



GOOD PRACTICE GUIDE:

# Global Information Systems Control and Compliance

Second Edition





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**Disclaimer:**

This Guide is intended to provide a risk-based approach to implementing and supporting regulated global information systems. 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 document, the *ISPE GAMP® Good Practice Guide: Global Information Systems Control and Compliance (Second Edition)*, is intended to be used in conjunction with *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* and other ISPE GAMP® guidance documents. It considers major issues related to multi-site computerized systems, and provides guidance on effective and efficient control and compliance of globally deployed IT systems throughout their life cycle.

This Second Edition is aligned with the Quality Risk Management and life cycle approaches defined in *ISPE GAMP® 5*. It reflects the move away from client-server application architecture, which was prevalent at the time of publication of the First Edition. This edition also covers Software as a Service (SaaS) and other cloud solutions, which can be economical options for global systems.

# Acknowledgements

The Guide was produced by a Task Team led by Arthur (Randy) Perez (Novartis (retired)). The work was supported by the ISPE GAMP Community of Practice (COP).

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# 1 Introduction

## 1.1 Background

Since the publication of the first edition of this Guide in 2005 there has been a continuing trend towards factors that complicate the landscape. Among the most significant are:

- Globalization in the life-science industries. This includes consolidation through mergers, outsourcing, and a trend toward fewer manufacturers making specific products, intermediates, and raw materials.
- The use of cloud technologies
- Expansion of applications to cover many areas that used to be managed by dedicated systems, e.g., Enterprise Resource Planning (ERP) systems that include a Laboratory Information Management System (LIMS) module

As organizations find themselves operating from multiple sites worldwide, with groups and departments split between multiple locations in a country, or even using third party distributors, the challenges of information sharing become more complex. There are many competitive advantages to efficient and effective information sharing. Research and development activities often cross international boundaries. Integrated activities can be achieved only with excellent communication between everyone involved, and this means that the ability to share electronic information effectively is a primary concern.

With escalating drug development costs, time to market is a significant factor in recouping investment, and ineffective information sharing can become a major cost factor if it slows down approval to market.

There are many ways to share information. An interface between applications can be a major requirement for different systems that facilitate integrated business processes. For processes that are conducted at multiple sites, however, there are clearly advantages to all participants using the same suite of software systems.

The implementation of multi-site computer systems can be difficult. Regulatory compliance creates an additional challenge for regulated systems such as a clinical database or an ERP system. This Guide considers major issues that confront organizations implementing and operating a regulated multi-site computerized system.

### 1.1.1 Drivers

The technical and regulatory landscape has also changed since the publication of the first edition of this Guide. In addition to the issues noted above, important factors include:

- The move away from client-server application architecture, upon which the first edition was based, but which is far less common today
- The substantial improvements in the power of applications
- The growth of outsourced services
- Beyond the simple use of cloud-based infrastructure, web-based Software as a Service (SaaS) can be a cost-effective option for global information systems
- The revision of EU GMP Annex 11 [1] and EU GMP Chapter 4 [2] (both adopted for wider use by PIC/S [3])
- The Quality Risk Management and Specification and Verification approach, such as that defined in *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* [4]