ECA Academy
Your GMP/GDP Information Source

Speakers

Frank Behnisch
CSL Behring, Germany

Bob McDowall
R.D.McDowall , UK

Stefan Münch
Körber Pharma Consulting, Germany

Yves Samson
Kereon, Switzerland

Dr Robert Stephenson
Rob Stephenson Consultancy, UK

GAMP®5 2nd Edition – What is new?

Live Online Training on 2 November 2022

Highlights

- Why Was a GAMP®5 2nd Edition Published?
- Why Was a GAMP®6 not Published?
- What Are the Consequences?
- What Does It Mean for Your Company?
- What Does It Mean for Suppliers?

Objectives

- Get to know the differences between GAMP®5 and GAMP®5 2nd Edition.
- What are the changes in the main part?
- What are the changes in the management and operation appendices?
- How has the 2nd edition been affected by new technological developments
- Critical Thinking in and about the 2nd Edition
- FDA CSA (Computer Software Assurance) and the 2nd Edition - how do the two fit together?

Background

With GAMP®5, published in 2008, this guide became the globally accepted standard for the validation of computerized systems. Due to new technological (Artificial Intelligence / Cloud Computing / Agile Software Development) and regulatory developments (ICH Q9 / FDA initiative in CSA), there was a need for adaptations after 14 years. These adaptations have now been integrated into the 2nd Edition, which has been available since July 2022.

The publication of a 2nd Edition instead of a completely new GAMP®6 shows that the basic principles of GAMP®5 are still relevant. In the 2nd Edition, changes and further developments have been made according to the motto evolution instead of revolution.

Target Audience

This Live Online Training is directed at employees from

- Production
- Quality Control / Quality Assurance
- Engineering
- IT

who have to deal with GAMP®5 in the field of computer validation.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

Programme

GAMP®5 Second Edition - What's Different - What's New? *Rob Stephenson*

- Reasons for a Second Edition
  - Critical Thinking
  - Advancing Technology
  - Enabling innovation
- Changes from the original GAMP®5 – a section by section overview
  - What has been retained?
  - Significant revisions
  - New topics
- How will this affect current good CSV practice?
  - Key Messages
  - Expected improvements

IT Infrastructure / Cloud Computing *Bob McDowall*

- Summarising Appendix M11
- IT Infrastructure changes in the 2nd edition
- Cloud computing and the business

Agile Software Development *Stefan Münch*

- Summary of new Appendix D8
- Agile and iterative – combining compliance and flexibility
- General impact on CSV and GAMP®5 best practices

Software Tools *Stefan Münch*

- Summary of new Appendix D9
- Enabling innovation, increasing quality
- Compliant selection and handling of tools for CSV

Critical Thinking *Bob McDowall / Yves Samson*

- What the industry oversaw (ignored?) during the last 20 years
- Enabling Innovation and GAMP®5 2nd Edition
- Quality Risk Management: the keystone process for Critical Thinking
- Practical application of critical thinking in projects and processes

GAMP®5 2nd Edition Impact on System Suppliers *Yves Samson*

- Differences between GAMP®5 1st and 2nd Edition
- Could system and equipment suppliers leverage critical thinking and CSA?
- Persistent expectations
- Supplier maturity: facilitating Leveraging Supplier Involvement

Artificial Intelligence and Machine Learning (AI / ML)
Frank Behnisch

- Summary new appendix D11 & Life Cycle Approach
- Concept Phase
- Project Phase & supporting processes

Pros / Cons
Frank Behnisch / Bob McDowall / Stefan Münch
Rob Stephenson / Yves Samson

- Individual statements from the speakers
- Panel discussion

Speakers

Frank Behnisch
CSL Behring GmbH, Germany
Frank is Senior Manager Project Engineering at CSL Behring GmbH in Marburg, Germany. He is member of the GAMP® D-A-CH Steering Committee and chairman of a GAMP® Special Interest Group (SIG) for "Small Systems".

Dr Bob McDowall
R.D.McDowall Limited, Bromley, Kent, UK
Analytical chemist with over 45 years experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 30 years. He was also a contributor to the GAMP IT Infrastructure control & compliance and Lab System Validation 2nd edition Good Practice Guides. He is a core member of the GAMP Data Integrity SIG.

Stefan Münch
Körber Pharma Consulting GmbH,
Karlsruhe, Germany
Stefan Münch, Business Director Validation, is responsible for all validation services of Körber Pharma Consulting. He has more than 20 years of experience in software development for the pharmaceutical industry (MES). Furthermore, Mr. Münch is actively engaged in GAMP D-A-CH for many years and member of the steering committee.

Yves Samson
Kereon AG, Basel, Switzerland
Yves joined the industry where he served as project and site engineer automation. In 2002, he founded Kereon AG. He is member of GAMP® Europe Steering Committee, co-founder and chairman of GAMP® Francophone and edited the French version of GAMP® 4 / 5. Membership: Active member of the GAMP working group 'IT Infrastructure Compliance and Control' / ECA 'DI & IT Compliance Group'.

Dr Robert Stephenson,
Rob Stephenson Consultancy, UK
Rob has had more than 30 years experience in Pharmaceutical and Personal products industries (Boots, Lilly, Unilever, Pfizer). As a long-standing member of the GAMP Europe Steering Committee Rob has contributed material to GAMP®5 and the ISPE GAMP Good Practice Guide on 'A Risk-Based Approach to Operation of GxP Computerized Systems' for which he was co-leader. Rob now works as an independent IT Systems Validation Consultant.

This could be of interest for you

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Why not online? GMP/GDP Training Courses/ Conferences, Webinars and E-Learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

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Reservation Form (Please complete in full)

GAMP®5 2nd Edition – What is new?
Live Online Training on 2 November 2022

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training
Wednesday, 2 November 2022, 09.00 – 18.00 h CET

Technical Requirements
We use Webex Events for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
ECA Members € 990
APIC Members € 1,090
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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