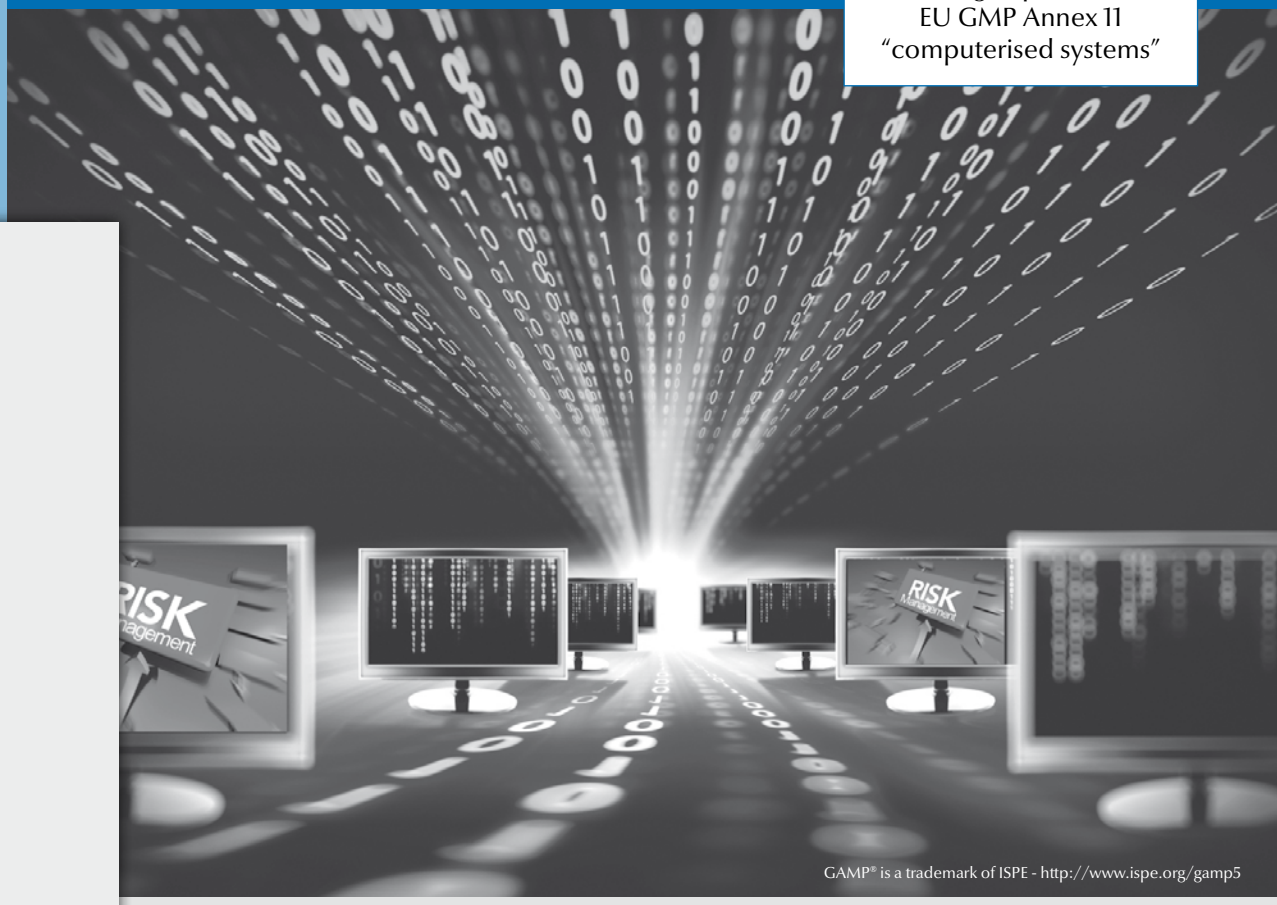
ECA Academy
Your GMP/GDP Information Source

Computer Validation
- Introduction to Risk Management
- The GAMP® 5 Approach

Including implications of EU GMP Annex 11 "computerised systems"



GAMP® is a trademark of ISPE - http://www.ispe.org/gamp5

SPEAKERS:

Frank Behnisch
CSL Behring GmbH

Yves Samson
Kereon

Dr Robert Stephenson
Rob Stephenson Consultancy

Learn How to Plan, Implement and Document Effectively Computer Validation Activities

26 and 27 – 29 March 2019, Vienna, Austria
19 and 20 - 22 November 2019, Copenhagen, Denmark

LEARNING OBJECTIVES:

- The EU GMP Guide Annex 11
- 21 CFR Part 11
- The GAMP® 5 Lifecycle
- Practical Risk Management – ICH Q9 and FMEA Methodology
- Validation Planning
- Change Control
- Validation Documentation
- Presentation to Inspectors
- **Learning by doing: up to 10 Workshops**

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager".
Please find details at www.gmp-certification.eu

Computer Validation: Introduction to Risk Management

26 March 2019, Vienna, Austria | 19 November 2019, Copenhagen, Denmark

Learning Goals

- You get to know the current risk management approaches of ICH Q9 and GAMP®5
- You become familiar with the latest methods and tools for risk analysis and can assess their relevance to practice in the validation of computerised systems
- You learn how the activities involved in the validation of computerised systems can be controlled efficiently by means of risk management
- In 4 workshops you can apply the procedures and discuss them

Background

The current GMP regulations and guidelines (ICH Q9, GAMP®5, EU GMP Guide Annex 11 "Computerised Systems") focus more and more on the topic of risk management. However, the regulations do not offer much concrete advice on how its principles should be translated into practice during the validation and operation of computerised systems. Therefore, it is the aim of this course to provide you with practice-oriented guidance in performing this task.

Target Group

This Education Course is directed at employees from Production, Quality Control / Quality Assurance, Engineering, IT who have to deal with risk assessment and risk management in the field of computer validation.

Programme

Introduction – What do you want from this day?

- Capturing delegates expectations
- Sharing and reducing to key points in groups
- Sharing with all delegates and tutors

An Introduction to Risk Management (including ICH Q9)

- Definition of "Quality Risk Management"
- Principles of Quality Risk Management
- Application of the principles in validation
- Methods of assessing and controlling risk
- Regulatory expectations for risk management

Risk Management the GAMP 5 Way

- The importance of Risk-based Decision Making
- How the GAMP 5 Risk Management Approach aligns with ICH Q9
- The 5-Steps you will need to follow described in detail
- Risk Management throughout the System Lifecycle
- Short workshop on Risk Identification and Risk Analysis

Risk Assessment the GAMP 5 Way

- The simple GAMP®5 Risk Assessment Method
- Assessment Scales for computerised systems that work
- Functional Risk Assessments and Risk Reduction Strategies
- Using risk to determine Test Rigour

Workshop 1: Risk Assessment in Validation
Risk management applied to a computer system

- Evaluating identified risks
- Classification of risks into H, M, L
- Controls to mitigate unacceptable risks
- Links to the validation plan and protocols

In this workshop, delegates will use the GAMP methodology. The participants will work on a case study in which the risks associated with a computer system are assessed and managed to reduce the testing workload in validation.

Workshop 2: Risk Management in Validation
Risk management applied to a control system

- What are the conclusions from the risk assessment?
- What options do you have to mitigate (reduce) the higher risks?
- How will the output affect the protocol?

Based on a real case study, delegates will use the same risk assessment techniques to determine where to focus the qualification of a packaging line.

An Introduction to Risk Ranking

- What is risk ranking
- How is it carried out
- How is it documented?
- A few useful applications

Workshop 3: Applying Risk Ranking to determine periodic review priorities

- How is severity determined?
- How can scales be created?
- Ranking the risks
- Developing a risk-based action plan.

Delegates will apply the techniques of risk ranking to determine which systems present the highest risk to the patient and should therefore be reviewed first.

Computer Validation: The GAMP® 5 Approach

27 – 29 March 2019, Vienna, Austria | 20 - 22 November 2019, Copenhagen, Denmark

Learning Goals

This is why you should attend this course:

- You will systematically be introduced to the principles and methods of the validation of computerised systems (according to GAMP®)
- You will learn the skills to plan, implement and document effectively validation activities for computerised systems and to assess them with respect to their GxP compliance
- You have the opportunity to practically apply the theoretical foundations in 6 workshops

Background

Computerised systems are a central factor determining work sequences in the pharmaceutical industry. Their use increases product safety and saves time and costs of manual intervention. This creates the requirement and necessity, however, to validate all computerised systems which can influence the quality of pharmaceutical products. The basis of the education course will be the current requirements for the validation of computerised systems like GAMP® and their GxP-oriented application in practice. Experts from the pharmaceutical industry and from the GAMP® Committee will show you efficient ways to validate your computerised systems.

Target Group

This course is directed towards specialists and executives in the pharmaceutical industry entrusted with the planning, implementation and evaluation of the validation of computerised systems.

Programme 1st Day

Introduction –What the Participants Expect

An open session capturing the expectations of the delegates

Laws, Regulations and Guidelines for Computer Validation

- The historical perspective
- Current regulations and regulatory guidelines from US
- New regulatory guidance (GAMP® 5, GAMP® Good Practice Guides, ASTM)
- New industry guidance
- Regulatory training
- Harmonisation

Electronic Records and Signatures

- What Part 11 means – Now!
- Identify e-records in predicate rules
- Identify risks to records
- Identify appropriate controls for records

The GAMP® 5 Approach to Computer Validation

- Validation needs structure
- The GAMP® approach
- What is new in GAMP® 5
- General validation activities
- The GAMP® Categorisation System
- Life Cycle cost reduction

The EU Annex 11 "Computerised Systems"

- What are the important points?
- How can you implement it?

Workshop 1: Self Evaluation of Compliance with Annex 11

User Requirement Specifications (URS)

- Why do we need user requirements and specifications?
- What should a URS look like – and who should be involved?
- How to capture requirements effectively
- How does User Requirements documentation go wrong?

Workshop 2: Evaluation of a User Requirement Specification

A short review of the URS and how to write specifications, as a prelude to a workshop in which delegates will evaluate a real requirements specification.

- What is a URS?
- Why is it important?
- Contents of a URS
- Characteristics of good specifications
- Testable specifications

Risk Management

- Q9 process
- GAMP®5 five steps approach
- Practical approach to Risk Management
  - High Level Risk Assessment – HLRA
  - System Risk Assessment – SRA
  - Functional Risk Assessment - FRA

Programme 2nd Day

Validation Planning
- Why is a validation plan important?
- Definitions and regulatory expectations
- Building risk management into planning phase
- Structure and contents of validation plans
- Discussion of best approach
- The impact of scaleability

Workshop 3: Validation Planning
Based on considerations of the type of application, knowledge of the supplier and how it will be used, delegates will work out the best approach to delivering the benefits of a GxP system
- What are the risks associated with delivering the system?
- What options do you have to manage the most critical risks?
- How can they best be managed?
- What are the key issues to monitor to ensure delivery of the project benefits?

Specifications, Design Review and Traceability
- What sorts of specifications are needed?
- How are they constructed?
- Can they be combined?
- How to carry out a design review?
- How to construct a traceability matrix?

Workshop 4: Risk Management in Protocol Planning
Based on a real case study, delegates will use the same risk assessment techniques as in Workshop 2 to determine where to focus the qualification of a packaging line.
- Risk management applied to a control system
- Using FMEA to assess risks to be managed and controlled in validation
- Identifying options to mitigate (reduce) the higher risks
- Using the output in creating the testing protocol

Protocols, Test Scripts and Deviation Management
- Principles of Risk-Based Qualification
- Leveraging the Supplier
- Commissioning vs Qualification
- Test Script Design
- Deviation Management

Workshop 5: Managing Deviations
In this workshop examples of deviations will be examined and methods of resolution discussed. The examples are based on real-life protocols.
- Test failures found during IQ/OQ
- Manage the deviations
- Suggest solutions

Change Control
- Regulatory requirements
- Configuration management
- Responsibilities
- Planned/unplanned changes
- Classification
- Sources of changes

Workshop 6: Change Control
The participants will work on a number of case studies and define the change control activities needed.
- Change Control forms
- Approval process
- Standard Changes
- Committees

Programme 3rd Day

Automation Aspects
- System Overview / Specifications
- GAMP® and risk analysis
- Findings & consequences

Validation Reporting & Presentation to Inspectors
- The link between the plan and the report
- Key documents
- Validation summary reports
- Style and emphasis
- Managing the inspection

Regulatory Comments
- Recent general trends
- Highlights from Warning Letters and 483s
- Lessons we must learn

Introduction to IT-Infrastructure Qualification
- The qualification lifecycle
- How to deal with user requirements
- Qualification documentation
- Critical issues
- Qualification summery report

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel.
Early reservation is recommended.

Registration

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

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
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D-69007 Heidelberg, Germany
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For questions regarding content:
Dr Andreas Mangel (Operations Director) at +49-(0)62 21 / 84 44 41, or per e-mail at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Rouwen Schopka (Organisation Manager) at +49-(0)62 21 / 84 44 13 or per e-mail at schopka@concept-heidelberg.de.

Social Event

On 27 March 2019 / 20 November 2019 you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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 (SIP) for “Small Systems”.

Yves Samson, Kereon AG
Basel, Switzerland
Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group “IT Infrastructure Compliance and Control”.

Dr Robert Stephenson
Rob Stephenson Consultancy, UK
Rob has had extensive experience with the implementation and operational control of a wide range of applications within the Pharmaceutical and Personal Products sector. He joined Pfizer Sandwich UK in 2000 as member of their Quality Unit operating within the IT group where his responsibilities included coordinating the manufacturing site’s initiative to achieve 21 CFR Part 11 compliance and authoring their IT Quality Management System. 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Computer Validation: Introduction to Risk Management
☐ 26 March 2019, Vienna, Austria
☐ 19 November 2019, Copenhagen, Denmark

Computer Validation – The GAMP® 5 Approach
☐ 27-29 March 2019, Vienna, Austria
☐ 20-22 November 2019, Copenhagen, Denmark

Mr. ☐ Ms. ☐

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number if applicable

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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 January 2012)

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 http://www.gmp-compliance.org/eca_privacy.html). 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 & Venue March 2019

Computer Validation:
Introduction to Risk Management
Tuesday, 26 March 2019, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computer Validation – The GAMP® 5 Approach
Wednesday, 27 March 2019, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 28 March 2019, 08.30 h – 17.30 h
Friday, 29 March 2019, 08.30 h – 13.00 h

Radisson Blu Park Royal Palace Hotel, Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
info.parkroyalpalace.vienna@radissonblu.com

Date & Venue November 2019

Computer Validation:
Introduction to Risk Management
Tuesday, 19 November 2019, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computer Validation – The GAMP® 5 Approach
Wednesday, 20 November 2019, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 21 November 2019, 08.30 h – 17.30 h
Friday, 22 November 2019, 08.30 h – 13.00 h

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Scandinavia.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

Computer Validation: Introduction to Risk Management
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Computer Validation – The GAMP® 5 Approach
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event including dinner on the first day, two lunches and all refreshments. VAT is reclaimable.

Save Money and book both courses:
ECA Members € 2,190
APIC Members € 2,290
Non-ECA Members € 2,390