



## 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 11-13 October 2023



*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

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#### Workshop: What Delegates want to know?

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

### Overview of the Operation Phase

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- 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?

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- 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?

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- 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

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



#### Case Study / Workshop: Establishing Responsibilities

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

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

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- 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

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- 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

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

## User Management and Access Control / Training

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

## Operational Change Control and Configuration Management

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

## Periodic Evaluation / Audit Trail Review

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- 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

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- 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

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- 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

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- 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

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- Examples from GMP and GLP will be discussed and presented

## Data Integrity in the Operation Phase

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- 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

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- 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

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- 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

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

## Decommissioning Case Study

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- 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

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.



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## Computer System Validation: Maintaining Control of Operation Live Online Training from 11-13 October 2023

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## Date of the Live Online Training

Wednesday, 11 October 2023, 09.00 h – 17.30 h

Thursday, 12 October 2023, 09.00 h – 17.30 h

Friday, 13 October 2023, 09.00 h – 13.30 h

Times mentioned are CEST.

## Technical Requirements

We use Webex 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 € 2,290

ECA Members € 2,090

APIC Members € 2,190

EU GMP Inspectorates € 1,145

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](http://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.

## You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings).

## 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](mailto:info@concept-heidelberg.de) | [www.concept-heidelberg.de](http://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](mailto: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](mailto: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](http://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

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