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Computer Validation: Maintaining Control of Operation

Including new requirements on **Data Integrity**

SPEAKERS:

Frank Behnisch
CSL Behring GmbH

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

29-31 October 2019, Copenhagen, Denmark

HIGHLIGHTS:

- Requirements from the EU GMP Guide Annex 11
- The GAMP 5 Risk-Based Approach to Operation of GxP Computerized Systems
- 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 Review
- Change Control and Configuration Management
- Business Continuity Planning
- System / Data Migration / Back-up / Restore
- Archiving and Retrieval
- Decommissioning / Retirement / Disposal

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager“. Please find details at www.gmp-certification.eu

Computer Validation: Maintaining Control of Operation

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Learning Goals

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 parts of systems.
- 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 to 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 new 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 Group

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 Delegates' Experience and Background

Workshop 1: What Delegates want to know?

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

Working in groups delegates derive their requirements from the training event and share them with 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?

Workshop 2: Patient Risk in Maintaining Control over your Computer Systems

- Identify the patient risks in selected activities from computer system in use
- Identify the controls or checks to be made
- Suggest ways of implementing the checks and controls

Working in groups, delegates will be asked to discuss and answer specific questions related to the above and feed back their answers to the other delegates.

Handover and Establishing Support Services

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

Workshop 3: Establishing Responsibilities

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

GAMP and RACI roles are applied to one of the Operational Support Processes.

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

Workshop 4: Record and Document Management - Audit of System Documentation

- What procedures would you expect to see to confirm a system is under control?
- Which procedures must QA sign?
- What records would you expect to see to confirm a system is under control?
- What standards would you reference to support your arguments?

Delegates prepare to audit systems documentation, making an 'aide memoire' of documentation to check.

Workshop 5: Establishing a simple Service Level Agreement

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

Delegates are given the opportunity to develop a simple Service Level Agreement for a specific Operational Control task.

Security and 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 Review and Assessment

- What is a periodic review?
- Which systems are most important?
- How do I decide?
- How do you perform a periodic review?

Workshop 6: Prioritisation for Periodic Review

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

Typically resources for performing periodic reviews are finite; therefore regulated companies must prioritise their activities in order to focus on critical business and compliance issues. Using a Risk Ranking approach delegates will consider how to perform and report this task for a diverse range of regulated systems.

System/Data Migration, Back-up and Restore

- 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

Workshop 7: Data Migration

- What are the issues with data mapping?
- What is the sequence of a migration?
- Must all the data be migrated?
- Impact of data migration on interfaces

New requirements on Data Integrity

- 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?

Raw Data Management

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

Workshop 8: Raw Data Management

- Samples from the area GMP and GLP will be discussed and presented

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

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.

Record Archiving and Retrieval

- When is archiving necessary?
- It will not be a perfect process!
- How should it be indexed?
- What are the security issues?
- Periodic electronic regeneration

Maintain Control in Operation: Regulatory Observations

- Regulatory observations
- Understand the regulatory approach
- The way in which observations are written by regulators for maximum impact.

Social Event

In the evening of the first course 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.

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 (SIP) 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.

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

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We offer practice-oriented GMP/GDP training courses on:

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  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

You will find a time schedule for each training course at www.gmp-compliance.com, button "Inhouse Training"

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Easy Registration

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69007 Heidelberg
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e-mail:
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Internet:
www.gmp-compliance.org

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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Date

Tuesday, 29 October 2019, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 30 October 2019, 08.30 h – 17.30 h
Thursday, 31 October 2019, 08.30 h – 12.30 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
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Scandinavia.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the first and second day, business lunch on the third day and all refreshments. VAT is reclaimable.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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