ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

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

Live Online Training on
17 November and 18-20 November 2020
23 March 2021 and 24-26 March 2021

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
  - Software Categorisation
  - Specifications
  - Verification / Testing
- Practical Risk Management – ICH Q9 and FMEA Methodology
- Validation Planning
- Change Control & Deviation Management
- Validation Documentation
- Presentation to Inspectors
- Data Integrity Considerations for CSV
- Up to 10 Case Studies / 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
- 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 case studies 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, ASTM E2500-13) 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 Live Online 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 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

Case Study: Risk Management Applied to a Computerised System

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

Case Study: 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?

An Introduction to Risk Ranking

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

Case Study: 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.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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 Live Online Training in detail and with which you document your training.

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 Live Online Training 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 online 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 case studies / 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 Live Online 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 Live Online 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 1st Day

Introduction – What the Participants Expect

An open session capturing the expectations of the delegates .

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

Validation Overview

- Qualification / Validation Plan
- Systems Description
- Specifications
  - URS / FS / CS / DS
- Verification
  - Design Review / IQ / OQ / PQ
  - FAT / SAT
- Qualification / Validation Report
- VMP – Validation Master Plan
  - Inventories
- Good Documentation Practices for CSV

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?

Case Study: Self Evaluation of Compliance With Regulatory Expectations

The GAMP®5: 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

User Requirements Specifications (URS)

- Importance of URS
- URS Scope and Contents
- Roles & Responsibilities
- Requirements Good Practices
- POLDAT

GAMP®5 Software Categories

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

Case Study: Software Categorisation According to GAMP 5

Programme 2nd Day

Functional Specifications – Building the Bridge

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

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

Case Study: 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

Deviation Management

- Deviation management overview
- What is a deviation?
- Deviation management process
- Taking a risk-based approach

Case Study: Managing Deviations

Programme 3rd Day

Change and Configuration Management During the Project Phase

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

Interactive Session: Change Control

CSV – Specific Aspects: Automation

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

CSV – Specific Aspects: IT/OT-Infrastructure Qualification

- The qualification lifecycle
- How to deal with user requirements
- Qualification documentation
- Critical issues
- Qualification summary report

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 we must learn

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.

Ordering a Recording
Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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

CONCEPT HEIDELBERG
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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.

PE/20082020

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Training

Computerised System Validation: Introduction to Risk Management

☐ *17 November 2020*

☐ *23 March 2021*

Computerised System Validation – The GAMP 5 Approach

☐ *18-20 November 2020*

☐ *24-26 March 2021*

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 of the Live Online Training

Computerised System Validation: Introduction to Risk Management
Tuesday, 17 November 2020, 09.00 h – 18.00 h
Tuesday, 23 March 2021, 09.00 h – 18.00 h

Computerised System Validation – The GAMP 5 Approach
Wednesday, 18 November 2020, 09.00 h – 17.30 h
Thursday, 19 November 2020, 09.00 h – 17.30 h
Friday, 20 November 2020, 09.00 h – 13.00 h
Wednesday, 24 March 2021, 09.00 h – 17.30 h
Thursday, 25 March 2021, 09.00 h – 17.30 h
Friday, 26 March 2021, 09.00 h – 13.00 h

All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

Computerised System 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.

Computerised System 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.

Save money and book both courses:

ECA Members € 2,190
APIC Members € 2,290
Non-ECA Members € 2,390
EU GMP Inspectorates € 1,195
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.