

ISPE GAMP® Community of Practice

Geetanjali Abbi
Heather Longden

October 2nd 2024



Geetanjali Abbi (Geetu) is a highly experienced leader in Computer System Validation & Compliance, with over 16 years of industry knowledge. Currently serving as the Head of Digital Quality at Alkermes, she oversees a global team and strongly emphasizes the importance of continuous learning and improvement. She encourages her team to think innovatively and create effective risk-based strategies.

Geetu graduated from DIT University in India in 2002 with a degree in Information Technology. Her passion for software quality led her to begin her career as a Testing Lead, later transitioning to CS Validation. Throughout her professional journey, she has been a strong advocate for Quality by Design (QbD) and has successfully delivered numerous digitalization projects in areas such as manufacturing, quality systems, clinical, information technology, and labs.

If you can't explain it simply; you
don't understand it well

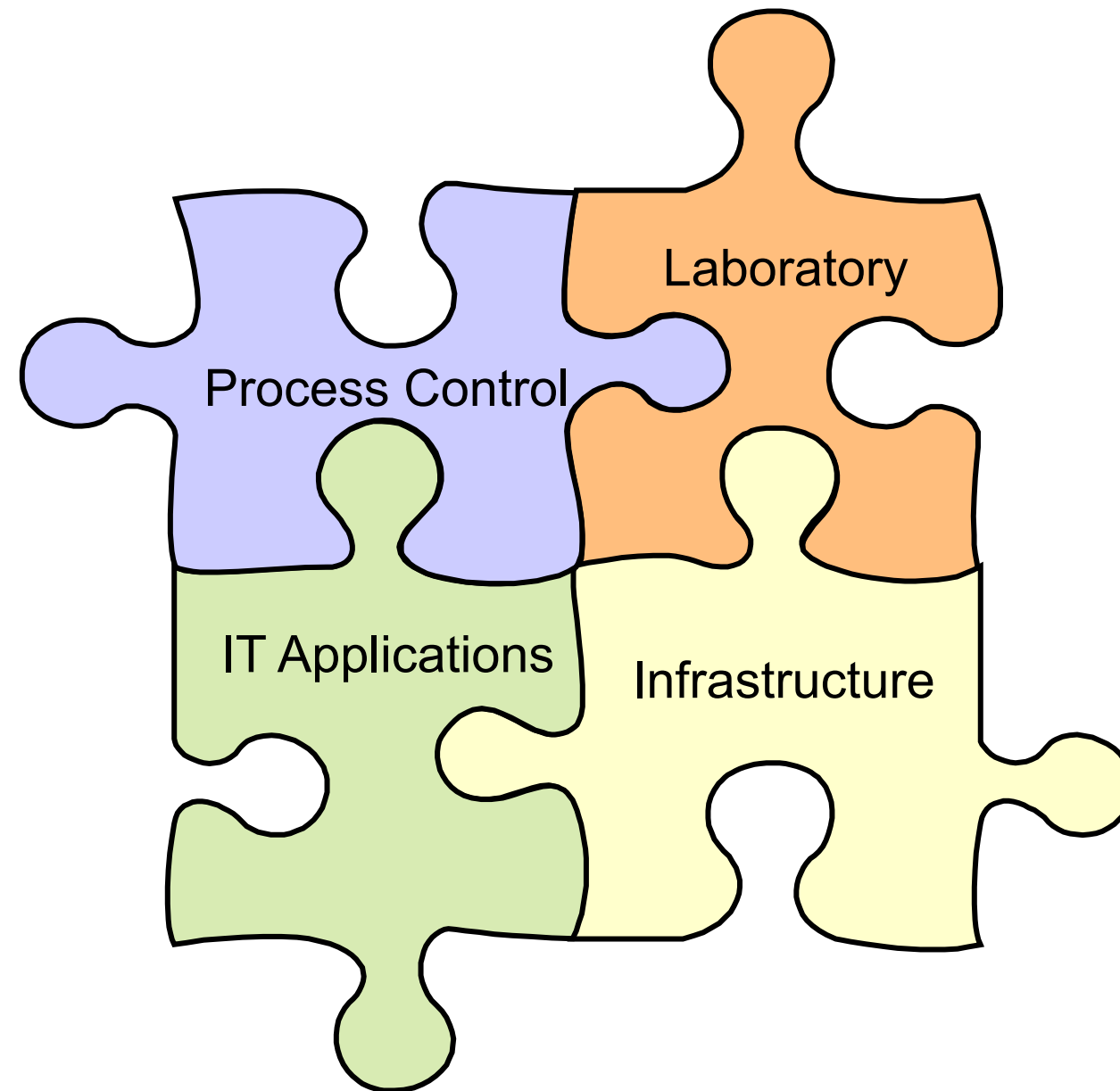
Albert Einstein

GAMP CoP

The ISPE GAMP Community of Practice (CoP) promotes the understanding of the regulations and use of computerized systems, control systems and intelligent instruments within the pharmaceutical, biopharmaceutical, medical device industries and other regulated healthcare institutions.

patient safety
product quality
data integrity

GAMP®5 Scope & Application



GAMP at-a-Glance

5000+ Members

Established in 1991

8 Global Special
Interest Groups

17 Local CoPs
Europe, Americas, &
APAC



20 Good Practice
Guides

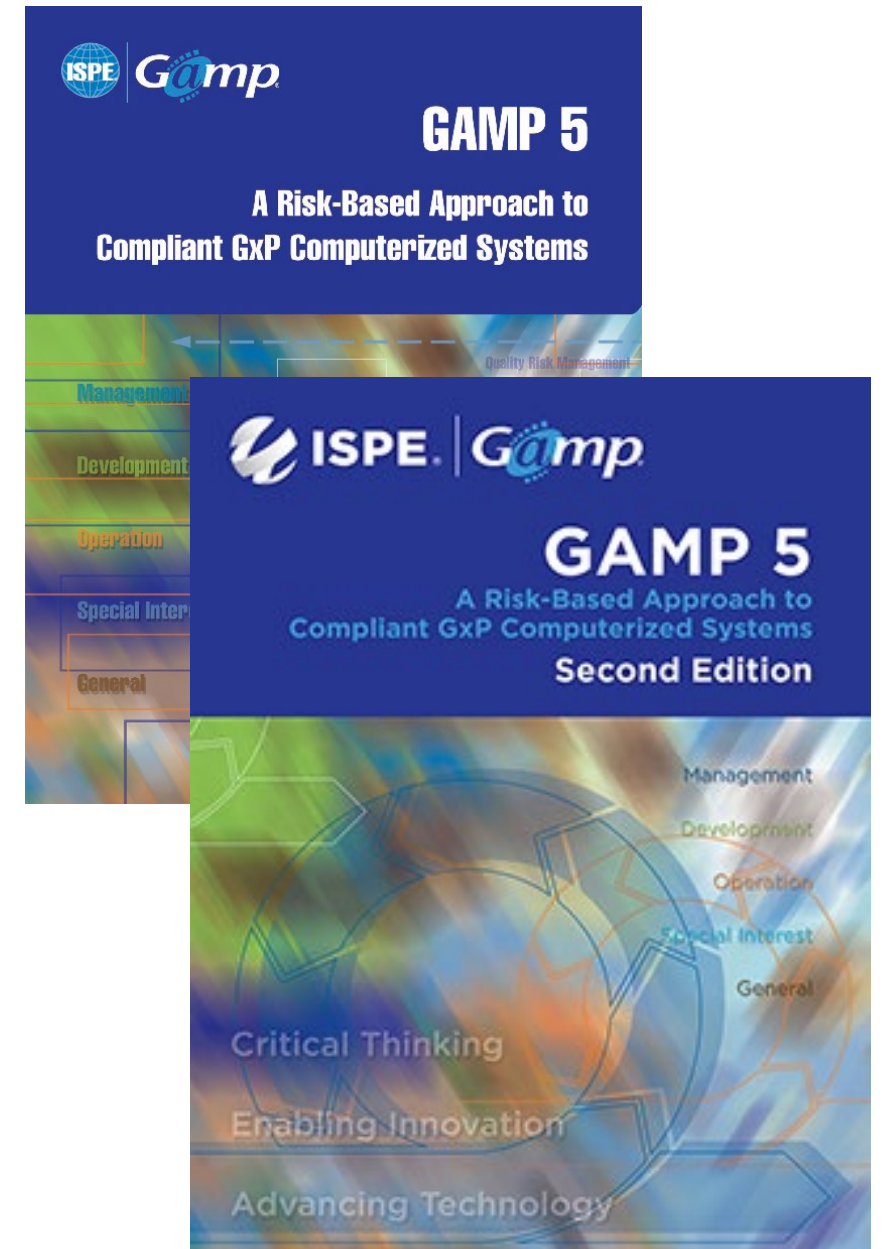
5 ISPE International
Board Chairs

11 Individual Honor
Awards

5 Committee Honor
Awards

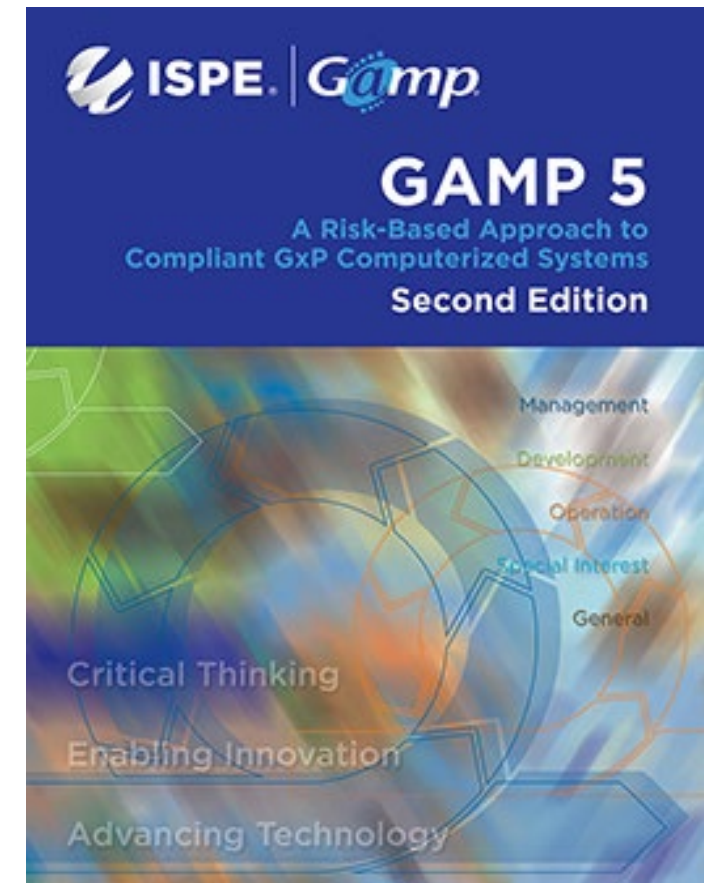
GAMP® 5 Baseline Guide

- The leading industry guidance on Computer Systems Compliance
- Significant regulatory input
- A common international framework for all
- Available in several languages
- Updated to GAMP® 5, 2nd Edition in 2022



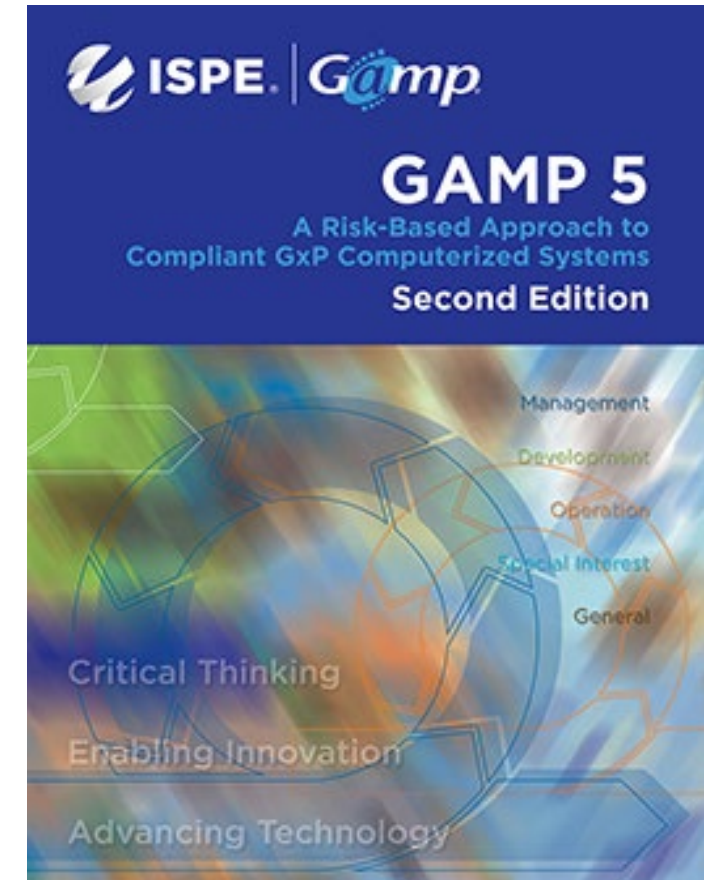
GAMP® 5 Second Edition

- New Content
 - Agile
 - Software Tools
 - Distributed Ledger Systems (Blockchain)
 - Artificial Intelligence and Machine Learning (AI/ML)
 - Critical Thinking



GAMP® 5 Second Edition

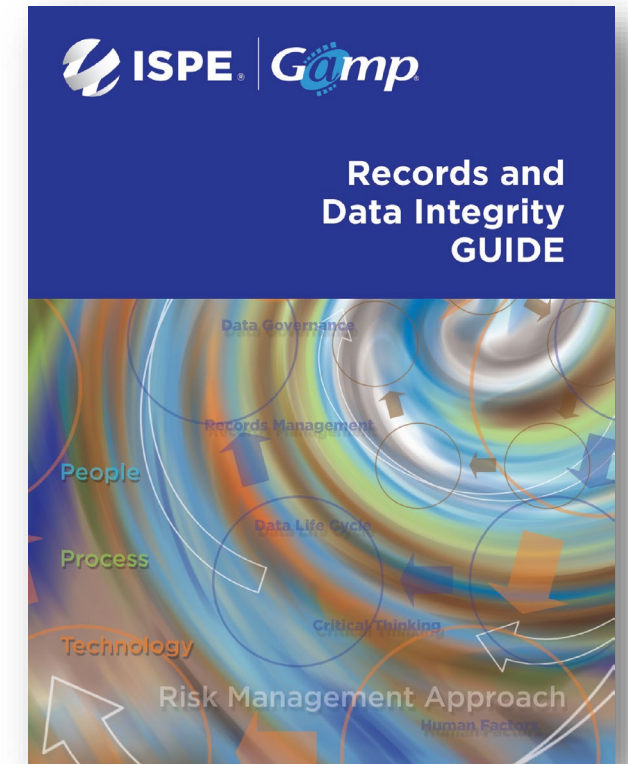
- Updated topics
 - Specifying Requirements
 - Electronic Production Records
 - Operation Phase and IT Service Management



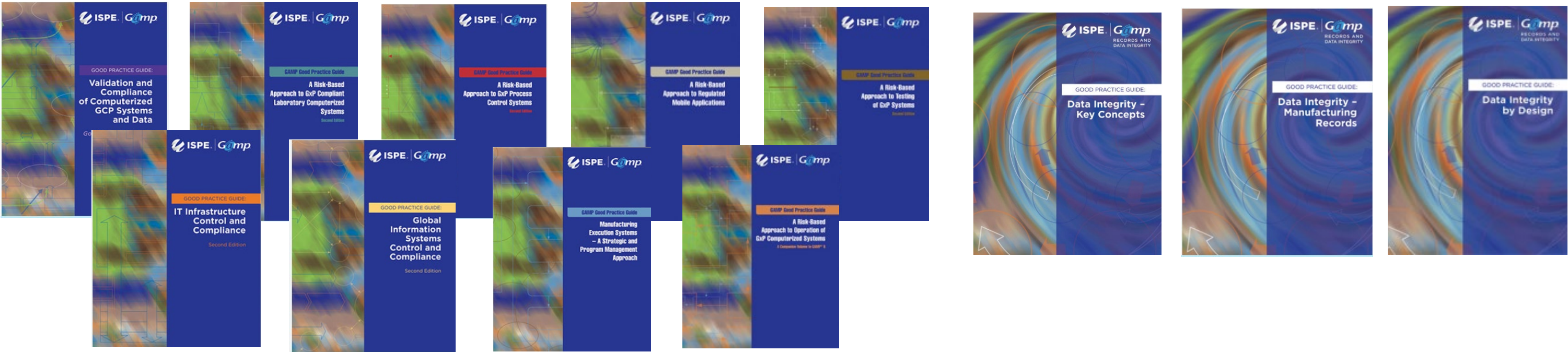
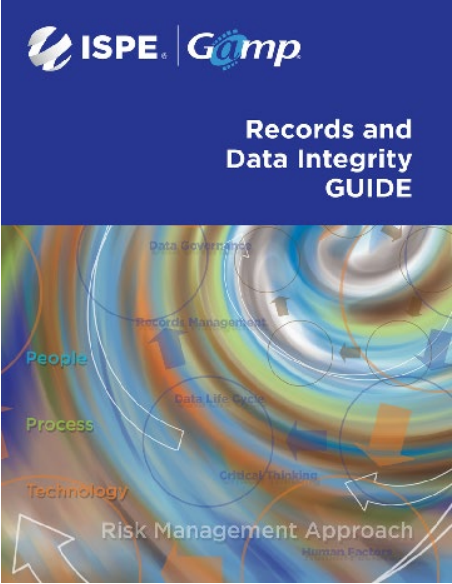
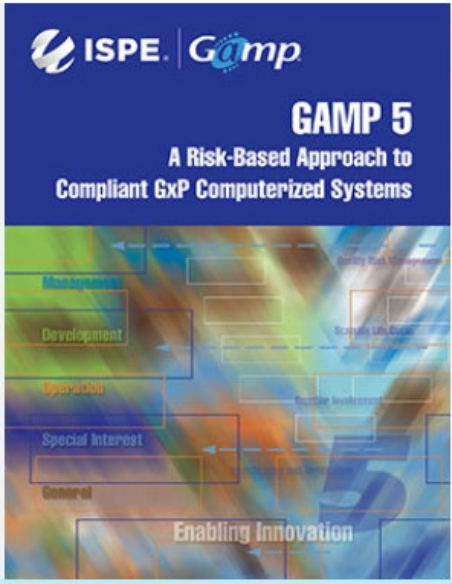
GAMP® Records and Data Integrity Baseline Guide

Key benefits:

- Data integrity requirements, critical areas of regulatory focus and concern, and key concepts
- Data governance and the importance of human factors
- Data life cycle approach as part of a Quality Management System (QMS)
- Applying the Quality Risk Management (QRM) approach to record and data integrity
- “How to” guidance for specific topics, in a series of
 - management,
 - development,
 - operation appendices



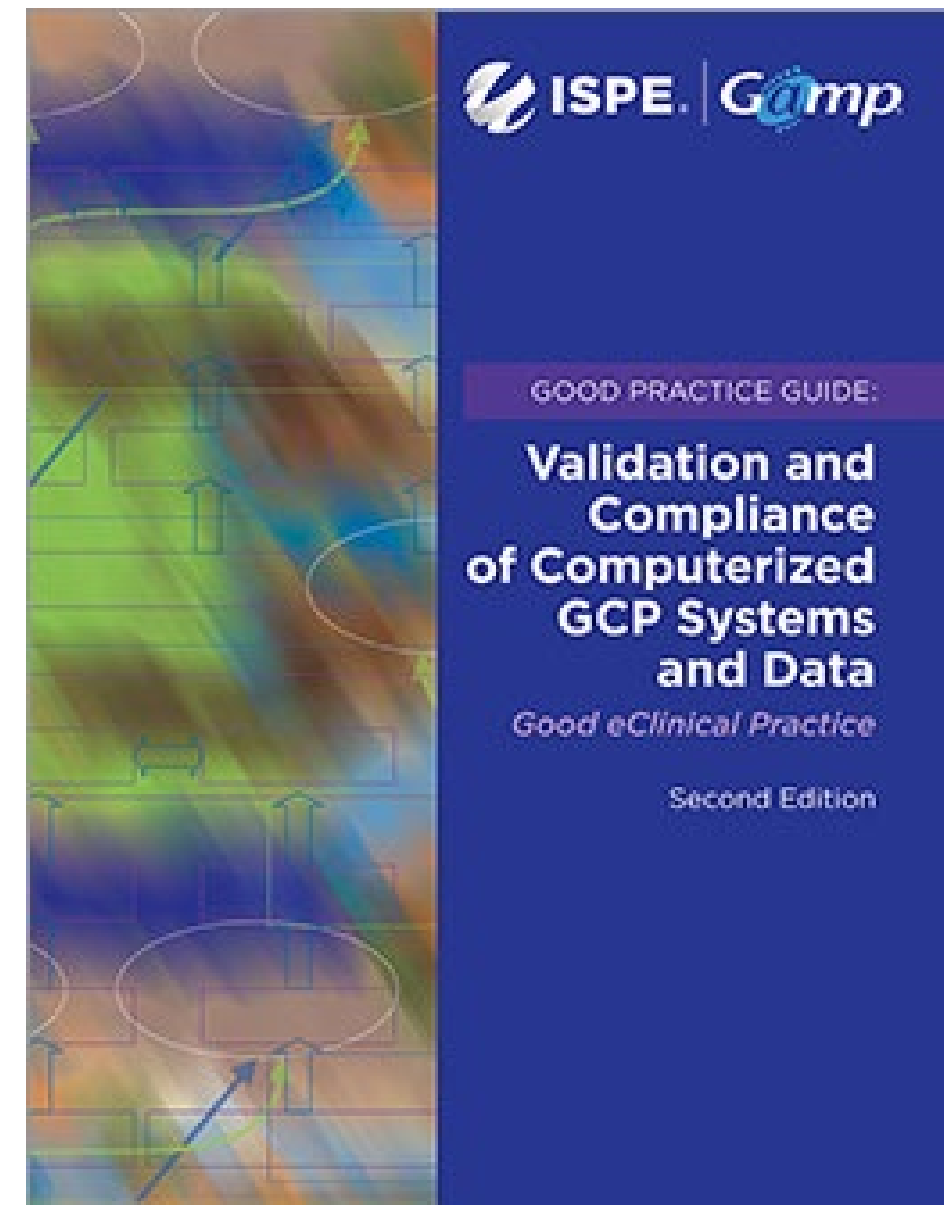
GAMP® Guidance - Good Practice Guides (GPGs)



Newest Good Practice Guides

Computerised GCP Systems

- Understanding GCP business processes
- Unique risks with clinical data
- Managing data on multiple platforms across multiple companies/sites
- Challenges of DI and describing dataflows wrt outsources services and technology



GAMP Good Practice Guide

Validation and Compliance of Computerized GCP Systems and Data 2nd Edition

Ch 01 Introduction

Ch 02 Scope

Ch 03 Regulatory Overview

Ch 04 Process Overview

Ch 05 Process Model

Ch 06 Data Integrity

Appendix 1 Data Privacy

Appendix 2 Decentralized Clinical Trials

Appendix 3 Assessment of Clinical Site Systems

Appendix 4 GCLP

Appendix 5 The Use of Data Science - AI enabled Systems

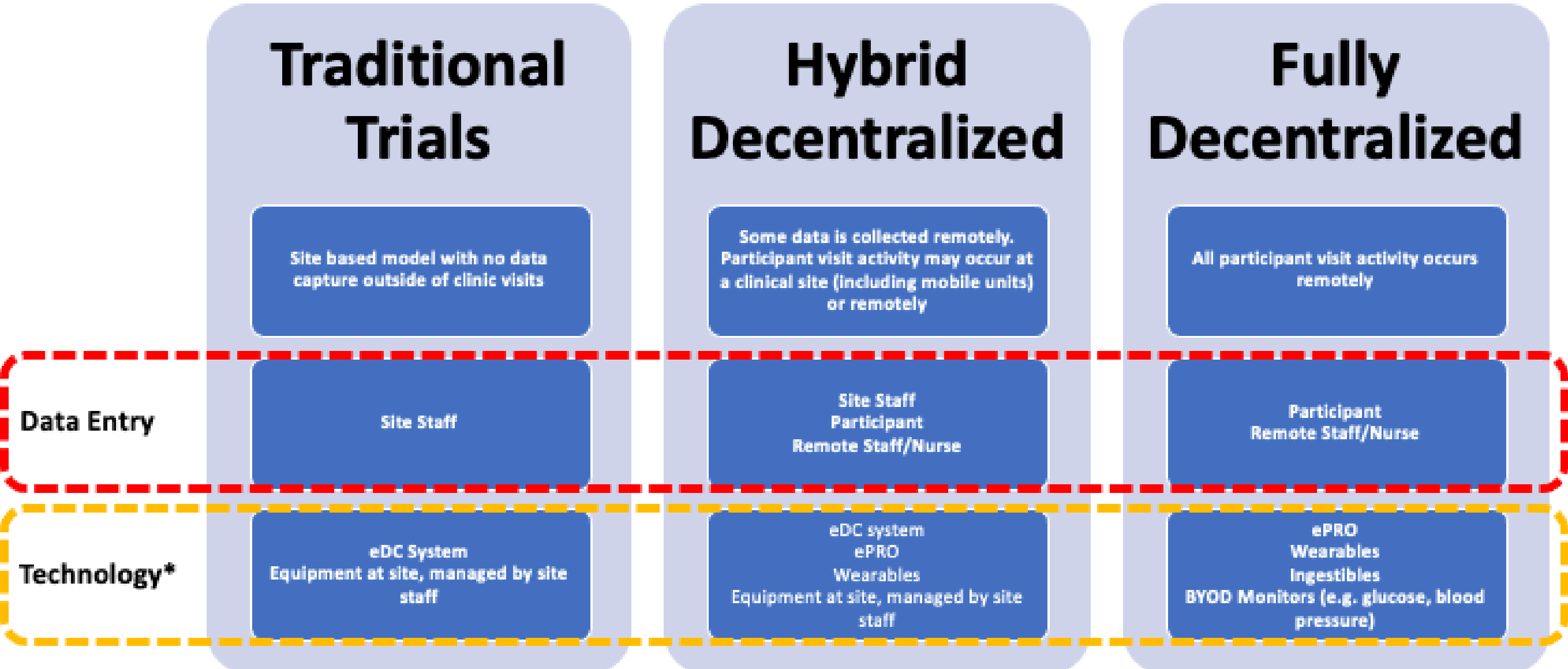
Appendix 6 RWD RWE

Appendix 7 Open Source Software

**SCHEDULED FOR
PUBLICATION IN
JULY 2024**

**MORE THAN
180 PAGES OF
NEW CONTENT!**

Decentralized Clinical Trials

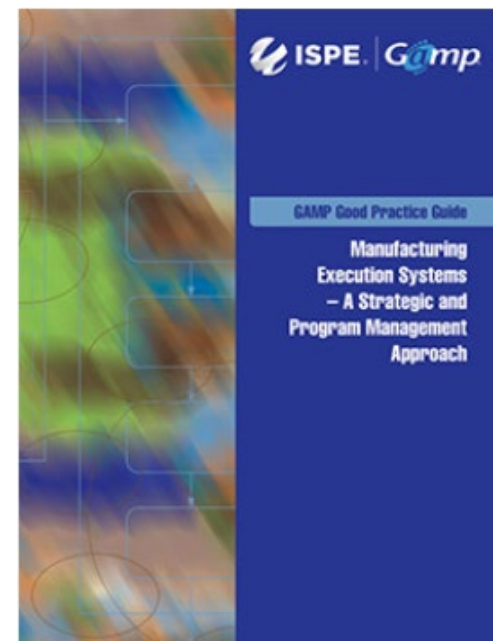


* Example of technologies, but not limited to these

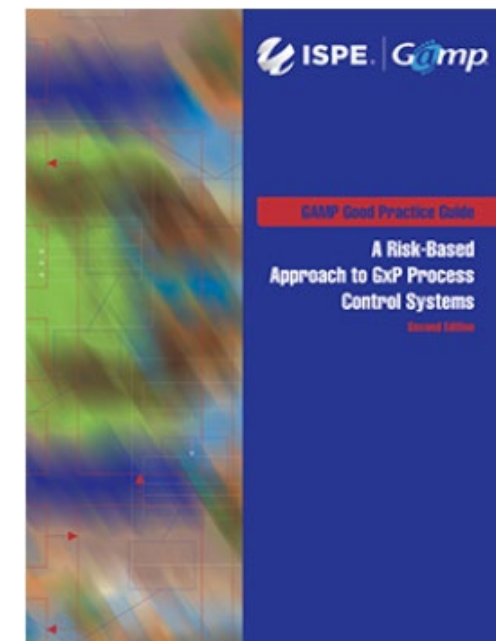
Interesting Validation Guides



IT
Infrastructure



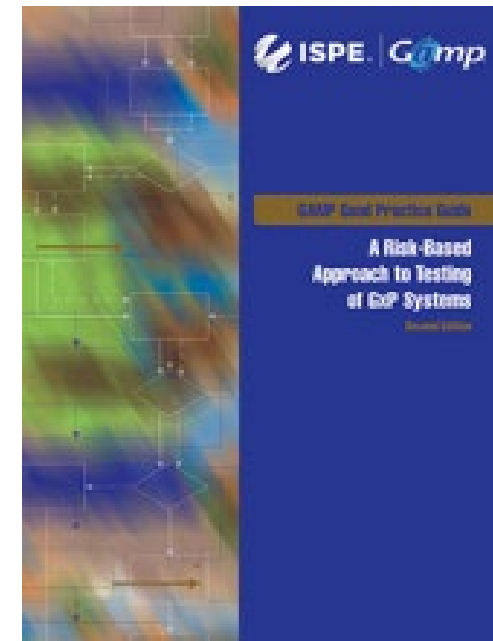
MES systems



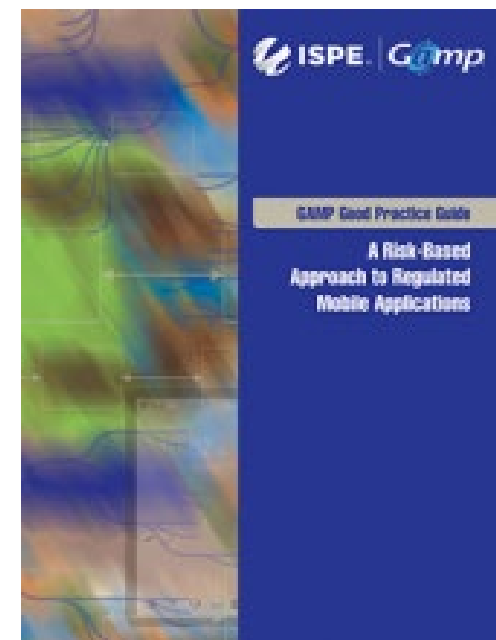
Process
Control
Systems



Lab Systems

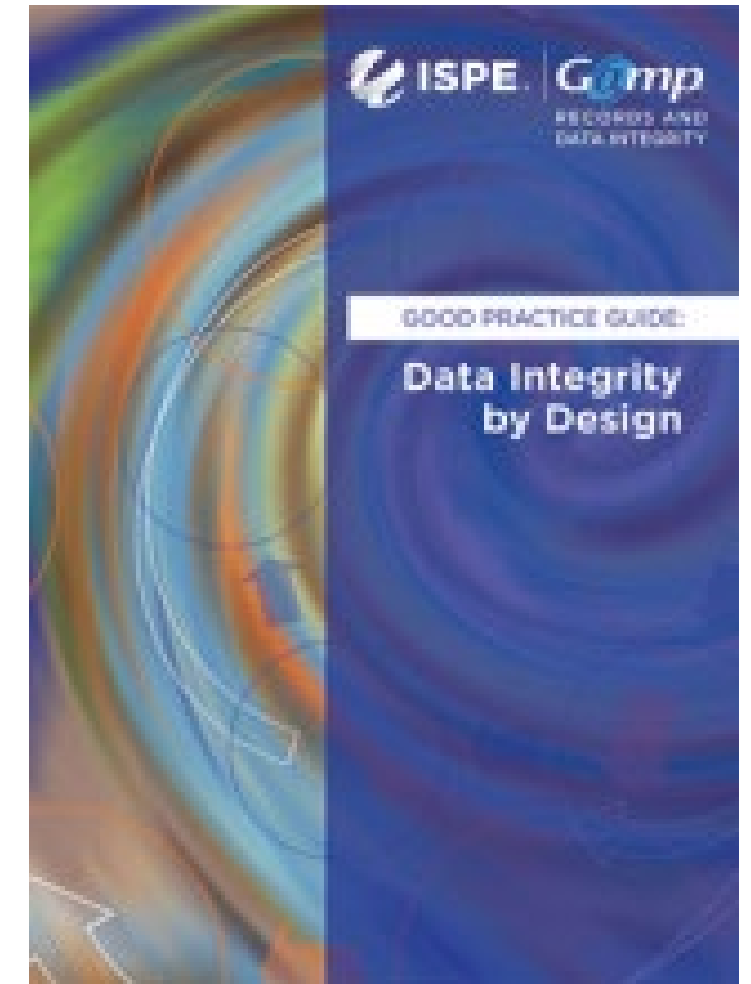
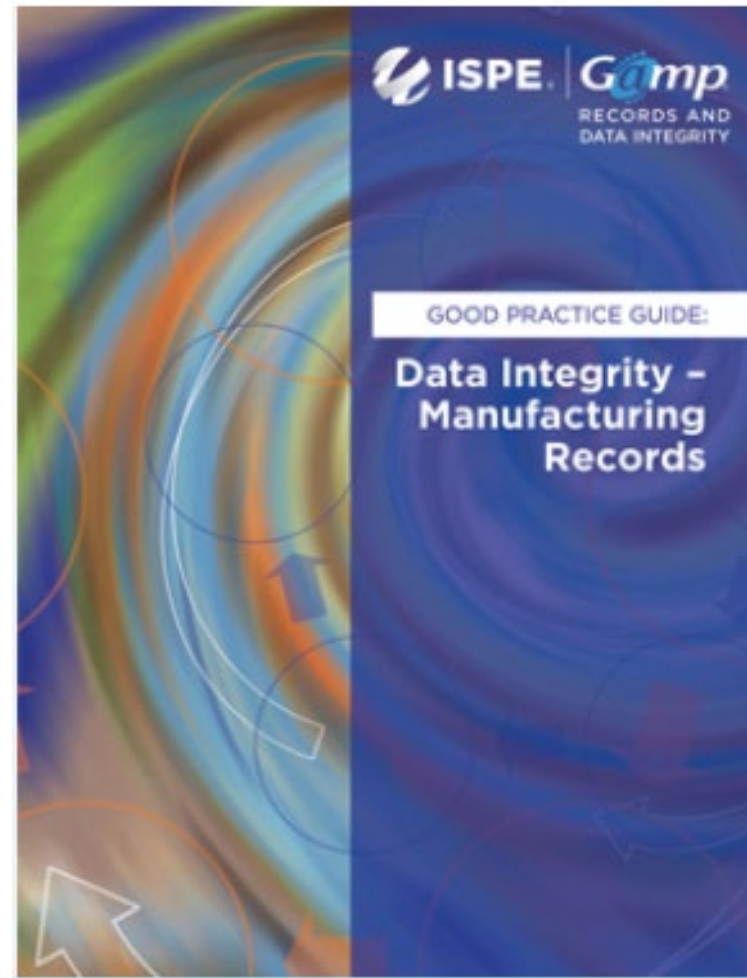
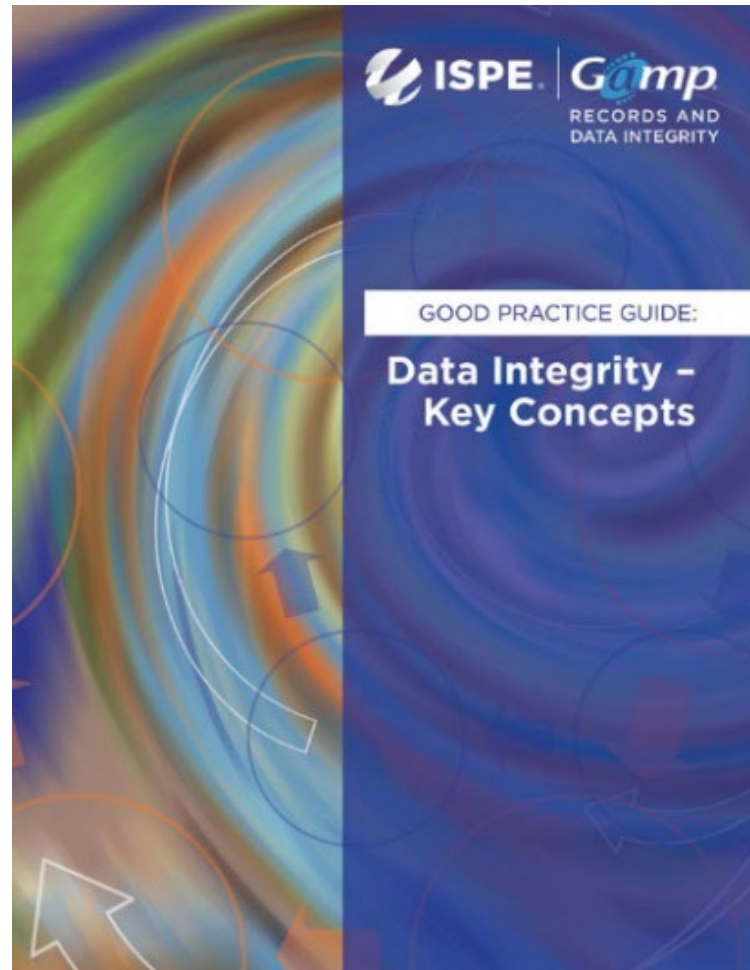


Testing



Mobile
Applications


Practical Data Integrity Guides



Viewing Guides on ISPE.org

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CONNECTING
PHARMACEUTICAL
KNOWLEDGE

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Enter a keyword to search Guidance Documents

ADVANCED SEARCH

Browse ISPE Guidance Documents

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Functional Area

Quality44

Facilities & Equipment38

Regulatory26


Information Systems25

Product Development16

More

1 - 20 of 96

Sort by: Recently Published




ISPE GAMP® Good Practice Guide: Validation and Compliance of Computerized GCP Systems and Data – Good eClinical Practice (Second Edition)

Published: July 2024

Pages: 258

Preview Description



ISPE Good Practice Guide: Unique Identification of Glass Primary Containers in Pharmaceutical Fill and Finish Operations


Published: May 2024

Pages: 86

Preview Description

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|---|-------------------------------------|--------------------------|
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| Guidance Document Title | Publication Date | Access |
| 2023 ISPE Drug Shortages Prevention Model | May 2023 | Included with membership |
| ISPE Readiness Report Bundle | May 2023 | Included with membership |
| ISPE GAMP® Good Practice Guide: Enabling Innovation – Critical Thinking, Agile, IT Service Management | September 2021 | Unlimited access |
| ISPE Good Practice Guide: Knowledge Management in the Pharmaceutical Industry | May 2021 | Included with membership |
| ISPE Good Practice Guide: Maintenance (Second Edition) | January 2021 | Included with membership |
| ISPE Good Practice Guide: Equipment Reliability | December 2020 | Included with membership |
| ISPE GAMP® RDI Good Practice Guide: Data Integrity by Design | October 2020 | Unlimited access |
| ISPE Good Practice Guide: Critical Utilities GMP Compliance – How to Be Compliant and Ready to Prove It | June 2020 | Included with membership |



Connecting Pharmaceutical Knowledge

ISPE.org

Global GAMP Special Interest Groups (SIGs)

The authors of the GAMP GUIDES

Software Automation & Artificial Intelligence

To explore, educate, and bring regulatory/compliance awareness of innovative technologies such as software automation (ex. RPA) and artificial intelligence (ex. ML) to the pharma and biotech industry.

Eric Staib  estaib@gmail.com

Blockchain

To help enable the adoption of blockchain technology in regulated environments by exploring use cases, sharing lessons learned, and contributing to thought leadership around this topic.

James Canterbury  james.canterbury@ey.com

Cloud

To provide industry guidance and establish clear roles and responsibilities for the use of Cloud solutions in regulated (e.g., GxP) space.

Anders Vidstrup  avid@nnit.com

Risk Management

To research, explore and propose new models, tools and approaches based on the latest technologies and innovations in the data science and computing areas (i.e., AI, ML) that can be applied to the Quality Risk Management process to make it more objective, predictive, and efficient in order to protect patients' safety and health.

 corinne.liabeuf@glpg.com

Global GAMP Special Interest Groups (SIGs)

The authors of the GAMP GUIDES

CSA

To develop practical approaches to optimizing validation activities through increased focus on Quality Risk Management and critical thinking in line with FDA's Case for Quality and GAMP 5 Second Edition.



charlie.wakeham@citadelhealth.com.au

Agile

To illustrate how Agile software development practices can be used in support of the validation of GxP regulated computerised systems.



mark.cherry@astrazeneca.com

MES

Define industry best practices for MES project initiation, planning, execution and operations by establishing a silo breaking collaboration of vendors, industry manufacturers, Quality organizations, consultants and regulators and all involved stakeholders.



christian.woelbeling@koerber.com

eClinical

To provide market support for all validation aspects related to computerized GCP system, including understanding the business process and the unique risks, enabling innovation and managing the complex computerized systems across a variety of infrastructure platforms and organizations. Working to update eClinical Guide.



oliverherrmann@q-finity.de

ISPE Announces ISPE AI[®], an Artificial Intelligence Initiative

.....ISPE AI[®], which includes the launch of the ISPE Community of Practice (CoP) on Artificial Intelligence (AI).

*“Recent advances in AI have brought attention to this rapidly accelerating technological innovation. The launch of this AI Community of Practice is a testament to ISPE’s commitment to shaping the future of the pharmaceutical industry. We are acutely aware of the **needs and interest areas of our members** and recognize the importance of supporting the pharmaceutical industry in the **responsible advancement of AI.**”*

Thomas B. Hartman

President ISPE

ISPE Engage GAMP Discussion Groups

Heather Longden



- **Heather Longden** is an independent regulatory compliance consultant to the pharmaceutical industry.
- With over 30 years experience at a major life sciences company, Heather specializes in data integrity, regulatory compliance, data management, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and computer system validation.
- Engaged in ISPE activities and leadership, specifically
 - In a leadership role on the ISPE GAMP Americas steering committee.
 - As a Boston Area Chapter Board director, and on their Education Program Committee (EPC), where she plays a vital role connecting regulatory and industry speakers and contributors

Making Compliance and
Data Integrity Interesting

Latest Discussion Posts [Add](#)

RE: High-impact systems vs. low-impact systems
By: [Stefan MÜNCH](#) , 3 days ago
[Posted in: GAMP](#)
Hi Sara, You're quote is taken from App. M3 (Science-based QRM), Section 11.5.3.1 (Initial Risk Assessment). The next sentence (that you missed) reads: "Process knowledge assists with determining system impact (see Section 11.7.2 for an example)". Though ...

High-impact systems vs. low-impact systems
By: [Sara Vilella Palacios](#) , 6 days ago
[Posted in: GAMP](#)
Hi everyone, I'm in the process of updating our supplier assessment procedure to align with the latest edition of GAMP 5. The guide is clear when classifying high impact systems: but it does not provide further clarification on the other ...

RE: What is Assurance, Really?
By: [Jeffrey Liss](#) , 28 days ago
[Posted in: GAMP](#)
Hi, Orlando. Thanks for your response. NASA-STD-8739.8A provides the following definition of "assure": "When software assurance personnel make certain that others have performed the specified software assurance, management, and engineering activities." ...
[1 person](#) recommends this.

Latest Shared Files [Add](#)

ISPE GAMP UK Community of Practice Forum Tuesday 25th ...
By: [Sam Andrews](#) 4 months ago
ISPE GAMP UK Community of Practice Forum Tuesday 25th April 2023 materials
#InformationSystems # ...

GAMP SIG MES Re-Launch Meeting - June 13 2023 - Call ...
By: [Christian Woelbeling](#) 4 months ago

Opportunity to Comment: Concept Paper on the revision ...
By: [Wendy McGhee](#) 9 months ago

[More](#)

GAMP – How to Get Involved

Update Your ISPE Member Profile to join GAMP CoPs

MEMBERSHIP

MY ACCOUNT

EVENTS

CART

MY PROFILE

MY INTERESTS AND COMMUNITIES

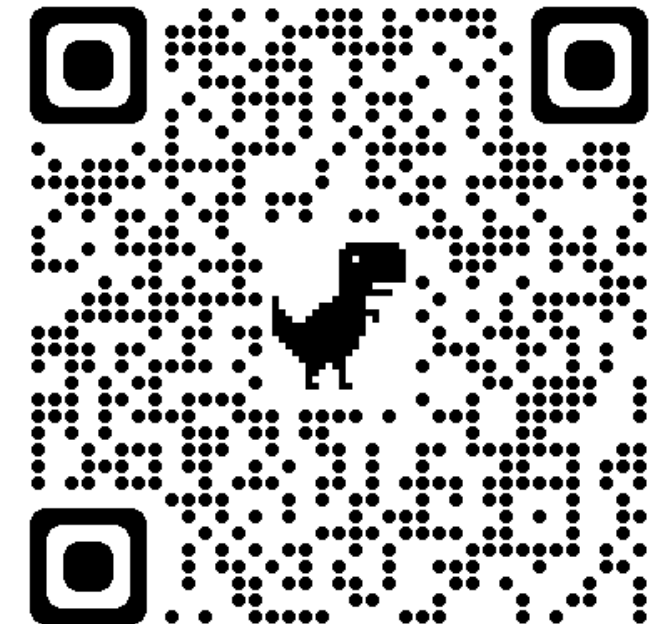
MY CEUS

MY ACTIVITY

MY DOWNLOADS

Place a check next to the communities you'd like to join.

- ☒ GAMP
- ☒ GAMP Blockchain Special Interest Group
- ☒ GAMP Computer Software Assurance Special Interest Group



Forums and Discussions to join

Follow discussions in your area of interest

Subscribe to have updates come to your email

- The email brings you the text content to read
- You only have to click and log in to comment

GAMP Community

GAMP Blockchain Special Interest Group

GAMP Computer Software Assurance SIG

GAMP Data Integrity Special Interest Group

GAMP MES Special Interest Group

Commissioning and Qualification

Regulatory and Quality Networking

ISPE News and Events Community

Emerging Leaders Community

Women in Pharma

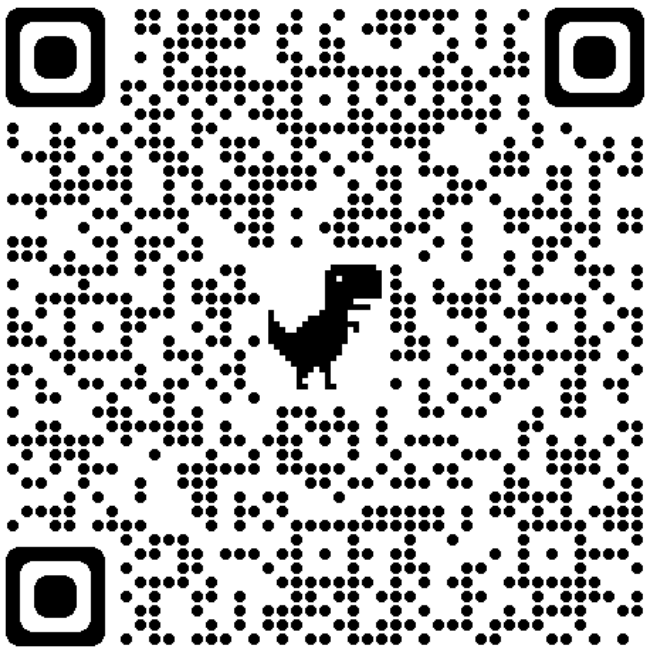
Boston Chapter or www.ispeboston.org

GAMP – How to Get Involved

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GAMP

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GAMP Computer Software Assurance Special Interest Group

GAMP Computer Software Assurance SIG

GAMP Software Automation and Artificial Intelligence SIG

GAMP Software Automation and Artificial Intelligence SIG

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Did you miss ISPE Expert Xchange: Pharma 4.0™ or ISPE Expert Xchange: GAMP: Implementing Data Integrity by Design? You can still take advantage of great content on demand!



ISPE Expert Xchange: Regulatory Summit on ICH Q9 Revision

Extended Learning – On Demand

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ISPE Expert Xchange GAMP®: Realizing the Value in Validation with Critical Thinking and Computer Software Assurance

Extended Learning – On Demand

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Pharma 4.0™

Extended Learning – On Demand



ISPE Expert Xchange GAMP®: Implementing Data Integrity by Design

Discover your Data – A Case Study on Data Flow Diagrams and Data Integrity

Complimentary Learning Level: Intermediate Session
Length: 1 hour Data integrity is strengthened through a detailed understanding of your data – how it is created, where it is stored, what other data is relevant, and how and...

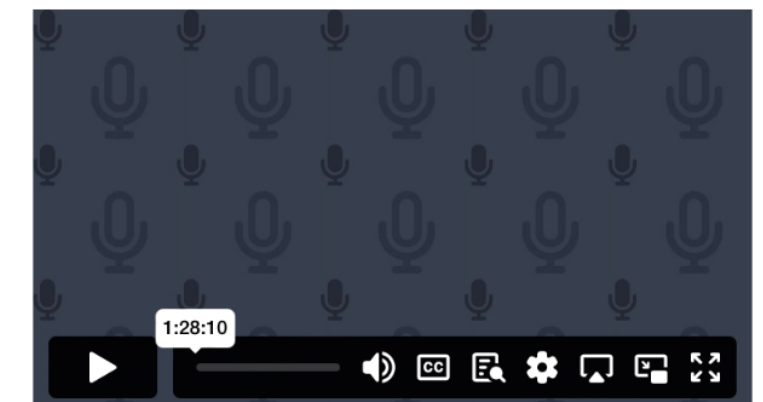
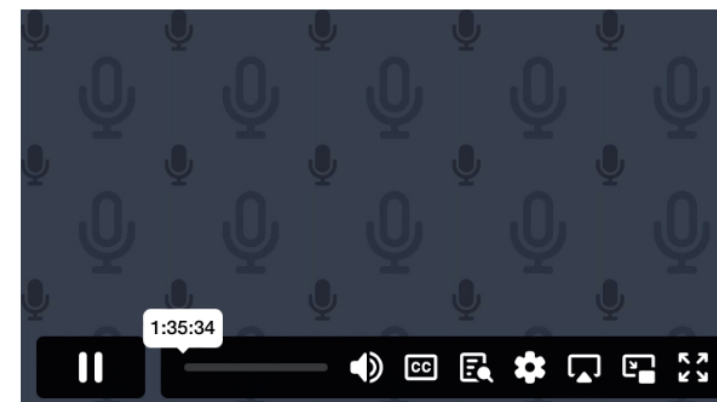
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Explore the GAMP Data Integrity by Design Guide Webinar

Complimentary Learning Level: Intermediate Session
Length: 60 minutes Based on the new ISPE GAMP Data Integrity by Design Guide, this webinar will examine the underlying concepts around designing data integrity into your...

[View Now](#)

FREE TO MEMBERS



GAMP Training by experts: Online, On Demand and Live In-Person

- Requirements for Computerized Systems Validation and Compliance
- Basic Principles of Computerized Systems Compliance
- GAMP® Basic Principles Training Course
- Practical Application of Computerized Systems Compliance: Applying the GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems
- GAMP® Part 11 Training Course
- GAMP® 5, Annex 11/Part 11 Basic Principles Training Course
- GAMP® Data Integrity 21 CFR Part 11 Training Course
- GAMP® 5 GxP Process Control Training Course

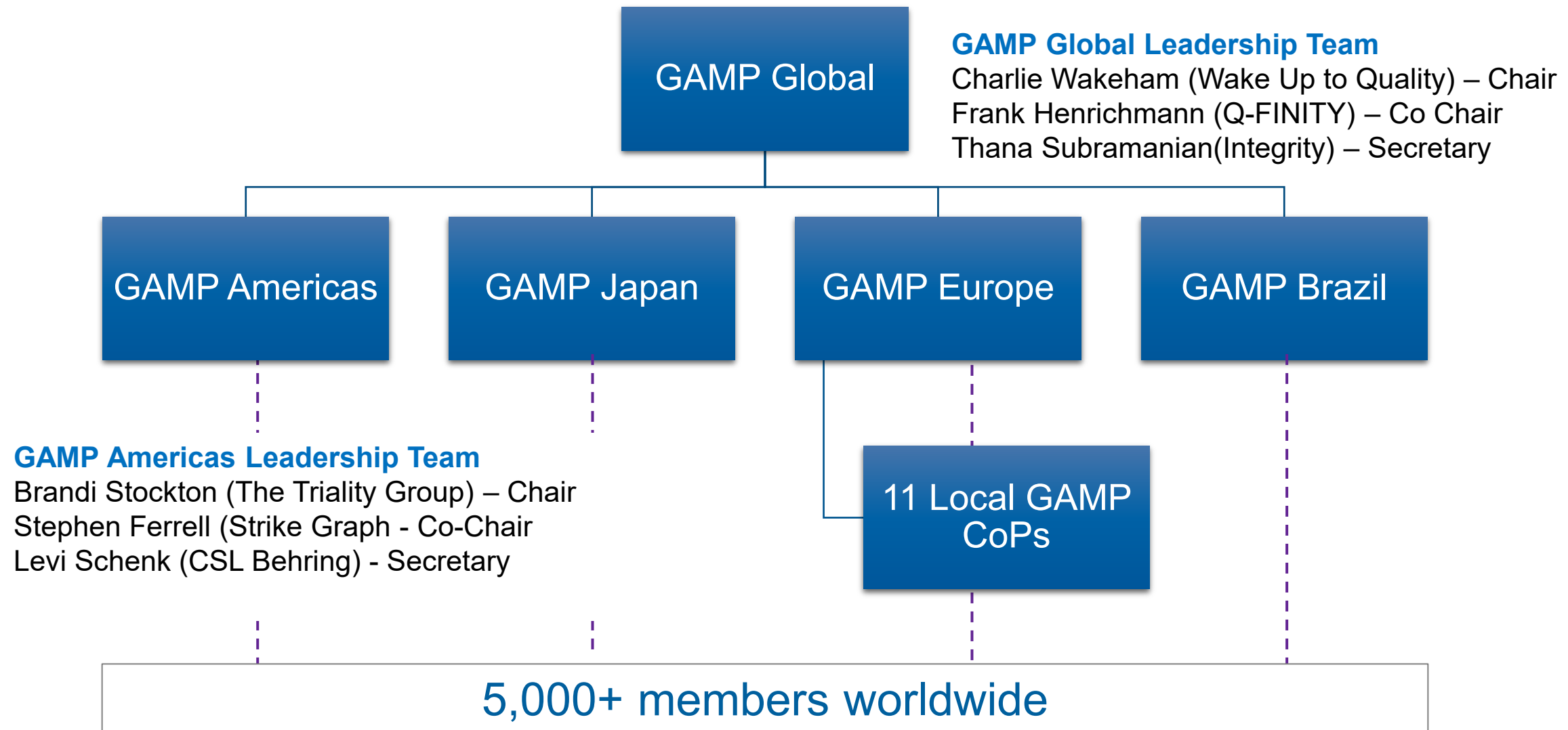
[link to ISPE GAMP Training page](#)



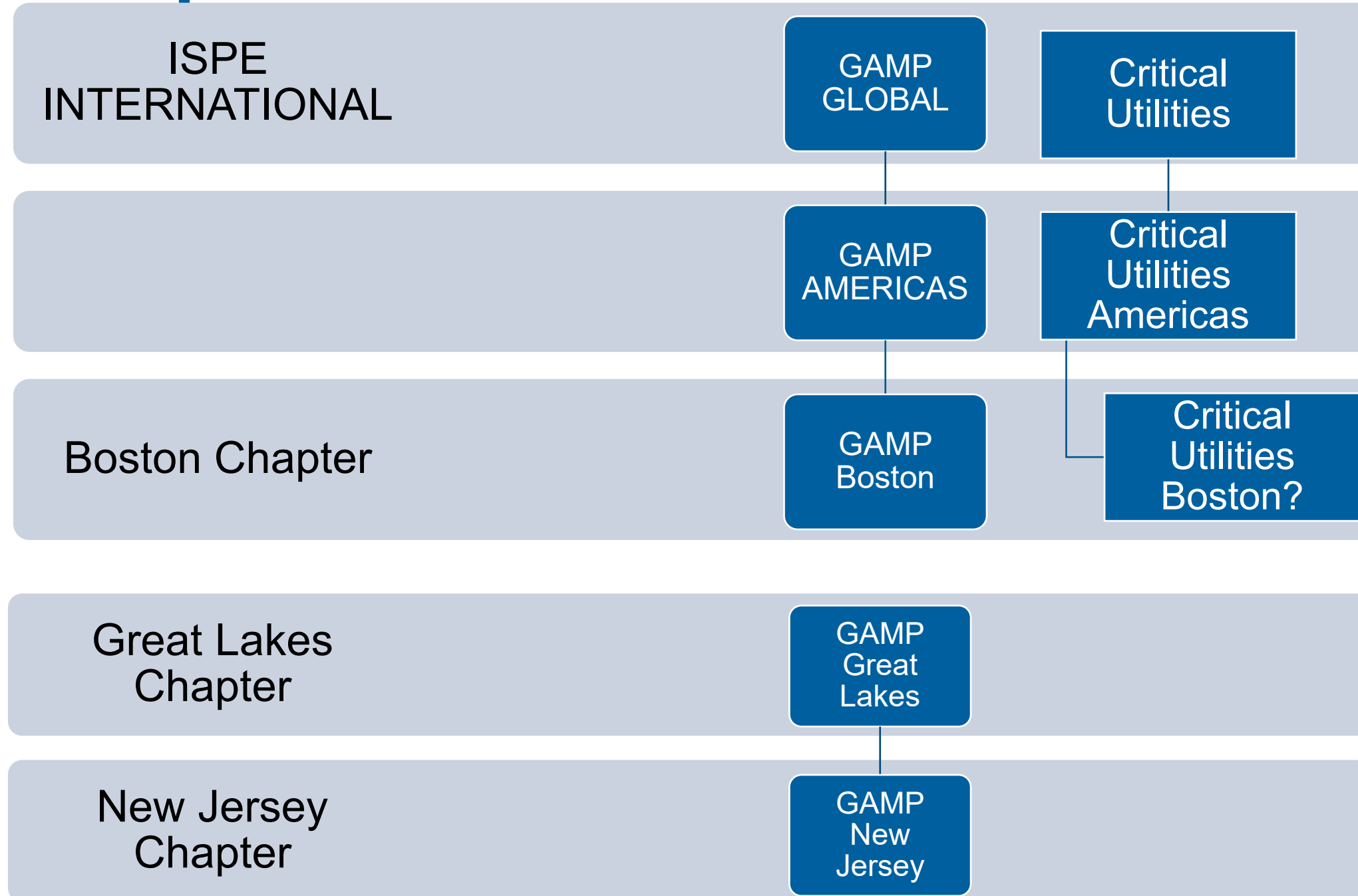
Local CoPs start in the Americas

FIRST ONE : BOSTON GAMP

GAMP Leadership and Structure



Chapter Level CoP's



IN PROGRESS:
GAMP LOCAL
COPs

- Delaware Valley
- San Francisco Bay
- CASA

Boston Chapter - GAMP Local CoP

Local GAMP CoP Objectives

- Networking
- Expert support and questions
- Education events
- Speaker connections



Connect w/
Geetu (Geetanjali) Abbi
Chris Ciampa
Heather Longden (Board Liaison)

Boston GAMP Quarterly Events

2024 Forum – June 2024

Chair and Co
Chairs set up

Steering Committee

February
Networking
Event

May
Networking
Event

Product Show
presentation
and Meet Up

GAMP Forum 2024: June 6th 2024

- with FDA Speaker Seneca Toms

- Half Day program included 2 Panel Discussions
- Leads of GAMP Americas flew in to present alongside FDA

• Panel- Impact of GAMP 5 2nd Edition

- Role of GAMP guides
 - in standardizing industry practices
 - Un shaping Health Authorities thinking
- Significance of quality culture in achieving mature quality systems.
 - Building a mature culture of Risk Management
 - Vs “lets continue to do EVERYTHING”
- Regulators view of mature risk-based culture
 - For manufacturing
 - For CSV activities
- **Real examples of accepted/approved changes to a more Risk Based approach.**

• Fireside chat with FDA

- Viewing Inspections through the eyes of an inspector
 - Prior knowledge
 - Objectives
 - Setting the stage
 - Following a thread
 - Report writing
- Preparing for inspections
- Explaining your process and overall QMS approach
- Answering FDA questions
 - Supporting evidence for answers
- **INSPECTORS ARE HUMAN TOO**

GAMP Forum 2024: June 6th 2024

- with FDA Speaker Seneca Toms

- Half Day program included 2 Panel Discussions
- Leads of GAMP Americas flew in to present alongside FDA

• Updates – Global GAMP CoP

- GAMP CoP objectives
- Focus on critical thinking
- Upcoming GAMP related publications
- Brief updates from the eClinical guide

• Managing Cloud XaaS suppliers in GxP

- Risk based approach to
 - Vendor qualification
 - Quality agreements
 - for cloud PaaS/ IaaS/ SaaS suppliers.
- Clear roles and responsibilities in quality agreements,
- Key Provisions
- Vendor compliance with standards
 - ISO 27001, HITRUST CSF, SOC2, and ISO 27017

• Use of a Control Framework to Limit risk of AI in GxP

- Integrating AI in computerized systems.
- Risk and control framework
- Emphasis on critical thinking,
- Risk management,
- Alignment with ICH Q9 (R1)

Boston Chapter – Upcoming GAMP Events

TODAY – at the Product Show

AGENDA:
INFORMAL GET TO MEET YOUR LOCAL
GAMPERS
MEET BETWEEN ? AND ?PM



Proposed GAMP WORKSHOP in NOVEMBER 2025

AGENDA: TBD



Plus 3-5 GAMP meet-ups in 2025

VIRTUAL OR IN PERSON... THEMED DISCUSSION AND NETWORKING