



## Speakers



**Dr Rainer Gnibl**  
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Upper Bavaria



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# Computer System Validation: GMP Compliant Documentation



Live Online Training from 22-24 September 2021



## 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

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- 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

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- 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

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

### CS-VMP and Inventory Lists

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- 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

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

### Supporting SOPs within a CSV Scope

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- What SOPs?
- SOP structure proposal
- Recommendation

### Data-/Documentation Management & Integrity

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

### Qualification / Validation Plan

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- 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

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- 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

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

## Design Review: Supplier Documentation / Solution Selection

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- 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

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- 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

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

## Project Design Review

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- 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

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- 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

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- 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 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.



Hannah Greiner,  
Epista Life Science, Denmark

Before she joined Epista Life Science in 2020 Ms Greiner was heading the Quality Assurance department of the Innovation & Development Center in Graz and was responsible for the site's GxP compliance related to development of pharmaceuticals and combination products for EU, US and PhM markets, as well as subsequent upscaling and transfer to commercial production sites.



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.

Reservation Form (Please complete in full)



## Live Online Training: Computerised System Validation - GMP Compliant Documentation 22-24 September 2021

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## Date of the Live Online Training

Wednesday, 22 September 2021, 09.00 – 17.15 h

Thursday, 23 September 2021, 09.00 – 17.15 h

Friday, 24 September 2021, 09.00 – 13.00 h

All times mentioned are CEST.

## 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)

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](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.

## 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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