



ISPE®

Greater Los Angeles
Area Chapter

GAMP®- Past, Present and Future

What to Expect:

- Brief history and Background – Why? What? How?
- GAMP®5 Overview and Key Concepts
- System Life Cycle and Specification and Verification Approach
- Key Roles and Responsibilities
- GAMP® Guide: Record and Data Integrity
- Current Challenges and Looking to the Future



**Sion Wyn, Director,
Conformity Ltd.**

COMPLIMENTARY WEBINAR FOR MEMBERS AND NON-MEMBERS

**JUNE 30, 2020 | NOON - 1 PM
GOTOWEBINAR**

RSVP: <http://www.atdevents.net/register.php>

Complimentary Webinar for ISPE Members and Non-Members

GAMP® (Good Automated Manufacturing Practice) Past, Present and Future



**Tuesday, June 30, 2020
Noon – 1PM**

Format:

GoToWebinar

Instructions to join will be emailed one day prior

Program Manager: Paul Crissman, Principal, Biotechnical Solutions

Moderator: Justin Cantor, Vice President - Operations, PSC Biotech

Speaker: Sion Wyn, Director, Conformity Ltd.

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GAMP® – Past, Present and Future

Tuesday, June 30, 2020

About the Speaker



Sion Wyn, Director, Conformity Ltd. is an acknowledged expert in computer system validation and compliance and international regulations in this field.

He assisted the FDA as a consultant with its re-examination of 21 CFR Part 11 and was a member of the core team that produced the FDA Guidance on 21 CFR Part 11 Scope and Application. He was the technical content expert for the FDA's ORA Virtual University on-line training modules on computerized systems validation and compliance. He received the FDA Group Recognition Award for work on Part 11.

Wyn is the editor of ISPE's GAMP5 Guide - A Risk-Based Approach to Compliant GxP Computerized Systems, co-lead of the ISPE GAMP Guide - Record and Data Integrity, and is a member of the ISPE GAMP Global Steering Committee, GAMP Editorial Board, and the GAMP Europe Steering Committee.

Wyn received the 2006 ISPE Professional Achievement Award, which honors an ISPE Member who has made a significant contribution to the pharmaceutical industry. He received the ISPE UK Fellow Award in 2016.



About GAMP® **Good Automated Manufacturing Practice**

ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems is regarded as the definitive industry guidance on GxP computerized system compliance and validation for companies and suppliers and is referenced by regulators worldwide.

GAMP® 5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10, and ASTM E2500.

This revolutionary Guide addresses the entire lifecycle of an automated system and its applicability to a wide range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end-user applications (such as spreadsheets and small database applications), and patch management. (source: ISPE website)

History of GAMP®

GAMP itself was founded in 1991 in the United Kingdom to deal with the evolving U.S. Food and Drug Administration expectations for good manufacturing practice (GMP) compliance of manufacturing and related systems. GAMP published its first guidance in 1994. Soon afterwards the organization entered into a partnership with ISPE, formally becoming part of ISPE in 2000. GAMP has enjoyed the support of numerous regulatory authorities over the years spanning the United States, Europe, and Japan and is now a recognized good practice worldwide. (source: Wikipedia)



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REGISTRATION INSTRUCTIONS

Online Registration Instructions:

- 1) Click on this link below then log on using your username and password: <http://www.atdevents.net/register.php>
- 2) Click on the appropriate event. Here is where you can download the event flyer also.
- 3) Scroll through the list of registration options and find the one that applies to you and complete the registration. Our site does not send confirmation emails for complimentary events, however, the link to join the webinar will be emailed to you the day before the webinar.

ISPE California Chapter Members:

If you are an ISPE Member in California, please do not set up a new account, as you should already be in our system (takes a few days after joining). You will need your username and password to log on.

How To Find Your ISPE Member Number or Update Your Account to a Member Account:

To update your existing account to a Member account, or to add your new ISPE Member account to our website, please forward your confirmation email from ISPE or your ISPE Membership information to Rob Fleming (rob.fleming@yahoo.com). We need your Chapter name, your ISPE Member number and expiration date. To retrieve this information, log onto the ISPE website. Click on "Account" on the top right side, then "My Account". Your Membership information (not including your chapter affiliation) is on the left side. Please take a screen shot or make a pdf of the page, then email it along with the name of your chapter to Rob Fleming to update your profile on the atdevents.net site.

ISPE Members of Other Chapters:

You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below then follow the instructions to update your account to a member account (see above).

Non Members:

If you do not have an account, you can set one up on the site using letters (not numbers) as your username.

For Help with Online Registration, Setting up an Account or to Reset your Password, please email Rob:
Rob.Fleming@yahoo.com

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