ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

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Computerised System Validation: - How to handle Legacy Systems? - Maintaining Compliance during Operation

Live Online Training on 25 February and 26-28 February 2025

Highlights How to handle Legacy Systems

- Regulatory requirements for the qualification / validation of legacy systems
- Considerations in the context of legacy system audits
- Legacy systems compliance from a QA perspective
- Data integrity for legacy systems
- Specifying requirements for existing systems
- Risk-based use of legacy systems

Highlights Maintaining Compliance during Operation

- Requirements from the EU GMP Guide Annex 11 and GAMP®5 2nd Edition
- The GAMP 5 Risk-Based Approach to Operation of GxP Computerized Systems Good Practice Guide
- Handover and Establishing Support Services
- Periodic Evaluation
- Change Control and Configuration Management
- CAPA Management
- Data Integrity and Audit Trail in Operation
- Security Management
- Service & Contract Management
- Retirement Management
- Inspection Readiness

Programme “Computerised System Validation: How to handle Legacy Systems”

Objectives

Systems must be qualified, and processes must be validated. These principles have applied in the pharmaceutical environment for many years. For many reasons, there are always cases in which this procedure cannot be implemented prospectively, or only with difficulty. These include equipment and systems that are purchased second-hand, equipment that has been used for non-GMP purposes, and equipment that has acquired from other companies.

Are such equipment/systems no longer fit for use in the GMP environment, or can they still be appropriately qualified and validated? This live online training offers you solutions on how to deal with this situation and focuses on the following questions:

- Can you still operate legacy systems, and if so, to what extent?
- What can the auditor expect, and what solutions would be considered acceptable?
- How can existing systems be specified retrospectively?
- How can compliance be achieved from a QA perspective?
- What can be done if important cybersecurity issues can no longer be technically controlled?

Target Audience

This live online training is aimed at subject matter experts from:

- IT
- Quality Assurance
- Production / Quality Control
- Technology
- System Suppliers and Service Providers

Programme

Query / Discussion - Problems / Expectations

- Which systems are affected?
- Why have these systems not been adequately qualified?
- Retrospective qualification

Legacy Systems regulatory Requirements and Inspections

- Old systems, legacy systems and existing non-compliant systems - characteristics and problems
- Regulatory considerations
- Annex 11 and Annex 15
- PIC/S PI 011
- GAMP GPG: The Validation of Legacy Systems
- Inspection considerations

Legacy Systems: Ensuring Compliance from a QA Perspective

- Legacy systems: IT security / virus protection / data protection
- On-site infrastructure
- System-side IT components
- Qualification / validation of legacy IT systems

How to write URS for existing Systems

- How to write URS for existing Systems
- URS for existing systems: Waste of time or added value?
- Why creating URS is easier for existing systems
- Beyond the URS: the functional description

Case Studies: Contingency Planning / Support from the Manufacturer

- Initial situation for existing systems
  - Manufacturer support: Hardware & software, Security Patches
  - Mechanical spare parts
- How and what can be planned?
- What “unsolvable” dependencies exist?

What does risk-based Deployment mean for existing Systems?

- Suitability for use
- Learning from operational experience
  - Importance of periodic evaluation and its results
- Quality efficiency

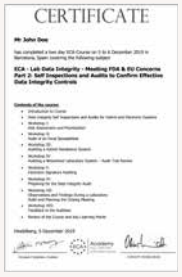
Old Systems, Legacy Systems and existing Systems - Data Integrity light?

- Brief overview of the ALCOA++ principles
- PIC/S PI 041-1: Data integrity
- General problems: inadequate knowledge of the pharmaceutical process and data flow, lack of data definitions, non-existent definition of the GxP relevance of the generated data
- Examples of problems with legacy systems and possible solutions
  - Missing audit trail functionality vs. necessity of an operational audit trail
  - Problems with user administration (no/too few users can be parameterized within the system)
  - Data management: ring memory, system data on USB sticks/SD cards > how to deal with this?

Your Benefit

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

Programme “Computerised System Validation: Maintaining Compliance during Operation”

Objectives

The programme has been substantially revised for 2025, with increased focus on the periodic review and evaluation of computerised systems in operation. What evidential records need to be maintained, and how can these be efficiently leveraged to confidently demonstrate ongoing compliance to auditors and inspectors?

Four additional 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 system components
- You will learn the importance of role clarity and making best use of Subject Matter Experts and the Quality Unit.
- In workshops / case studies / exercises, you will get the chance to put the theory into practice and discuss suitable solution strategies with your colleagues

Target Audience

This Education Course is directed at anyone who must deal with the validation and operation of computerised systems and the maintenance of the validated state.

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 GAMP Guides (GAMP®5 2nd Edition and ‘A Risk-Based Approach to Operation of GxP Computerized Systems – A Companion Volume to GAMP®5’).

Programme

Welcome / Opening session: What the delegates expect?

- Overview of the Operation Phase
- Capturing delegates expectations
- Sharing and reducing to key points in groups
- Sharing with all delegates and tutors

Periodic Evaluation: Establishing a scalable PE strategy

- Objectives and intention
- Scope of Periodic Evaluation
- Periodic Evaluation: Between efficiency and effectiveness
- What information should be considered?

Handover

- Objectives and purposes
- Roles & Responsibilities
- Handover process
- Acceptance criteria
- Records and reports

Data Integrity in Operation

- ALCOA++ principles
- Technical controls vs procedural controls
- Data governance principles and responsibilities
- Data governance vs IT governance
- Governance pitfalls

Risk Management in Operation

- Risk management according to Q9(R1)
- Risk management applied to change management
- Risk management applied to incident and deviation management
- Keeping risk information up-to-date

Data Management in Operation & Business Continuity

- Understanding the data management processes
- Backup & Restore
- Archiving & Retrieval
- Disaster Recovery & Business Continuity
- Monitoring data management activities
- Records and reports

Change & Configuration Management in Operation

- Objectives
- Configuration management
- Change management
- Types of change
- Organizing effective operational change and configuration management

Incident, Problem & Deviation Management in Operation

- Objectives
- Incident & problem vs deviation
- Incident & problem management process
- Effective Root cause analysis
- Records and reports

CAPA Management in Operation

- CAPA objectives
- Correction vs prevention
- Process collaboration
- Records and reports

Service & Contract Management

- Objective of service and contract management
- Establishing a Service Level Agreement (SLA) and contracts
- SLA key topics
- Monitoring SLAs and contracts
- Records and reports

System Management / System Administration

- Objectives
- Roles & Responsibilities
- Activities to cover
- Records and reports

User Management & Access Control

- Objectives
- User management process
- User management pitfalls
- Records and reports

Security & Performance Monitoring

- Objectives
- Security areas of concern
- Efficient and effective performance monitoring
- Records and reports

Repair & Maintenance

- Objectives
- Points to consider
- Reporting
- Records

Patch & Update Management

- Between security, performance, and compliance
- Risk-based approach to patch and update management
- Patch and update management pitfalls
- Records and reports

Maintaining Cloud / SaaS compliance

- Objectives
- Required controls
- What and how to monitor
- Securing data availability
- Record and reports

Audit Trail / Audit Trail Review in Operation

- Objectives of audit trail review during operation
- Process relevant vs administrative audit trails
- What to review & how to review
- Records and reports

Performing Periodic Evaluation

- Implementing a scalable approach
- Leveraging existing records
- Learning from the experience
- Securing operational reliability and capability

Retirement Management

- Retirement process objective
- Retirement planning
- Performing retirement
- Consideration to data migration
- Retirement report

Inspection Readiness

Workshops / Case Studies / Exercises

- MCO Benchmarking Exercise
- What are the problems with Handover?
- Identifying Risks for Computer Systems in use
- Creating a SLA – What are the key elements?

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.

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
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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:
Ms Marion Grimm (Organisation Manager) at
+49(0)62 21/84 44 18, or at
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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.

Why not online? GMP/GDP Training Courses/Conferences, Webinars and E-Learning
Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

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".

Uwe Mai, Bayer
Leverkusen, Germany

With Bayer AG since 1990, responsible for quality assurance since 2012, particularly in the areas of qualification and computer validation.

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.

PE/06122024

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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)

Live Online Training

Computerised System Validation:
How to handle Legacy Systems?

☐ *25 February 2025*

Computerised System Validation:
Maintaining Compliance during Operation

☐ *26-28 February 2025*

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 http://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 Live Online Training

Computerised System Validation:
How to handle Legacy Systems?
Tuesday, 25 February 2025, 09.00 h – 17.30 h

Computerised System Validation:
Maintaining Compliance during Operation
Wednesday, 26 February 2025, 09.00 h – 17.30 h
Thursday, 27 February 2025, 09.00 h – 17.30 h
Friday, 28 February 2025, 09.00 h – 13.00 h

All times mentioned are CET.

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)

Computerised System Validation:
How to handle Legacy Systems?
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.

Computerised System Validation.
Maintaining Compliance during Operation
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.

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.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the numbers 22051 (How to handle Legacy Systems?), 21144 (Maintaining Compliance during Operation) and 22050 (How to handle Legacy Systems? + Maintaining Compliance during Operation).

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.