

Speakers



Frank Behnisch
CSL Behring, Germany



Yves Samson
Kereon, Switzerland



Dr Robert Stephenson
Rob Stephenson Consultancy,
UK

Computerised System Validation: Maintaining Control of Operation

Live Online Training from 12-14 October 2022



*Keep your regulated systems and data in compliance throughout
their operational life!*

Highlights

- Requirements from the EU GMP Guide Annex 11
- The GAMP 5 Risk-Based Approach to Operation of GxP Computerized Systems Good Practice Guide
- Computer Systems in Use: Where are the Risks?
- Handover and Establishing Support Services
- Keeping the System Running Smoothly
- CAPA Management
- Record and Document Management
- Periodic Evaluation
- Change Control and Configuration Management
- Data Integrity and Raw Data management
- Business Continuity Planning & Disaster Recovery
- Data Management Processes / Back-up and Restore / Archiving / Retrieval / Deletion
- Decommissioning / Retirement / Disposal

Including new requirements
on Data Integrity

Objectives

Four good reasons why you should attend:

- Delegates will gain understanding of the controls needed to maintain validated systems in compliance throughout their operational lifecycle.
- Taking a risk-based approach, you will learn how these controls can be scaled across a wide range of computerised systems, allowing you to focus your resources on the most critical systems and the most critical systems components
- You will learn the importance of role clarity and making best use of Subject Matter Experts and the Quality Unit.
- In workshops, you will get the chance to put the theory into practice and discuss suitable solution strategies with your colleagues

Background

The greatest part of the system life cycle is represented by daily operation. It is now a clear regulatory requirement that GxP computerised systems must be kept in compliance throughout their operational lifetime. Audit experience shows that companies struggle with this task. Once the implementation project is complete and the computerised system is handed over for use how can the validated state be maintained? What exactly is required and how can these requirements be successfully established and maintained?

The course reflects the requirements of the EU Annex 11 and the approaches contained in the ISPE/GAMP Good Practice Guide ,A Risk-Based Approach to Operation of GxP Computerized Systems – A Companion Volume to GAMP®5’.

Experts from the GAMP® Committee will give you the answers to these questions and give you the opportunity to deepen your understanding by participating in a set of training workshops based on practical real-life examples.

Target Audience

This Education Course is directed at anyone who has to deal with the validation and operation of computerised systems and the maintenance of the validated state. Typically delegates come from:

- Manufacturing and Production
- Quality Control /Quality Assurance /IT Compliance
- Engineering /Automation/IT
- Software Suppliers and IT Service Providers

Programme

Introduction – Understanding Delegate Experience and Background



Workshop: What Delegates want to know?

- Capturing delegates expectations
- Sharing and reducing to key points in groups
- Sharing with all delegates and tutors

Overview of the Operation Phase

- Regulatory Context and links with Annex 11
- Business process approach, Operational Activities and Information Flows
- Roles and Responsibilities, the RACI Model
- Periodic Assessment, checks and triggers
- Scalability and Risk Management
- Other Support Processes

How well do you maintain the Validated State?

- Delegates score themselves
- Results consolidated and fed back
- Allows delegates to compare their maintenance against best practice and other practitioners

Computer Systems in Use: Where are the Risks?

- What are the inspectors’ concerns?
- Where does the inspector believe the risks lie?
- What will his experience tell him to ask questions about?
- How will he assess the seriousness of any failings?

Handover and Establishing Support Services

- Why does Handover go wrong?
- Roles and Responsibilities
- Handover Planning
- Handover Review and Reporting
- Putting Support Services in Place



Case Study / Workshop: Establishing Responsibilities

- What tasks are required?
- What roles are involved?
- What are their responsibilities?

Keeping the System Running Smoothly 1 – Service Management and Performance Monitoring

- What Support services are required?
- How will Service Delivery be controlled?
- Defining Quality Requirements
- Performance Monitoring
- Periodic Review considerations
- Taking a risk-based approach

Keeping the System Running Smoothly 2 – Incident Management, CAPA and System Administration

- Dealing with unexpected events
- Capturing and Tracking Preventative Actions and Corrective Actions
- Preventing Failures and Driving Continuous Improvement
- Taking a risk-based approach



Case Study / Workshop: Establishing a simple Service Level Agreement

- What are the customer requirements?
- What is the supplier specification?
- How is performance to be measured?

User Management and Access Control / Training

- The role of the System Administrator
- Security
- Training for everyone!
- Training records

Operational Change Control and Configuration Management

- Roles and Responsibilities
- Sources of changes
- Types of changes
- Scaling Change and Configuration Management based on Risk

Periodic Evaluation / Audit Trail Review

- What is a periodic evaluation (periodic review)?
- Which systems are most important?
- How do I decide?
- How do you perform a periodic evaluation?
- Audit trail review considerations during periodic evaluation



Case Study / Workshop: Prioritisation for Periodic Evaluation

- What are the important factors to consider?
- How can they be effectively assessed?
- How can this information be used to determine overall priorities?

Data Management Processes / Back-up and Restore / Archiving / Retrieval / Deletion

- Regulatory expectations for record retention
- What are the considerations for migration?
- It will not be perfect process!
- Which techniques are most appropriate?
- The importance of back-up and its management
- The difficulties encountered

Raw Data Management

- Definition in regulations and in recent guidances (e.g. MHRA, WHO, FDA)
- Risk assessment raw data
 - Direct product influence
 - In-direct product influence
- Defining raw data
- Defending integrity of raw data



Case Study / Workshop: Raw Data Management

- Examples from GMP and GLP will be discussed and presented

Data Integrity in the Operation Phase

- What are the EU and FDA regulatory expectations?
- What are the consequences of data integrity failures – FDA Warning letters etc.
- What are the criteria for achieving consistent data integrity – ALCOA+
- What are the implications for systems in operation?
- How should Audits Trails be managed and reviewed?

Business Continuity Planning and Disaster Recovery

- Business Continuity Planning and Disaster Recovery – how are these processes integrated?
- How to develop a Business Continuity Plan and Disaster Recovery Plan for critical systems
- Taking a risk-based approach to disaster recovery testing



Case Study / Workshop: Business Continuity Planning

- In a pharmaceutical manufacturing company what systems typically need 24/7 up-time?
- Which of these systems has a regulatory requirement for 24/7 up-time?
- What are the key elements of a business continuity plan for IT?
- Whose responsibility is it to produce the plan?
- How would you test it?

Decommissioning, Retirement and Disposal

- Withdrawal from active service
- Shutting down the system and transfer of data
- Disposal of the system

Decommissioning Case Study

- A Presentation of a real-life case study demonstrating a risk-based approach taken to decommissioning a group of operational systems whilst ensuring that regulatory records were retained for their specified retention periods.

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”.



Yves Samson, Kereon AG
Basel, Switzerland

Automation and system engineer with over 25 years experience, including 11 years as regulated user, Yves is the founder of Kereon AG, Basel. He supports his customers as consultant, trainer, and e-compliance auditor. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone. He edited the French version of GAMP 4 and GAMP 5. In 2017, Yves launched the e-Compliance Requirements Initiative (eCRI) with the aim to help the regulated pharmaceutical industry and its suppliers to address and to implement accurately, consistently, and effectively the regulatory e-Compliance requirements.



Dr Robert Stephenson
Rob Stephenson Consultancy, UK

Rob has had extensive experience with the implementation and operational control of a wide range of applications within the Pharmaceutical and Personal Products sector. He joined Pfizer Sandwich UK in 2000 as member of their Quality Unit operating within the IT group where his responsibilities included coordinating the manufacturing site’s initiative to achieve 21 CFR Part 11 compliance and authoring their IT Quality Management System. 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.



Date of the Live Online Training

Wednesday, 12 October 2022, 09.00 h – 17.30 h

Thursday, 13 October 2022, 09.00 h – 17.30 h

Friday, 14 October 2022, 09.00 h – 13.30 h

Times mentioned are CET.

Technical Requirements

We use Webex Events for our live online training courses and webinars. At <https://www.gmp-compliance.org/training/online-training-technical-information> you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

Non-ECA Members EUR 1.990,-

ECA Members EUR 1.790,-

APIC Members EUR 1.890,-

EU GMP Inspectorates EUR 995,-

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.

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 Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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 Rouwen Schopka (Organisation Manager) at

+49(0)62 21/84 44 13, or at

schopka@concept-heidelberg.de.

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 seminar 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 appropriate 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

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>.

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

Reservation Form (Please complete in full)



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Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

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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 %.
- 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 HEIDELBERG will 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 can-

cellation 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.

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