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

23 & 24 - 26 May 2023 | Berlin, Germany

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
- Scalability of Validation
- Advanced Risk Management
- IT Governance
- Data Integrity
- Change Control Management
- Upcoming Challenges in IT
- Learning by doing: up to 10 Workshops
- Interactive sessions

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 supplier organisations 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 Suppliers 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 1:
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

Workshop 2:
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

Supplier Audit – The Supplier’s View

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

Workshop 3: Leveraging Supplier Testing

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

IT Service Management

- Making a Business Case
- Outsourced Supplier Specification and Selection
- Implementation
- Monitoring
- Contract Change and Exit

Programme “Computer Systems Validation Master Class”

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, 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

Current Challenges and Evolution for CSV Activities

- What does compliance really mean?
- Data Integrity
- Securing operation: cybersecurity
- Project agility
- Cost efficiency vs effective risk management
- Applying critical thinking

Roles, Responsibilities and Governance

- PQS – Pharmaceutical Quality System according to ICH Q10
- Responsibilities
  - Operational ownerships
  - Supporting roles
- QA oversight

Workshop 2:
Governance Benchmark

- Polling Exercise plus facilitated discussion
- IT and System Governance
- CSV Roles and Responsibilities
- Role of Quality Unit

Practical Use of Scaleability

- What do we mean by Scaleability?
- How does it work in practice?
- How can we combine documents successfully?
- How much is enough?

Workshop 3:
Scaleability of Validation Activities

- LIMS – Laboratory Information Management System
- Laboratory computerised equipment
- Process control system: PLC – Programmable Logic Controller

Writing Requirements Documents

- Requirements gathering
- Writing good requirements
- Use of templates / boilerplates
- Requirement Quality

Requirements: The Good, the Bad and the Ugly

- Good, bad, and could-be-better requirements
- Testability
- Use of templates / boilerplates
- What you should never write

Ideal Content of a CSV SOP

- Embedding the CSV SOP into the PQS
- Topics to address

Data Integrity and Record Management: A Necessary Long-Term Approach

- Regulatory context
- Document life cycle
- Retention requirements and constraints
- Supporting processes
- Areas of concern

Programme “Computer Systems Validation Master Class”

System Classification – A Record-based Approach

- Needs for record-based system classification
- Classification criteria
- Class A, B, C, D

Workshop 4: System Classification

Design Review – How to Apply Critical Thinking?

- CSA – Computer Software Assurance
- Scaleable Risk Management
- Document Review

Workshop 5: Design Review Scaleability

- Combining Risk Management & Design Review

Bringing Legacy Systems into Compliance

- How to approach legacy system remediation
- Examples
  - Learning management system
  - Laboratory Instruments

Interactive Session Good Validation Practices

Open session in which delegates score their CSV approach against 12 good validation practices

- Each good practice introduced
- Delegates score themselves
- Results consolidated and fed back
- Allows delegates to compare their CSV system against best practice and other practitioners

Alternative & Agile Approaches

- Alternative software development models
  - Unified Process, Scrum
- Agility objectives
  - Need for flexible engineering methodologies
- What Agile engineering is not
  - What Agile engineering needs
- Practical approaches and recommendation
  - Conditions for success

Validating Spreadsheets

- Why are spreadsheets high risks?
- Design considerations
- What is important (risk again!)
- How to document spreadsheet validation

Code Review

- Principles of code reviewRequirements
- Regulatory expectations
- Performing code reviews
- How to document code reviews

Elaboration of a Data Integrity Programme

- Data Integrity Programme: What to do?
  - Topics to address
  - Action planning
- Embedding the Data Integrity Programme into the PQS
- Progress Reporting

Case Studies: Complex Projects

- Global projects
  - Roles & Responsibilities
  - Data-related requirements
- Large systems
  - Phase-based implementation and deployment
- Interface projects
  - Roles & Responsibilities
  - Testing

Today / Future IT Compliance Challenges

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

Real Life Qualification / Validation Projects

- Real Life Qualification / Validation Projects
- Requirements
- Constraints
- Issues identified
- Lessons learned

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 Live Online Training 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 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

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
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 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 the first couse day, 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.

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 (SIG) for "Small Systems".

Stefan Münch
Körber Pharma Consulting / Systec Services GmbH, Karlsruhe, Germany

Stefan Münch, Business Director Validation, is responsible for all validation services of Körber Pharma Consulting. He has more than 20 years of experience in software development for the pharmaceutical industry (MES). Furthermore, Mr. Münch is actively engaged in GAMP D-A-CH for many years and member of the 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/21122022

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

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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, 23 May 2023, Berlin, Germany
☐ Computerised System Validation Master Class, 24 - 26 May 2023, Berlin, Germany

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, 23 May 2023, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computerised System Validation Master Class
Wednesday, 24 May 2023, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 25 May 2023, 08.30 h – 17.30 h
Friday, 26 May 2023, 08.30 h – 16.00 h

Venue

H10 Berlin Ku'damm
Joachimsthaler Straße 31-32
10719 Berlin, Germany
Phone +49(0)30 322 922 300
Email h10.berlin.kudamm@h10hotels.com

Fees (per delegate plus VAT)

Computerised System Validation:
Leveraging Suppliers
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 Master Class
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 the first day, three lunches 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, four 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 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 message.
Or you register online at www.gmp-compliance.org.