Speakers

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

21 April 2026 and 22-24 April 2026, Barcelona, Spain

Save € 600,- by booking both courses!

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

Highlights

- The use of GAMP® 5 Second Edition
- The EU GMP Guide Annex 11 including Draft 2025
- 21 CFR Part 11
- The GAMP® 5 Lifecycle
  - Software Categorisation
  - Specifications
  - Verification / Testing
- Practical Risk Management – ICH Q9 (R1) 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"

Objectives

- Get to know the current risk management approaches of ICH Q9 (R1) and GAMP® 5 Second 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 (R1), GAMP® 5 Second Edition, ASTM E2500-25) 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.

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

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® 5)
- 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

EU Annex 11 "Computerised Systems"

- General principles
- Project phase
- Operation
- ERES requirements
- Annex 11 vs 21 CFR Part 11
- How can you implement it?
- About Annex 11 draft (2025)

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**

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

- Applicability
- GAMP® 5 Key Principles
- Life Cycle / ASTM E2500-25 / 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

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**

Specifying Requirements

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

Functional Specifications – Building the Bridge

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

Workshop: Self Evaluation of CSV Regulatory Compliance

Interactive Discussion: 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 / Design Review

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

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 THE 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
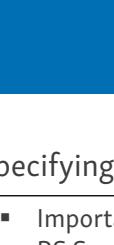
Workshop: Test Incidents

Change and Configuration Management During the Project Phase

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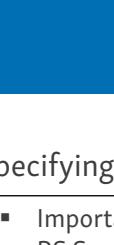
Workshop: Change Management

Validation Reporting and Handover to Operation

- Linking the Validation Plan and Validation 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

CSV – Specific Aspects: Automation

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

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
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69007 Heidelberg, Germany
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For questions regarding content please contact:

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For questions regarding organisation please contact:

Ms Manuela Luckhaupt (Organisation Manager) at
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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
Formerly CSL Behring GmbH, Germany

Frank Behnisch was CSV Lead Execution Systems EMEA/Marburg at CSL Behring GmbH and was responsible for computerised system validation at the interface between IT and engineering. He was a founding member of GAMP D-A-CH and a member of the GAMP EU and D-A-CH Steering Committees.

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 and GAMP® 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.

Dates of the Training Courses

Computerised System Validation:
Introduction to Risk Management
Tuesday, 21 April 2026, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computerised System Validation –
The GAMP® 5 Approach
Wednesday, 22 April 2026; 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 23 April 2026, 08.30 h – 17.30 h
Friday, 24 April 2026, 08.30 h – 16.00 h

All times mentioned are CEST.

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona
España
Phone +43 (93) 503 53 00
E-Mail: sants@barcelo.com

Fees (per delegate plus VAT)

Computerised System Validation:
Introduction to Risk Management
ECA Members € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 645

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 € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245

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 € 600,-by booking both courses!
We will offer you a discount of € 600 if you book both training courses.

The conference fee is payable in advance after receipt of invoice and includes conference documentation, 4 lunches, social event including dinner on April, 22th, 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 search and register directly at www.gmp-compliance.org under the numbers 22405 (Introduction to Risk Management), 22407 (The GAMP® 5 Approach), 22406 (Introduction to Risk Management + GAMP 5 Approach).

Reservation Form (Please complete in full)

Computerised System Validation –
The GAMP® 5 Approach
☐ 22 - 24 April 2026

Computerised System Validation:
Introduction to Risk Management
☐ 21 April 2026

Company

Purchase Order Number, if applicable

Title, first name, surname

Department

Important: Please indicate your company's VAT ID Number

City   ZIP Code   Country

Phone / Fax

E-Mail (Please fill in)

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

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