ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Frank Behnisch
CSL Behring

Yves Samson
Kereon

Dr Robert Stephenson
Rob Stephenson Consultancy

Computerised System Validation - Introduction to Risk Management - The GAMP® 5 Approach

23 April 2024 and 24-26 April 2024, Berlin, Germany

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

Highlights

- The new GAMP® 5 Second Edition
- The EU GMP Guide Annex 11
- 21 CFR Part 11
- The GAMP® 5 Lifecycle
  - Software Categorisation
  - Specifications
  - Verification / Testing
- Practical Risk Management – ICH Q9 and FMEA Methodology
- Validation Planning
- Change Control & Test Incident Management
- Validation Documentation
- Presentation to Inspectors
- Data Integrity Considerations for CSV
- Up to 10 Workshops / Interactive Sessions

Including implications of
EU GMP Annex 11 “computerised systems”

Programme “Computerised System Validation: Introduction to Risk Management”

Objectives

- Get to know the current risk management approaches of ICH Q9 and GAMP® 5 2nd Edition
- Become familiar with the use of the latest methods and tools for risk analysis when validating computerised systems
- Learn how the activities involved in the validation of computerised systems can be controlled efficiently by means of risk management
- In 3 workshops you can see how these procedures are applicable

Background

Current GMP regulations and guidelines (EU-GMP Guide Annex 11 ‘Computerised Systems’, ICH Q9, GAMP® 5 2nd Edition, ASTM E2500-20) focus more and more on the topic of risk management. However, the regulations do not offer much concrete advice on how their 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 Training 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 computerised system 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: Risk Management Applied to a Computerised System

- High Level and System Risk Assessment
- Evaluating identified risks
- Controls to mitigate unacceptable risks

Workshop: Functional Risk Assessment Applied to a Control System

- How to document a FRA
- Classification of risks into H, M, L
- What are the conclusions from the risk assessment?
- What options do you have to mitigate (reduce) the higher risks?
- Using the output to determine verification tasks

An Introduction to Risk Ranking

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

Workshop: Applying Risk Ranking to Determine System Remediation Priorities

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

Your Benefits

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 course in detail and with which you document your training.


CERTIFICATE

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropiate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

Programme “Computerised System Validation – The GAMP® 5 Approach”

Objectives

Why you should attend this training:

- 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
- In workshops / interactive sessions you can see how the theoretical foundations will apply practicable

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

Programme

Introduction – What the Participants Expect

An open session capturing the expectations of the delegates.

Validation Overview

- What do we mean by Validation?
- Validation and Qualification
- Organising and Planning
- Good Documentation Practice
- Specification & Verification
- System Inventory
- System Description

Computerised Systems in Practice

- Definition of a Computerised System
- Scope of CSV (Computerised System Validation)
  - Laboratory Equipment
  - Automation / Process Control
  - Facility Management
  - GxP Applications – GCP / GLP / GMP / GDP / GVP
  - IT / OT Infrastructure

Regulatory Framework Overview

- GxP: Regulated Good Practices
- EudraLex
  - Relevant Regulatory Framework for CSV Purposes
- US GxP Regulations
- Industry Standards

Annex 11 “Computerised Systems” to European GMP

- General principles
- Project phase
- Operation
- ERES requirements
- Annex 11 vs 21 CFR Part 11
- How can you implement it?

Workshop: Self Evaluation of CSV Regulatory Compliance

The GAMP® 5 2nd Edition: A Risk-Based Approach to Compliant GxP Computerised Systems

- Applicability
- GAMP® 5 Key Principles
- Life Cycle / ASTM E2500-13 / V-Model
- Guide Structure
- Risk Management according to ICH Q9

Data Integrity Considerations for CSV

- What data are relevant?
- ALCOA+: Data Integrity criteria
- Paper vs hybrid vs electronic systems
- Data integrity requirements for CSV projects

Specifying Requirements

- Importance of Requirements Specification (RS)
- RS Scope and Contents
- Roles & Responsibilities
- Requirements Good Practices
- POLDAT

GAMP® 5 Software Categories

- System Structure
- Software Categories 1, 3, 4, 5
- End User Applications
- User View vs IT Perspective

Workshop: Software Categorisation According to GAMP® 5

Functional Specifications – Building the Bridge

- Importance of URS – FS linking
- FS Scope and Contents
- Roles & Responsibilities
- FS and FRA
- FS Good Practices

Workshop: Specifying Requirements - URS vs. FS

Design Specification

- CS – Configuration Specification
- Detailed Specification
  - SDS – Software Design Specification
  - SMS – Software Module Specification
  - HDS – Hardware Design Specification
  - NDS – Network Design Specification

Requirement Traceability

- Regulatory expectation vs Good Engineering Practice
- Vertical Traceability / Horizontal Traceability
- How to trace? - Embedded Traceability / Traceability Matrix

Design Review ... More Than a Milestone: A Process

- GAMP® 5 recommendation on 'Design Review'
- Functional & technical design review
- Scaleability of the review activities
- Design review: a life cycle supporting process
- Design review documentation
- From 'Design Review' to 'Periodic Evaluation'

Validation Planning

- CSV: A Life cycle approach embedded into the QMS
- Validation Master Plan
- Qualification & Validation on Project / System Level
  - Qualification / Validation Plan
  - Supplier Assessment / Supplier Management
  - Risk Management
  - Documentation
  - Verification
  - Supporting Processes / System Release

Workshop: Validation Planning

Testing of GxP Systems

- Verification vs Validation Terminology
- Software testing
- Acceptance testing / Factory acceptance test (FAT) / Site acceptance test (SAT)
- Qualification testing
  - Installation qualification (IQ) / configuration testing
  - Operational qualification (OQ) / functional testing
  - Performance qualification (PQ) / requirements testing
- Good Testing Practice
- Management of test environment
- Verification of data migration activities
- Optimising the test strategy

Test Incident Management

- Test incident management overview
- What is a test incident?
- Test incident management process
- Taking a risk-based approach

Workshop: Test Incidents

Change and Configuration Management During the Project Phase

- Regulatory requirements
- Configuration management
- Change management
- Responsibilities
- Recommendation
  - When to start?
  - Areas of concern

Workshop: Change Management

CSV – Specific Aspects: Automation

- System Overview / Specifications
- GAMP® 5 and risk analysis
- Findings & consequences

Validation Reporting and Handover to Operation

- Linking the Validation Plan and Report
- Key documents
- Validation summary reports
- Handover to Operation

CSV: Presentation to Inspectors

- Managing the inspection
- What inspectors want to see
- Warning Letters and 483s
- Inspection experiences
- Lessons to learn

Conference language
The official conference language will be English.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr. Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or at
mangel@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49(0)62 21/84 44 51, or at
strohwald@concept-heidelberg.de.

This could be of interest for you as well

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.

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 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 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 Wednesday evening, 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.

PE/21022024

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

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

ECA Training Courses

Computerised System Validation: Introduction to Risk Management

☐ *23 April 2023*

Computerised System Validation – The GAMP® 5 Approach

☐ *24-26 April 2024*

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 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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 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 http://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.

Dates of the Training Courses

Computerised System Validation: Introduction to Risk Management
Tuesday, 23 April 2024, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computerised System Validation – The GAMP® 5 Approach
Wednesday, 24 April 2024; 09.00 – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 25 April 2024, 08.30 h – 17.30 h
Friday, 26 April 2024, 08.30 h – 16.00 h

All times mentioned are CEST.

Venue

HYPERION Hotel Berlin
Prager Straße 12
10779 Berlin
Germany
Phone +49 (0)30 236250 0
E-Mail: hyperion.berlin@h-hotels.com

Fees (per delegate plus VAT)

Computerised System Validation: Introduction to Risk Management
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 and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Computerised System Validation – The GAMP® 5 Approach
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event including dinner on Wednesday, lunch on each day and all refreshments. VAT is reclaimable.

Save money and book both courses:
ECA Members € 2,690
APIC Members € 2,790
Non-ECA Members € 2,890
EU GMP Inspectorates € 1,445

The conference fee is payable in advance after receipt of invoice and includes conference documentation, 4 lunches, social event including dinner on Wednesday, and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG 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.