



GOOD PRACTICE GUIDE:

# Enabling Innovation

*Critical Thinking, Agile,  
IT Service Management*





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The *ISPE GAMP® Good Practice Guide: Enabling Innovation – Critical Thinking, Agile, IT Service Management* seeks to apply *ISPE GAMP® 5* principles and current good practice to these areas to promote innovation and advancement. This Guide is solely created and owned by ISPE. It is not a regulation, standard or regulatory guideline document. 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

The drive within life sciences to improve patient safety and product quality, and provide value to society, while simultaneously reducing costs requires constant and effective innovation. Operating in a highly regulated sector can result in some practitioners applying unthinking, prescriptive, and rigid approaches that are not commensurate to the needs of the process, the nature of the system, and the real risk to the product and the patient.

This *ISPE GAMP® Good Practice Guide: Enabling Innovation – Critical Thinking, Agile, IT Service Management* discusses three topic areas where regulated companies can apply innovation to meet rapidly changing industry needs. This Guide facilitates the effective and efficient use of valuable resources by the application of appropriate and proportionate practices, so that companies can introduce innovative approaches to reduce risk to patient safety, product quality, and data integrity.

This Guide is aligned with the concepts and framework of the *ISPE GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems*.

# Acknowledgements

The Guide was produced by a Task Team led by Heather Watson (GlaxoSmithKline, United Kingdom), Chris Clark (TenTenTen Consulting Limited, United Kingdom), and Sion Wyn (Conformity Ltd., United Kingdom). The work was supported by the ISPE GAMP Community of Practice (CoP).

## Core Team

The following individuals took lead roles in the preparation of this document.

|                         |                             |                |
|-------------------------|-----------------------------|----------------|
| Mark Cherry             | AstraZeneca                 | United Kingdom |
| Chris Reid              | Integrity Solutions Limited | United Kingdom |
| Judith Samardelis       | Syneos Health               | USA            |
| Lorrie Vuolo-Schuessler | Syneos Health               | USA            |
| Charlie Wakeham         | Waters Corporation          | Australia      |
| Guy Wingate             | GlaxoSmithKline             | United Kingdom |

## Contributors

The Leads thank the following individuals for their valuable contribution during the preparation of this Guide.

|                    |                                     |                |
|--------------------|-------------------------------------|----------------|
| Karen Ashworth     | Karen Ashworth Consulting Ltd.      | United Kingdom |
| Carsten Bierans    | Körber Business Area Pharma         | Germany        |
| Stephen Ferrell    | Compliance Path Ltd.                | USA            |
| James Gunning      | Johnson Matthey                     | USA            |
| Frank Henrichmann  | QFINITY                             | Germany        |
| Oliver Herrmann    | QFINITY                             | Germany        |
| Paul James-Martin  | Integrity Project Solutions Limited | United Kingdom |
| Kevin C. Martin    | Azzur Group LLC                     | USA            |
| Andrew McDonagh    | Emergn                              | United Kingdom |
| Elizabeth McLellan | Suvoda, LLC.                        | USA            |
| Khaled Moussally   | Compliance Group                    | USA            |
| Ray Murphy         | Boston Scientific                   | USA            |
| Donal O'Brien      | Dassault Systèmes                   | Ireland        |
| Michael Osburn     | Cornerstone OnDemand                | USA            |
| Randy Perez        | Novartis (retired)                  | USA            |
| Jens Seest         | Novartis                            | Germany        |
| Ken Shitamoto      | Gilead Sciences, Inc.               | USA            |
| Andy Tyrrell       | Cornerstone OnDemand                | United Kingdom |
| Anders Vidstrup    | NNIT A/S                            | Denmark        |
| Mark Walton        | Cornerstone OnDemand                | United Kingdom |
| Anette Westphal    | Novo Nordisk A/S                    | Denmark        |
| Christopher White  | National Resilience, Inc.           | USA            |

## Regulatory Input and Review

Particular thanks go to the following for their review and comments on this Guide:

|                               |   |         |
|-------------------------------|---|---------|
| Arno Terhechte, GMP Inspector | Bezirksregierung Münster<br>(District Gouvernement Münster) | Germany |
|-------------------------------|---|---------|

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Company affiliations are as of the final draft of the Guide.



600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA  
Tel: +1-813-960-2105, Fax: +1-813-264-2816

[www.ISPE.org](http://www.ISPE.org)

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# 1 Introduction

The ISPE GAMP® Community of Practice (CoP) [1] promotes the understanding of regulations and use of GxP computerized systems within the pharmaceutical, biopharmaceutical, medical device, and other regulated industries. *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* [2] is the leading international guidance document in this area:

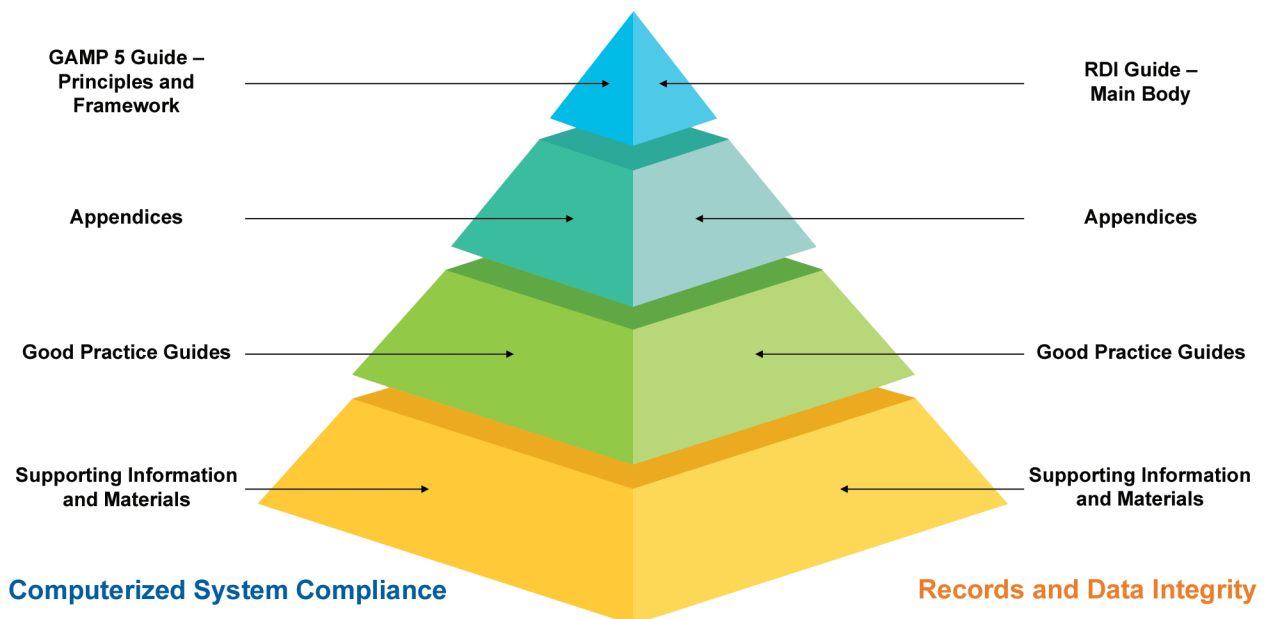
*“GAMP® guidance aims to achieve computerized systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner”* to safeguard patient safety, product quality, and data integrity.

This *ISPE GAMP Good Practice Guide: Enabling Innovation* discusses critical thinking, incremental and iterative (Agile) software development models and methods, and IT service management. By applying *ISPE GAMP 5* [2] principles and current good practice, the GAMP CoP seeks to enable life-science industry innovation and advancement in these areas. This *ISPE GAMP Good Practice Guide: Enabling Innovation – Critical Thinking, Agile, IT Service Management* shows how these concepts are interwoven: applying critical thinking when leveraging software development practices, and using both concepts to effectively manage IT/IS service providers.

## 1.1 GAMP Guidance

This Guide is part of a family of guidance documents<sup>1</sup> that provide a comprehensive body of knowledge covering all aspects of GxP computerized systems good practice and compliance.

Figure 1.1: GAMP Documentation Structure



<sup>1</sup> For more information on the GAMP CoP and GAMP documentation, see [www.ispe.org](http://www.ispe.org) [3].