ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Dr Bernhard Appel
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Computerised System Validation:
GMP Compliant Documentation

Live Online Training from 5-7 October 2022

Highlights

- Which Documents for the Validation of Computer-based Systems are Required by Regulation?
- Which Documents are Checked in the Course of an Inspection?
- What Level of Detail must Documents Have?
- Who is Responsible for Review and Approval?

Objectives

GMP-relevant computerised systems must be validated. The validation activities shall be sufficiently documented in order to allow inspectors as well as internal and external auditors to review and to understand the validation rigour and accuracy. The Live Online Training will give an overview of the necessary qualification and validation documentation, including its structure and level of detail. The responsibilities of both suppliers as well as their regulated customers will be considered.

Background

"What is not documented has not been done!" The accurate documentation of all CSV activities is the prerequisite for successfully passing regulatory inspections as well as customer audits. On the other hand, creating the documents and maintaining their integrity is also time-consuming and costly. Here it is important to find a balance between "as few as possible but as much as necessary".

Target Audience

This Live Online Training is directed at employees from the pharmaceutical industry and suppliers who have to prepare CSV documents and to document the validation activities of the computerised systems or who will have to carry this out in the future. Both beginners and employees with initial experience are addressed.

Programme

Qualification Documentation Overview

- Qualification / Validation Plan
- System Description
- Specifications
- Requirements management / requirement traceability
- Risk management
- Verification
  - Design Review, IQ, OQ, PQ
  - FAT, SAT
- SOPs, agreements
- Qualification / Validation Report
- Qualification documentation scalability

Inspector's Preconditions & Principles

- Guidelines
- Definitionen & Wording
- Overall Responsibility
- Essential PQS-Elements
- Lifecycle Approach IT-System
- Good Documentation Practice (incl. ALCOA)

Computerised System Validation: From Quality Manual to CSV SOP and CS VMP

- Regulator expectations to the PQS
- PQS structure
- Quality Manual
- High level CSV SOP
- IT- / CS-VMP

CS-VMP and Inventory Lists

- CS VMP objective and purpose
  - Planning / Reporting
- CS VMP structure proposal
- Management of the inventory lists
- Proposal for system classification

Inspector's View to Structure & Documents

- Validation Structure
- Documentation Structure
- Essential Topics Project Phase (Validation)
- Essential Topics Operational Phase (Routine)

Supporting SOPs within a CSV Scope

- What SOPs?
- SOP structure proposal
- Recommendation

Data-/Documentation Management & Integrity

- Lifecycle Approach Data/Documents
- Identification of critical data/documents
- Lifecycle & Integrity Risk
- Data Governance Masterplan

Qualification / Validation Plan

- Objectives
- Responsibilities
- Structure proposal for a Qualification / Validation Plan
- Critical aspects
  - Data flows
  - Identification of the GxP relevant data
  - Life cycle
  - Risk management
  - Overall acceptance criteria
  - System release

Qualification / Validation Report - System Description

- Objectives
- Responsibilities
- Structure proposal
- Critical aspects
  - Deviation from the planned procedure
  - Failure and deviation handling
  - Maintaining the qualified/validated state
- System Description
  - Objectives
  - Responsibilities
  - Structure proposal

URS – User Requirements Specification

- URS objectives
- URS structure proposal
  - Functional vs non-functional requirements
- Responsibilities
- Recommendation

Design Review: Supplier Documentation / Solution Selection

- Design review objectives
- Leveraging supplier effort
  - Review of services offered
  - URS vs system functionalities
  - URS vs system support, e.g.: SLA
  - Quality and usability of the user manual
  - Quality and usability of technical documentation
- Design review report
- Consolidation of the qualification/validation process

FS – Functional Specification

- FS objectives
- How much is enough?
  - When is a FS required / needed?
  - What content?
- Responsibilities
- FS structure proposal
- Recommendation
  - Process workflow and user roles
  - Print-outs / reports
  - Audit trail entries

CS – Configuration Specification

- CS objectives
- Responsibilities
- Structure proposal
- Content
- Recommendation
  - When is a CS required / needed?
  - Configuration report vs Configuration Specification

Project Design Review

- Project consistency check
  - Project approach
  - Documentation
  - Are the risk management outcomes properly taken into account?
  - Are the audit report measures properly implemented?
- Traceability matrix
- Design Review Report

Testing Documentation: IQ / OQ / PQ

- Installation Qualification (IQ) & Configuration Specification (CS)
- Operational Qualification (OQ) vs Functional Specification (FS)
- Performance Qualification (PQ)
- Scalability
- Recommendation: How to leverage FAT & SAT results?

Q/V Project Close Down

- Planning and supporting system handover
  - Closing the project
    - Which documents are needed?
    - Which documents need to be updated?
  - Final system release
  - Previous System Retirement

Speakers

Dr Bernhard Appel, Roche Diagnostics, Germany

Dr Bernhard Appel works as a pharmacist in quality assurance pharmaceutical production at Roche Diagnostics GmbH, Mannheim. He has focused on computer system validation ever since he joined the pharmaceutical industry.

Dr Rainer Gnibl, District Government of Upper Bavaria, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health.

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".

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 seminar in detail and with which you document your training.


CERTIFICATE

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Reservation Form (Please complete in full)

Live Online Training: Computerised System Validation - GMP Compliant Documentation
5-7 October 2022

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

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Date of the Live Online Training
Wednesday, 5 October 2022, 09.00 h – 17.15 h
Thursday, 6 October 2022, 09.00 h – 17.15 h
Friday, 7 October 2022, 09.00 h – 13.00 h

All times mentioned are CEST.

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)
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.

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 https://www.gmp-compliance.org/on-demand-online-training/recorded-online-training-webinars. 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 Live Online Training.

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