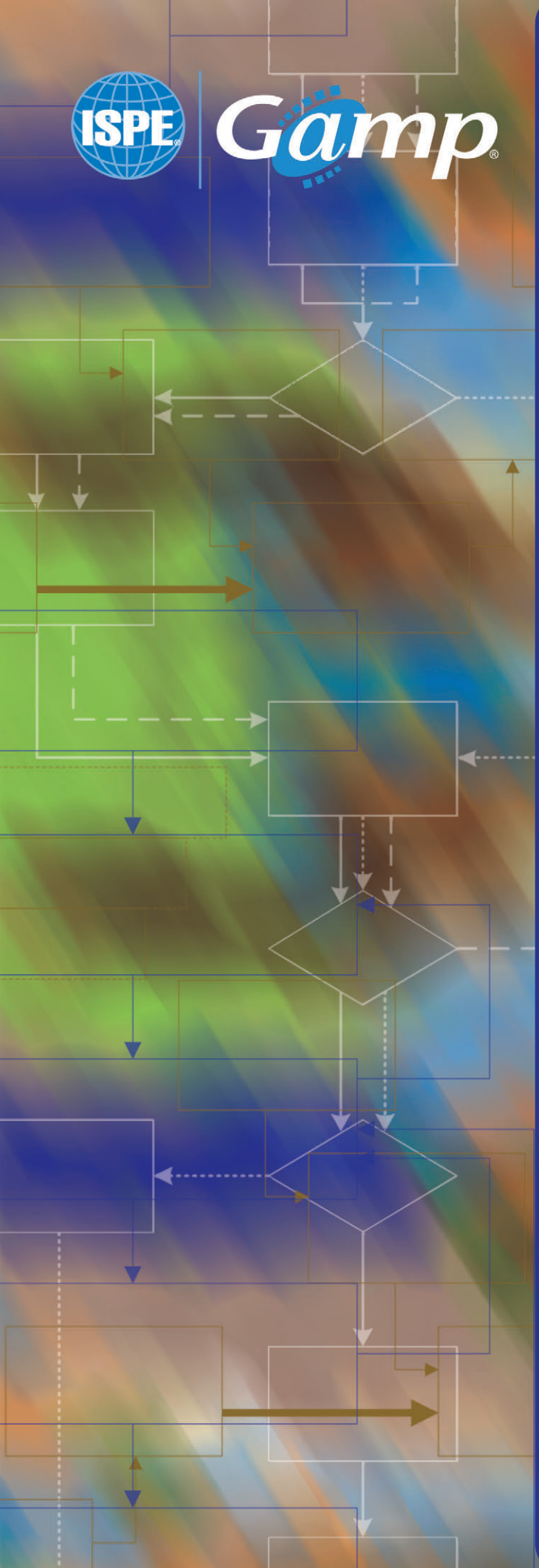

GAMP Good Practice Guide

A Risk-Based Approach to Testing of GxP Systems

Second Edition

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Disclaimer:
This Guide focuses on functional, structural, and performance testing of GxP systems and is intended to assist regulated organizations and suppliers to work together to ensure sufficient test coverage to guarantee fitness for intended use, while minimizing any duplication of effort. 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 978-1-936379-51-4

Preface

This document, the ISPE GAMP® Good Practice Guide: A Risk-Based Approach to Testing of GxP Systems, represents a revision of the first edition, ISPE GAMP® GPG – Testing and is intended as a supplement to ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems. This Guide focuses on functional, structural, and performance testing. 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.

The ISPE GAMP® Community of Practice Document Task Team was asked to revise this Guide. The team consisted of representatives from regulated organizations, contract research organizations, suppliers of pharmaceutical systems and equipment, and consultants.

Acknowledgements

The production of the ISPE GAMP® Good Practice Guide: Risk-Based Approach to Testing of GxP Systems was initiated by the Testing Task Team at the request of the GAMP® Council.

The following members of the GAMP® Community of Practice (COP) Testing Task Team worked on one or more sections of this Guide and volunteered countless hours to attend meetings and review the many drafts. The members committed to, and achieved, a challenging timescale for this substantial revision and their exceptional efforts are much appreciated.

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Within this highly professional and committed team, special thanks are due to David Stokes, Kimberly Stanton, and Steve Tinson for their expertise in innovative technologies and methodologies, and their dedication in formulating the guidance in these areas.

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The GAMP® Testing Task Team would like to acknowledge the support of their direct management and companies in this endeavor.

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

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The Leaders of the GAMP® Testing Task Team wish to thank GAMP® Council, GAMP® Europe 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

1.1 Overview

This Guide is a revision of the first edition of the ISPE GAMP® Good Practice Guide (GPG): A Risk-Based Approach to Testing of GxP Systems. It has been updated to align with the concepts and terminology of GAMP® 5 [1], associated GAMP® guidance, 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. This Guide builds on the framework described in GAMP® 5, and provides detailed guidance on testing GxP systems.

GAMP® is an ISPE Community of Practice (COP). For further information, see www.ispe.org [2].

The approach and terminology used in this Guide are generally harmonized with the following industry guidance:

- International Conference on Harmonization (ICH) Guidance including Q8 [3], Q9 [4], and Q10 [5]
- ASTM Standard E2500-07, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment [6]
- EU GMP EudraLex Volume 4 (Chapter 4) [7] and Annex 11 [8]

This edition of the Guide also has been aligned with advances in industry best practice, including:

- Increased adoption and implementation of Process Analytical Technology (PAT) and Quality by Design (QbD)
- Increased industry focus on risk-based approaches
- Increased use of non-linear development life cycles
- Increased use of automated test tools

Consideration should be given to the existing policies and procedures within a regulated organization and to other external industry standards and practices when applying the principles described in this Guide.

1.2 Purpose

This Guide has been written to provide regulated organizations and suppliers with pragmatic guidance on the testing of computerized and software based systems that impact patient safety, product quality, and data integrity. The key objective of this Guide is to encourage regulated organizations and suppliers to work together to ensure sufficient test coverage to guarantee fitness for intended use, while minimizing any duplication of effort.

The Guide seeks to identify the testing that should be performed and the associated level of documentation. Where suppliers' systems do not meet the expectations of a regulated organization, the Guide identifies suitable risk control strategies. These strategies can include the execution of additional testing, or the selection and use of alternative suppliers or products, by the regulated organization.