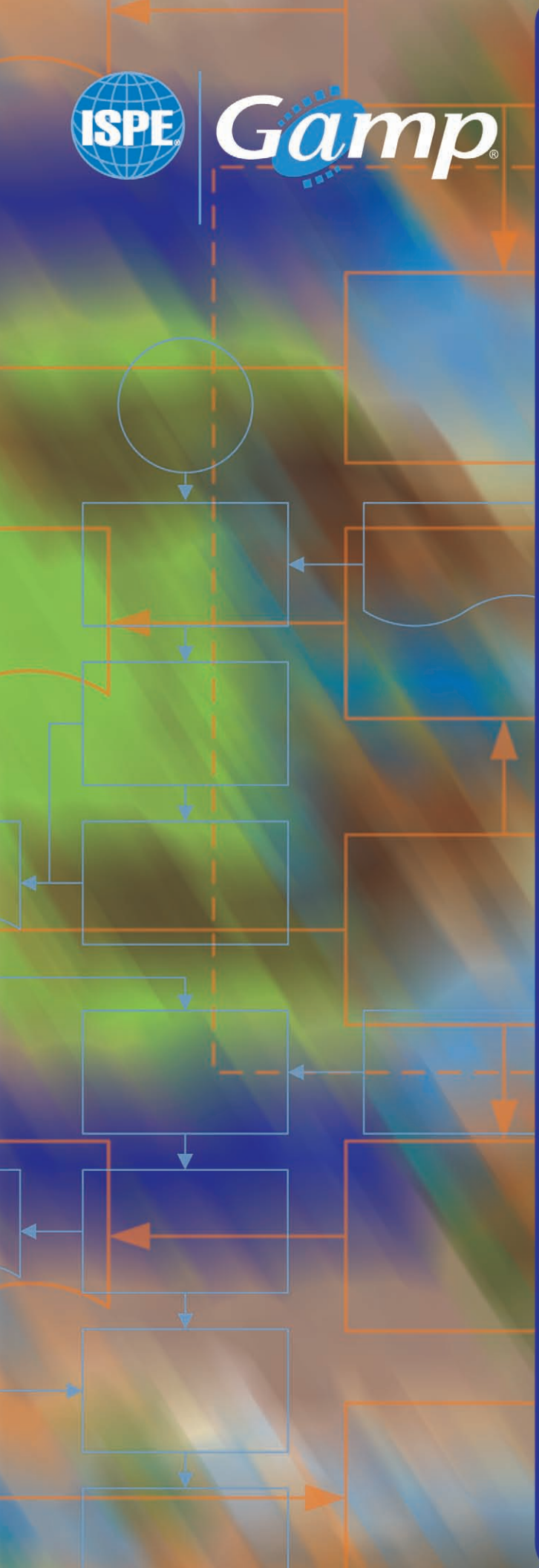

GAMP Good Practice Guide

A Risk-Based Approach to Operation of GxP Computerized Systems

A Companion Volume to GAMP® 5

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Disclaimer:
This Guide is meant to assist pharmaceutical organizations in determining a common understanding of the concept and principles of operation of GxP computerized systems.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

Regulated computerized systems should be maintained in a demonstrable state of control and in accordance with regulatory requirements. Maintained regulated data and records should be complete, accurate, and secure. Some regulated data and records need to be retained after system retirement.

For regulated organizations, the Return On Investment (ROI) for the significant time and resources expended in implementing new computerized systems is achieved during the Operation Phase. Recovery from a failure to maintain control of a regulated system during the Operation Phase can be both time-consuming and expensive, and increase the risk to data integrity, product quality, and patient safety.

The purpose of this ISPE GAMP® Good Practice Guide, a Risk-Based Approach to Operation of GxP Computerized Systems, is to provide detailed information to enable organizations to support their systems more effectively during the Operation Phase of the system life cycle.

It provides comprehensive guidance for maintaining control of regulated systems throughout their operational life (including acceptance and release, system handover, through to system retirement and decommissioning). When applied as intended, this Guide can provide detailed direction on the required control processes which form a substantial part of an appropriate Quality Management System (QMS).

This Guide focuses on achieving effective and efficient business processes aligned with regulatory expectations, by providing generic principles which can be applied to regulated systems using a systematic and scalable approach.

This Guide addresses the operational and support processes that need to be established to receive regulated computerized systems into the Operation Phase of their life cycle and to maintain them in a state of compliance throughout their operational life, through to system retirement.

It is applicable to systems consisting of hardware and software of all GAMP® categories.

Guidance provided is scalable and can be applied to a range of systems, including:

- laboratory systems
- process control systems
- IT applications

Whereas GAMP® 5 is primarily concerned with strategic approaches and planning of operational activities, this Guide contains more detailed information, including:

- a fuller consideration of process scope
- risk-based scalability considerations
- the appropriate assignment of roles and responsibilities
- identification of associated records
- example procedures

Process flow diagrams provided are intended to assist in making the process steps and their interrelationships clear and accessible. Wherever possible a common terminology has been adopted to describe the required management processes, to allow the guidance to be accessible to as wide a readership as possible.

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Section Writers and Reviewers

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1 Introduction

1.1 Overview

For regulated organizations, the Return On Investment (ROI) for the significant time and resources expended in implementing new computerized systems is achieved during the Operation Phase. The Operation Phase is usually significantly longer than the time spent in developing and delivering the system to the user community.

Regulated computerized systems should be maintained in a demonstrable state of control and in accordance with regulatory requirements. This applies to all components of the system (e.g., hardware, software, infrastructure, documentation, and personnel) throughout the system life cycle, from concept to retirement. Maintained regulated data and records should be complete, accurate, and secure. Some regulated data and records need to be retained after system retirement. Organizations should ensure that their integrity is assured for any required trending, re-evaluation, or inspection purposes within the defined retention period.

During the operational life of a GxP system, regulators usually focus on the integrity, consistency, and completeness of controls required to maintain compliance.

Recovery from a failure to maintain control of a regulated system during the Operation Phase can be both time-consuming and expensive, and increase the risk to data integrity, product quality, and patient safety.

Operational management controls should be established prior to acceptance and release and maintained throughout the Operation Phase of the system life cycle. Incidents and changes to systems should be managed effectively and efficiently, and the required records produced and retained.

These controls are similar to those employed to comply with the Sarbanes-Oxley (SOX) Act, the Federal Information Security Management Act (FISMA), and other regulations. All share common elements with ISO 20001 (ISO 17799) (Reference 4, Appendix 4).

1.2 Purpose

The purpose of this ISPE GAMP® Good Practice Guide, a Risk-Based Approach to Operation of GxP Computerized Systems (OGCS), is to provide detailed information to enable organizations to support their systems more effectively during the Operation Phase of the system life cycle.

It provides comprehensive guidance for maintaining control of regulated systems throughout their operational life (including acceptance and release, system handover, through to system retirement and decommissioning). When applied as intended, this Guide can provide detailed direction on the required control processes which form a substantial part of an appropriate Quality Management System (QMS).

This Guide focuses on achieving effective and efficient business processes aligned with regulatory expectations, by providing generic principles which can be applied to regulated systems using a systematic and scalable approach.

Risk-based controls should be implemented at a level of formality and complexity appropriate to an organization and system.

This Guide addresses the operational and support processes that need to be established to receive regulated computerized systems into the Operation Phase of their life cycle and to maintain them in a state of compliance throughout their operational life, through to system retirement.

It is applicable to systems consisting of hardware and software of all GAMP® categories.