



## Speakers



Stefan Münch  
Körber Pharma Consulting,  
Germany



Yves Samson  
Kereon, Switzerland

# IT for Non IT-Professionals



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.



Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code or visit [www.gmp-compliance.org/gmp-newsletter](http://www.gmp-compliance.org/gmp-newsletter)



## 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

## 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

## 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'.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)



## IT for Non IT-Professionals 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

E-Mail (Please fill in)

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg

GERMANY

### 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 HEIDELBERG will not be re-

sponsible for discount, airfare penalties or other costs incurred due to a cancel-

lation.

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 can-

cellation 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 con-

ference (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 Perso-

nal 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 pro-

cessed. 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 <https://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

Thursday, 09 October 2025, 09.00 h – 18.00 h

Friday, 10 October 2025, 09.00 h – 16.00 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](http://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](http://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?

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](http://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

Phone +49(0)62 21/84 44-0

Fax +49(0)62 21/84 44 34

[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)

[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:

Dr Andreas Mangel (Operations Director) at

+49(0)62 21/84 44 41, or per e-mail at

[mangel@concept-heidelberg.de](mailto: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

[marion.grimm@concept-heidelberg.de](mailto:marion.grimm@concept-heidelberg.de)