

ISPE GAMP® Community of Practice

Heather Longden
Geetanjali Abbi

September 20th 2023

1



- **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

2

Disclaimer

This presentation contains statement of facts and opinions of the presenter and not necessarily the opinion or position of our employers

Acknowledgement: CoP-related content developed from slides shared by GAMP Steering Committee



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3

50

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.

And focus to ensure...

patient safety
product quality
data integrity



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4

Slide 4

LSO suggest something about promotes the understanding
of the regulations and controls for the use...
and
focused to ensure....patient safety etc.

Lorrie Schuessler, 2023-09-01T16:00:10.962

Quick Quiz – What Do You Know About GAMP?

1. GAMP® stands for:
 - a. Grand Attempts at Maximizing Paperwork
 - b. Gradually Achieving Maximum Perfection
 - c. A large umbrella named after Mrs. Gamp, a character in Charles Dickens's novel "Martin Chuzzlewit."
 - d. Good Alcohol Management Practice
 - e. Good Automated Manufacturing Practices
 - f. GAMP®
2. True or False – GAMP® is limited to Manufacturing

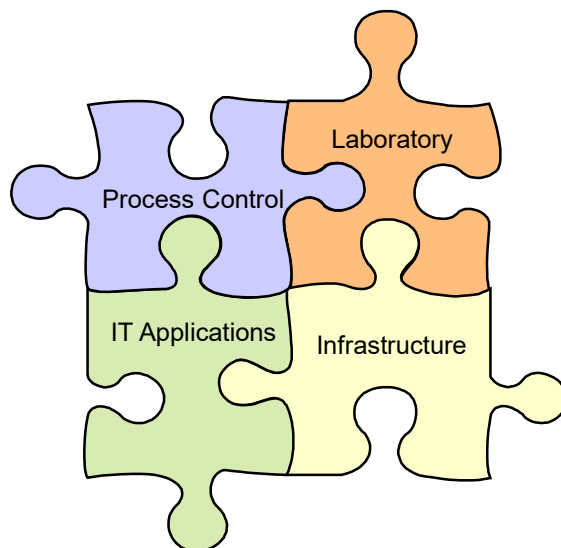


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5

GAMP®5 Scope & Application



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6

GAMP at-a-Glance

5000+ Members

Established in 1991

8 Global Special
Interest Groups

17 CoPs Europe,
Americas, & APAC



19 Good Practice
Guides

5 ISPE International
Board Chairs

11 Individual Honor
Awards

5 Committee Honor
Awards



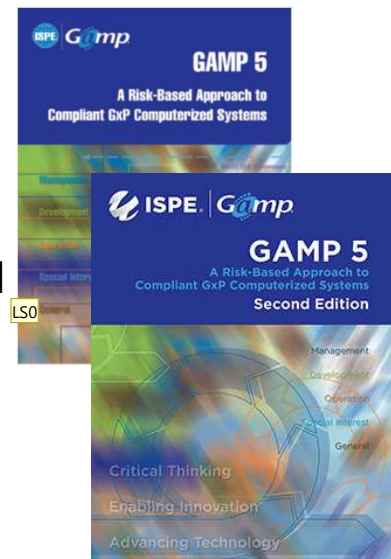
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7

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



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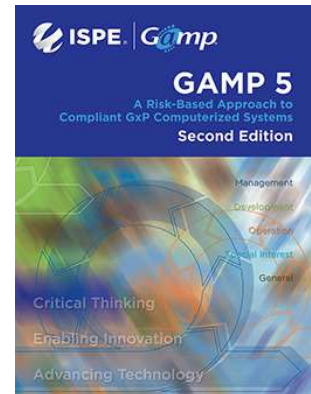
8

LS0 missing something

Lorrie Schuessler, 2023-09-01T16:01:06.457

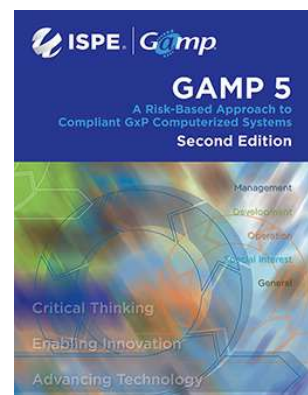
GAMP® 5 Second Edition

- New Content
 - Agile
 - Software Tools
 - Distributed Ledger Systems (Blockchain)
 - Artificial Intelligence and Machine Learning (AI/ML)
 - Critical Thinking
 - Essential for “CSA” concept and Risk Based Testing activities



GAMP® 5 Second Edition

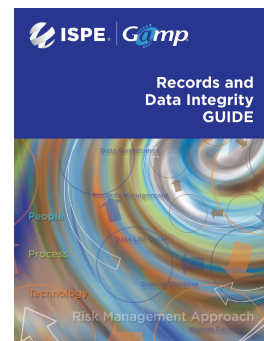
- Updated topics
 - Specifying Requirements
 - Electronic Production Records
 - Operation Phase and IT Service Management



GAMP® Records and Data Integrity Baseline Guide

Key benefits:

- Data integrity requirements, critical areas of regulatory focus and concern, and key concepts
- Framework for data governance and the importance of human factors
- Complete data life cycle approach as part of a Quality Management System (QMS), from creation to destruction
- How to apply the Quality Risk Management (QRM) approach from ISPE GAMP® 5 to record and data integrity
- More detailed information, including “how to” guidance for specific topics, in a series of management, development, and operation appendices

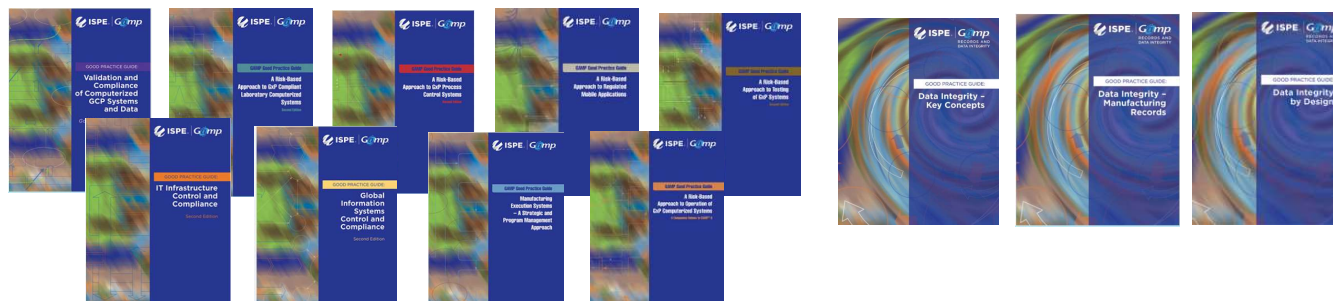
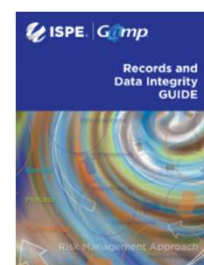
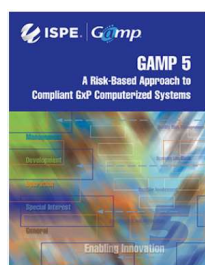


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11

GAMP® Guidance - Good Practice Guides (GPGs)



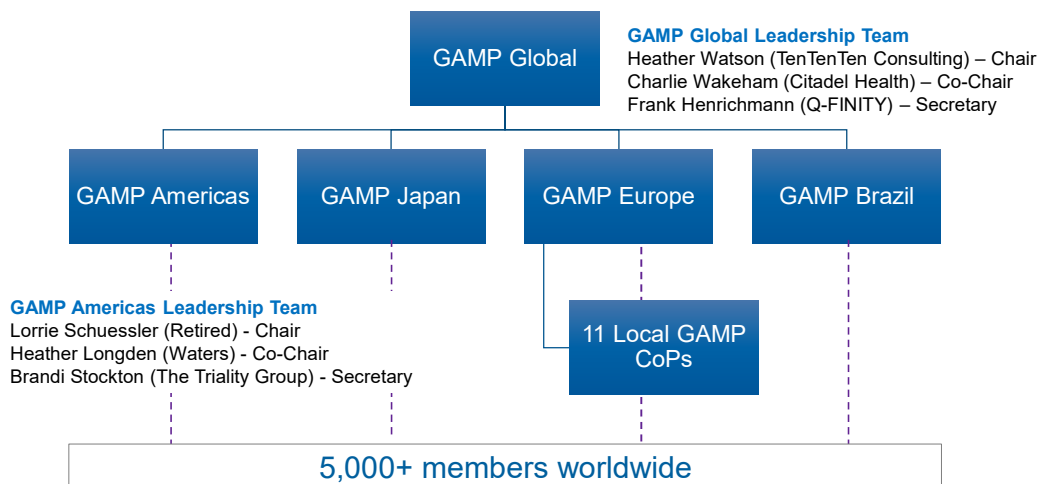
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12

50

GAMP Leadership and Structure



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13

Global GAMP Special Interest Groups (SIGs)

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.

Jamey 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



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14

Slide 13

LS0 not related to slides - maybe the way to simplify would be to promote all of the gamp european cops to the same level as americas

Lorrie Schuessler, 2023-09-01T16:04:37.244

Global GAMP Special Interest Groups (SIGs)

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



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15

ISPE Engage GAMP Discussion Groups

Heather Longden

16



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

17

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MEMBERSHIP & COMMUNITIES

PUBLICATIONS

PROGRAMS

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2022 ISPE
**ANNUAL
MEETING & EXPO**

30 Oct - 2 Nov | Orlando, FL and Virtual

Upcoming Events

- Membership
- Volunteer Opportunities
- Communities of Practice
- ISPE Engage Forums
- Affiliates and Chapters
- Women in Pharma
- Emerging Leaders
- Students
- Career Opportunities in Pharma

Over 65 Guidance Documents
published. View recently published
Guides!



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18

WWW.COP.ISPE.org

The screenshot shows the homepage of the ISPE Community of Practice (COP) website. The header includes navigation links: Home, Open Forum, Forums, Directory, Conferences, Browse, Membership & More FAQs, and ISPE.org. A search bar is located on the right. Below the header, there are statistics: Discussion (2.1K), Library (46), and Members (4.7K). The main content area is divided into two columns. The left column, titled 'Latest Discussion Posts', features three posts: 'RE: High-impact systems vs. low-impact systems' by Stefan.M.Ott, 'High-impact systems vs. low-impact systems' by Sara.Venla.Fernandez, and 'RE: What is Assurance, Really?' by William.Lee. The right column, titled 'Latest Shared Files', features two files: 'ISPE GAMP UK Community of Practice Forum Tuesday 25th ...' by Sam.Andrews and 'GAMP SIG MES Re-Launch Meeting - June 13 2023 - Call ...' by Christian.Wiedebach. At the bottom of the main content area, there is a 'More' button. A footer banner at the bottom of the page states: 'ISPE uses cookies to improve site functionality and to provide you with a better browsing experience. By using our site or clicking on "OK", you consent to the use of cookies.' with an 'OK' button.



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19

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



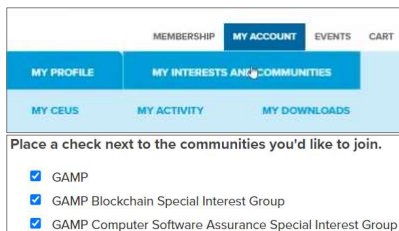
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20

GAMP – How to Get Involved

Update Your Member Profile to join GAMP CoPs



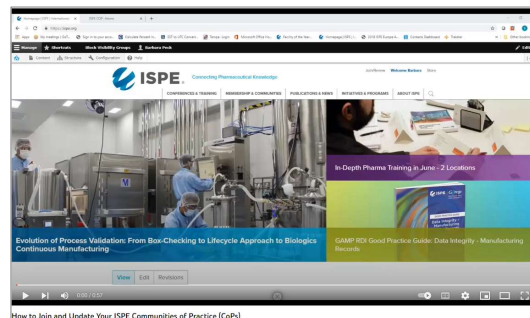
MEMBERSHIP **MY ACCOUNT** EVENTS CART

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



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21

GAMP – How to Get Involved

Follow discussions and/or subscribe



GAMP

GAMP

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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22

Continued Education for GAMP Topics

Chris Ciampa

23

Webinars/Expert Xchanges

*NEW: All Webinars will be **free to ISPE Members** with registration fees for non-Members*

- **Webinar: Ensuring Data Integrity - Trends, Challenges and Best Practices**
20-September-2023

11:00 - 12:00 EDT

Charles Yardley (Verista), Jeff Onis (Catalent Pharma Solutions), James Li (Abbott), Don Brown (Verista), Wesley A. Bloemker (Verista), Eric Watkins (Verista)

- ***Sponsored complimentary webinars***
- ***On demand replay of webinars for ISPE Members***
- ***Expert Exchange 'tutorial style' webinars - PAID***



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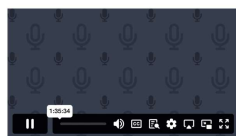
24

Examples of free on-demand extended webinars from GAMP

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...

[View Now](#)



6 October 2020 | Video

The Importance of Data Integrity for Machine Learning: A Data Lifecycle Model

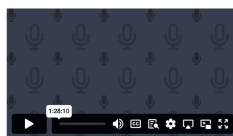
Extended Learning Learning Level: Intermediate Session Length: 1.5 hour Artificial Intelligence (AI) is a broad field of study within computer science that includes technologies such as Machine Learning (ML), as well as deep...

[View Now](#)

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](#)



25 August 2020 | Video

Foundation of Proof – Exploring the Cryptography behind Blockchain

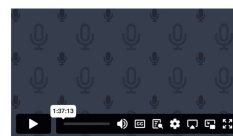
Extended Learning Learning Level: Intermediate Session Length: 1.5 hours In this 90-minute webinar we will take a closer look at the technology that is used behind blockchain protocols with a focus on the cryptographic...

[View Now](#)

Analytical Instrument Qualification – A Continuum of Requirements, from USP <1058> to GAMP® 5 Webinar

Learning Level: Basic/Intermediate - Analytical laboratories are required to demonstrate the suitability of their equipment during audits and will typically follow USP requirements defined in Chapter <1058> on analytical...

[View Now](#)



29 July 2020 | Video

GAMP® 5, FDA CSA, and the Future of Computer Systems Validation Webinar

Extended Learning Learning Level: Intermediate Session Length: 1.5 hours Extended Learning Webinars take a 90-minute deeper dive into industry-critical topics you want and need to learn more about. Benefit from in-depth...

[View Now](#)



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25

GAMP Expert Exchange tutorials

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

[BUY ON DEMAND](#)



ISPE Expert Xchange GAMP®: Realizing the Value in Validation with Critical Thinking and Computer Software Assurance
Extended Learning – On Demand

[BUY ON DEMAND](#)



Pharma 4.0®
Extended Learning – On Demand



ISPE Expert Xchange GAMP®: Implementing Data Integrity by Design

Extended style Expert Exchange tutorials
-paid registration required



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26

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



[link to ISPE GAMP Training page](https://www.ispe.org/training)

- 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
- PLUS: Custom courses for delivery WITHIN single companies



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27

2023 GAMP® Training Courses (Completed)

Date	Course	Type	Instructor
JAN	GAMP Data Integrity	Custom	Wyn
FEB	Basic GAMP5 & Part 11	ILC	Wyn
FEB	GAMP Data Integrity	ILC	Cappucci
APR	Basic GAMP5 & Part 11	ILC	Wingate
APR/MAY	Basic GAMP5 & Part 11 / GAMP Data Integrity	Custom	Perez
MAY (@ EU Annual Mtg.)	Basic GAMP5 & Part 11	ILC	Wyn
JUN	GAMP GAMP5 & Part 11	ILC	Cappucci
JUN	Process Control GAMP	ILC	Wingate
JUN	Process Control GAMP	Custom	Wingate
JUN	Basic GAMP5 & Part 11	Custom	Wingate
JUN	GAMP Data Integrity	ILC	Henrichmann
JUL	Basic GAMP5 & Part 11	Custom	Cappucci



Custom: There are multiple inquiries for custom GAMP training that are in the various negotiating stages.

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28

Slide 27

LS0 in addition to the general course offerings, custom courses can be provided to individual companies....I do not think I am saying that well...but hopefully you understand what I am saying

Lorrie Schuessler, 2023-09-01T16:06:44.337

2023 GAMP® Training Courses (Planned)

Date	Course	Type	Instructor
SEP	Basic GAMP5 & Part 11	ILC	Henrichmann
SEP	Basic GAMP5 & Part 11	Custom	Wyn
OCT	Basic GAMP5 & Part 11	ILC	Perez
OCT (@ Annual Mtg)	Basic GAMP5 & Part 11	ILC	Herrmann
OCT (@ Annual Mtg)	GAMP Data Integrity	ILC	Cappucci
OCT	Cloud Computing Concepts	Custom	Wyn
DEC	Basic GAMP5 & Part 11	ILC	Herrmann
DEC	Basic GAMP5 & Part 11	ILC	Wyn



Custom: There are multiple inquiries for custom GAMP training that are in the various negotiating stages.

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29

Boston Chapter - GAMP Local CoP

Local GAMP CoP Objectives

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



Connect w/
Heather Longden
Geetu (Geetanjali) Abbi
Christopher White
Chris Ciampa



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30

Boston Chapter – Upcoming GAMP Events

TODAY – at the PQE stand

AGENDA:
INFORMAL GET TO MEET YOUR LOCAL
GAMPERS
MEET BETWEEN 2:30 AND 4PM

Hosted by: PQE

Proposed GAMP Forum in May/June

AGENDA: TBD



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