ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Stefan Münch
Körber Pharma Consulting, Germany

Yves Samson
Kereon, Switzerland

Pharma meets IT

Live Online Training on 09/10 October 2025

Understand the Relevance of your IT

Highlights

- The Technology behind your IT
- Requirements for Data Handling, Data Life Cycle and Data Management
- IT System Landscapes
- The Life Cycle of IT Systems
- Software Development and its Special Features
- Current IT Trends
  - AI (Artificial Intelligence)
  - Cloud Computing
  - Cybersecurity

Objectives

- You will gain a basic understanding of IT systems and how they work.
- You will learn how software is developed and tested.
- Data integrity is one of the basic requirements in the GMP world. What are the relevant data and how can the integrity be ensured?
- You will be able to assess how the diverse and often very short-term technological developments in the IT sector are to be evaluated against the background of pharmaceutical requirements.

Background

In today's world, company operation is no longer possible without the use of IT. In the healthcare industry, as well, IT systems play an important role in all areas. In many cases, it is sufficient for the user to be able to operate the IT systems without knowing their basic functions.

In a highly regulated industry, the use of IT systems, especially with their ever-increasing networking, is also associated with risks and dangers. Currently, for example, the media extensively report about topics such as data and system security or Artificial Intelligence. The pharmaceutical industry has to face these topics in many respects.

Only those who know the characteristics in the operation of the systems can evaluate these problems and hazards to be in a position to ensure the proper and safe operation of these systems.

Target Audience

The seminar is aimed at employees of pharmaceutical and medical companies, suppliers and service companies who deal with IT systems, but do not have a detailed understanding of their technical functions.

Programme

CSV regulatory Background

- What is a computerised system?
- Applicable regulatory framework
- What the heck does qualification and validation actually mean?
- PIC/S

Technology: Hardware & Software Components

- Company IT infrastructure
- Network components
- Switches, hubs and firewalls
- Server farm vs blade centre
- Storage systems
  - NAS & SAN

IT Landscape

- IT vs OT
- Specificities and features of IT systems
  - Controllers and process control systems
  - MES
  - ERP
  - LIMS
  - CDS
  - DMS
- Technology
  - Bare metal
  - Virtualisation

About Data

- Process data
- Initial / raw data
- Data integrity: ALCOA+
- The importance of data

Data Management

- Definitions
  - Terminology
  - Roles
  - Data lifecycle
  - Data governance
- Challenges of today's data management
- RAID Technology
- Disaster Recovery & Business Continuity
- Data Migration

Basics of Software Engineering

- Reference model
- V-model according to GAMP®
- ASTM E2500-20
- Spoon model
- Operation

Alternative System Development Approaches

- Alternative software development models
- Agility objectives
- Example: Scrum4LS as an agile SW development model
- Icing on the cake: Continuous integration and test automation
- DevOps: How far can we go?

Computerised System Validation - 1 -

- Basic principles
- URS – User Requirements Specification
- Responsibilities
- GAMP® software categories
- Risk management

Computerised System Validation - 2 -

- Use cases / User stories
- Creating URS interactively
- Testing
- Automated testing
- Traceability

GAMP 5 2nd Edition

- Why a second edition?
- Documents vs records
- Agility and tools
- Critical Thinking and CSA (Computer Software Assurance)

Audit Trail (Review)

- EU-GMP Annex 11 and Audit Trail
- Which systems require an Audit Trail?
- Audit Trail Review
- GAMP 5 2nd Edition and Audit Trail

IT Trends and Challenges

Introduction to Cloud Computing

- Cloud as part of IT Infrastructure
- Cloud Service models
- Opportunities and risks

AI – Artificial Intelligence

- Basics of AI, ML, and DL
- Life cycle of an AI-enabled system
- Innovation vs regulation
- Use cases

Cybersecurity

- Threats
- Security concepts

Leveraging Supplier Involvement

- What leveraging really means
- Common pitfalls (and how to avoid them)
- How to reduce duplicate efforts?
- Supplier audits

Speakers

Stefan Münch, Körber Pharma Consulting GmbH, Karlsruhe, Germany

Stefan Münch, Vice President of Validation and Qualification, is responsible for the validation and qualification services of Körber Pharma Consulting. He has more than 25 years of experience in software development (MES) and consulting for the pharmaceutical industry. Furthermore, Mr. Münch is actively engaged in GAMP D-A-CH for many years and member of the steering committee.

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: ECA 'DI & IT Compliance Group'.

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Reservation Form (Please complete in full)

Pharma meets IT
Live Online Training on 9/10 October 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

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Date of the Live Online Training

Thursday, 09 October 2025, 09.00 h – 18.00 h
Friday, 10 October 2025, 09.00 h – 17.30 h

All times mentioned are CEST.

Technical Requirements

We use Webex for our live online training courses and webinars. At 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
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 number 21681.

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.

You cannot attend the Live Online Event?

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Organisation and Contact

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

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