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

31 March and 1–3 April 2020 | Vienna, Austria
17 November and 18–20 November 2020 | Copenhagen, Denmark

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

Highlights
- 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

Including implications of
EU GMP Annex 11 "computerised systems"
Objective

- 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 Audience

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.

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.
Objectives

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.

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 regulatory expectations

These are the important points to consider:
- What is a URS?
- Why is it important?
- Contents of a URS
- Characteristics of good specifications
- Testable specifications

User Requirements 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 Requirements 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 requirement 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
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 scalability

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

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
- Using the output in creating the testing protocol

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

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 summary report
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 European 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 joined Pfizer Sandwich UK in 2000 as member of their Quality Unit operating within the IT group. 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.

Social Event

On 1 April / 18 November, 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.
**Reservation Form (Please complete in full)**

**Computer Validation: Introduction to Risk Management**
- 31 March 2020, Vienna, Austria
- 17 November 2020, Copenhagen, Denmark

**Computer Validation – The GAMP 5 Approach**
- 1-3 April 2020, Vienna, Austria
- 18-20 November 2020, Copenhagen, Denmark

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**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 cannot attend entirely we will charge the following fees for any processing fees.

- Cancellation until 2 weeks prior to the conference: 50% of the conference fee will be charged.
- Cancellation within 2 weeks prior to the conference: 100% of the conference fee will be charged.
- Cancellation of non-appearance: If you cannot take part, you have to inform us in writing. The cancellation fee will be calculated according to the point in time at which you withdraw your registration.

**Important:**

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**VAT is reclaimable.**

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**Save money and book both courses:**

**Fees (per delegate plus VAT):**

- EU GMP Inspectorates: €995
- Non-ECA Members: €1,990
- APIC Members: €1,890
- ECA Members: €1,790

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**Important:** Please indicate your company’s VAT ID Number.

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