ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

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Computer System Validation: Maintaining Control of Operation

Live Online Training from 3-5 November 2021

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

Objective

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.

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GERMANY

Reservation Form (Please complete in full)

Live Online Training: Computer System Validation: Maintaining Control of Operation
3-5 November 2021

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
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1. We are happy to welcome a substitute colleague at any time.
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- Cancellation until 2 weeks prior to the conference 10 %,
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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 http://www.gmp-compliance.org/eca_privacy.html). 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 Live Online Training

Wednesday, 3 November 2021, 09.00 h – 17.30 h
Thursday, 4 November 2021, 09.00 h – 17.30 h
Friday, 5 November 2021, 09.00 h – 13.30 h
Times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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

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Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

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