ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Frank Behnisch
CSL Behring, Germany

Stefan Münch,
Körber Pharma Consulting, Germany

Yves Samson
Kereon, Switzerland

Dr Robert Stephenson
Rob Stephenson Consultancy, UK

Computerised System Validation:
- Leveraging Suppliers
- Computerised System Validation Master Class

3 June 2025 and 4-6 June 2025 | Copenhagen, Denmark

Qualify yourself as an expert for the validation of computerised systems

Highlights

- Regulatory Update
- Leveraging Suppliers
  - Managing Quality
  - Leveraging Test Activities
  - Supplier Assessment
- Good Validation Practices
- Types of Specifications
- Validation Planning Activities
- Design Activities
- Testing Activities
- How to Report Validation Activities
- What to do with Legacy Systems?
- Scalability
- Alternative & Agile Approaches
- Today / Future IT Compliance Challenges
- Learning by doing: up to 11 Case Studies / Workshops
- Interactive sessions

Computerised System Validation - Leveraging Suppliers, 3 June 2025

Objectives

- Learn what activities and deliverables you should expect to see from your IS/IT supplier to demonstrate Supplier Good Practice
- Learn how to verify your supplier's capabilities so that there are "no surprises".
- Learn how to plan verification and validation activities, leveraging the expertise of your supplier
- Learn how to minimise duplication of effort between the supplier and your regulated company in order to achieve lean and effective processes throughout the system life cycle
- Learn how to work with your supplier to build a strong and lasting client-supplier relationship

Background

Recognising the potential savings and flexibility available, regulated companies are increasingly withdrawing from 'in-house' developed solutions and looking to their external suppliers to provide them with innovative and compliant products and services which fulfil their operational and business needs.

The EU-GMP Annex 11 on Computerised Systems states that 'the competence and reliability of a supplier are key factors when selecting a product or service provider'; 'Leveraging Supplier Involvement' is also one of the 5 key concepts of the GAMP®5 guidance 'A Risk-Based Approach to Compliant GxP Computerized Systems'.

This course aims to provide attendees with the knowledge, and opportunities to practice the skills required, to achieve successful partnerships with their IS/IT suppliers and to improve the efficiency and effectiveness of their validation processes.

Target Audience

This ECA Training is directed at employees from Production, Quality Control/Quality Assurance, Engineering and IS/IT, who have to assess, manage or work with computerised system or service providers.

The Training will also be of value to representatives from suppliers that are working or seeking to work with Regulated Companies in the Life Sciences Sector.

Programme

Introduction – What the Participants Expect

An open session capturing the expectations of the delegates

Leveraging Supplier Expertise: An Overview of Good Practice

- What is current Good Practice?
- Optimising Supplier involvement
- Integrating the Supplier's expertise and deliverables into your validation process
- How to do more with less

Performing a Supplier Assessment

- Why Assess the Supplier?
- The Overall Process
- Assessment Topics
- Types of Assessment
- Corrective Actions & Follow Up Audits

Workshop: Selecting a Supplier

- What factors to consider?
- How to focus the assessment?
- How to engage with the supplier?
- How to report and manage the findings?
- Regulatory expectations

Supplier Audit – The Supplier's View

- Defining the role of the supplier
- What must the supplier do?
- What must the regulated company do?

Quality Planning within a Supplier's QMS - Developing a Quality Plan that Delivers

- Quality Management System
- Establishing Requirements
- Producing Specifications
- Testing and Release
- Support and Maintenance

Workshop: Quality Planning within a Supplier's QMS - Developing a Quality Plan that Delivers

Leveraging Supplier Testing

- Test script development
- Test script execution
- Test script review and approval

Computer Systems Validation Master Class, 4-6 June 2025

Objectives

As a specialist in the validation of computerised systems, this event will provide you with

- Suggestions on how current regulatory guidance on computerised systems relating to data integrity, critical thinking and CSA (Computer Software Assurance) can be put into practice
- Real-life examples of how validation effort can be scaled according to risk-based approaches
- Answers to specific questions, e.g. on source code review or on creating specification documents
- The opportunity to bring questions from your own practice up for discussion

Background

The V-model has become a standard worldwide methodology for the validation of computerised systems. Regulatory requirements, as well as industry guidelines, like GAMP®5 2nd Edition, are orientated towards this model. In practice, you as a validation specialist will want to know how to apply this model to current and increasingly complex validation projects.

Target Audience

The Master Class is directed at employees from

- IT
- Production
- Engineering
- Quality Assurance
- Quality Control

Participants should already have gained experience in the validation of computerised systems, and preferably will have also attended a basic CSV Course.

Programme

Introduction – Gain Understanding of Delegate Experience and Background

Workshop 1: What the Delegates expect

- Capturing delegates expectations
- Sharing and reducing to key points
- Facilitated discussion

Project Life Cycle

- Life cycle refresh
- Life cycle activities and deliverable by Agile approaches

Interactive Session: Good Validation Practices

- IT and System Governance
- CSV roles and responsibilities
- Role of Quality Unit

Presentation of the Project Mandate

- Presentation of the case study application
- Project mandate

Workshop 2: Elaborating URS

- Outlining and drafting URS for the case study application
- Debriefing and plenum discussion

URS (User Requirement Specification): Structure and Content

- URS: Purpose and objectives; Roles & responsibilities
- URS structure
- Prioritizing user requirements
- URS: how much is enough?

Workshop 3: Elaborating URS

- Elaboration of a consolidated URS draft for the case study application
- Debriefing

Introduction to Qualification Planning

- Qualification Planning refresh
  - Q-Plan Purpose and objectives
  - Roles & responsibilities
- Topics to be covered

Workshop 4: Elaborating a Qualifcation / Validation Plan

- Filling out a High Level and System Risk Assessment for the case study application
- Outlining & drafting a Qualification Plan for the case study application
- Debriefing

Qualification / Validation Plan: Structure and Content

- Q-Plan structure
- Q-Plan scalability
- Qualification/Validation strategy

Introduction to Functional Specifications

- FS refresh
  - Purpose and objectives
  - Roles & responsibilities
- Recommendation regarding the elaboration of FS

Workshop 5: Elaborating Functional Specifications

- Outlining FS for the case study application
- Drafting some functionalities
- Debriefing

Risk Management Refresh: Scalability and Objectives

- Risk management refresh: purpose and objectives; process; roles & responsibilities; scalability
- Risk Management traps to avoid

Workshop 6: Performing Functional Risk Assessment

- Performing a functional risk assessment for functionalities of the case study application
- Debriefing

Migration and supporting Activities

- Risk mitigation measures: Purpose and objectives; roles & responsibilities; scheduling and scalability; risk mitigation: more than testing
- Supporting activities: What supporting processes

Introduction to Design Review

- Design Review: Purpose and objectives; Roles & responsibilities
- Design Review more than Design Qualification

Workshop 7: Design Review Planning

- Planning and elaborating a design review strategy for the case study application
- Debriefing

Practical Approach to Design Review

- Design review process: points to consider
- Design review scalability
- Recommendation

Source Code Review

- Source code Review: Purpose and objectives; Roles & responsibilities
- What should be reviewed; how to review document

Interactive Session: Good Validation Practices

- IT and System Governance
- CSV roles and responsibilities
- Role of Quality Unit

Testing and Verification: Objectives and Content

- Testing and verification: Purpose and objectives; roles & responsibilities
- Efficient Testing

Workshop 8: Elaborating OQ / FT Test Cases

- Outlining OQ/FT and PQ/FT for the case study application
- Drafting some functional test cases
- Drafting some performance test cases
- Debriefing

Alternative & Agile Approaches

- Alternative software development models
  - Unified Process, Scrum
- Agility objectives
- Needs for flexible engineering methodologies
- Practical approaches and recommendations

Integration Project vs bespoke Development

- Roles & responsibilities, life cycle for: Integration projects; development projects
- What to leverage and how to leverage?

Workshop 9: Elaborating a Qualification / Validation Report

- Outlining & drafting a Qualification Report for the case study application
- Debriefing

Qualification / Validation Report: Objectives and Content

- Qualification/Validation report:
  - Purpose and objectives
  - Roles & responsibilities
- Report structure
- Recommendation

Bringing Legacy Systems into Compliance

- Objectives
- What shall be done?
- Recommendation

System Classification – A record-based Approach

- Needs for a system classification
- Classification criteria
- How-to classify a systems?

Today / Future IT Compliance Challenges

- Open Source Software validation
- Challenge demands Infrastructure platforms for applications
- Global systems validation vs local defence
- Paperless recipe-based production – ISA 95 / S 88
- Cloud Computing – Data Integrity
- Validating Artificial Intelligence (AI)
- Challenges for data integrity on Lab-Systems

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.

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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69007 Heidelberg, Germany
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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 reservation, hotel, organisation etc. please contact:
Mr Maximillian Bauer (Organisation Manager) at
+49(0)62 21/84 44 25, or at
bauer@concept-heidelberg.de.

Social Event

In the evening of 4 June 2025, 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 (SIG) for "Small Systems".

Stefan Münch
Körber Pharma Consulting GmbH, Karlsruhe, Germany

Stefan Münch, Vice President Validation & Qualification, is responsible for all validation and qualification services of Körber Pharma Consulting. He has more than 25 years of experience in software development (MES) and consulting for the pharmaceutical industry. Furthermore, Mr. Münch is actively engaged in ISPE, PDA, and GAMP D-A-CH for many years and member of the GAMP D-A-CH steering committee.

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 has had more than 30 year experience in Pharmaceutical and Personal products industries (Boots, Lilly, Unilever, Pfizer). 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.

PE/5032025

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Computerised System Validation: Leveraging Suppliers, 3 June 2025, Copenhagen, Denmark
☐ Computerised System Validation Master Class, 4-6 June 2025, Copenhagen, Denmark

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 https://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.

Date of the Training Courses

Computerised System Validation:
Leveraging Suppliers
Tuesday, 3 June 2025, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computerised System Validation Master Class
Wednesday, 4 June 2025, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 5 June 2025, 08.30 h – 17.30 h
Friday, 6 June 2025, 08.30 h – 16.00 h

Venue

RadissonBLU
Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen, Denmark
Phone +45 (0)33 96 50 00
Email guest.copenhagen@radissonblu.com

Fees (per delegate plus VAT)

Computerised System Validation:
Leveraging Suppliers
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 Master Class
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 the first day, three lunches 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.

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 conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax or search and register directly at www.gmp-compliance.org under the numbers 21560 (Leveraging Suppliers), 21562 (Master Class) and 21561 (Leveraging Suppliers + Master Class).