ECA Academy
Your GMP/GDP Information Source

Speakers

Stefan Münch
Körber Pharma Consulting, Germany

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IT for Non-IT Professionals

Live Online Training on 27/28 February 2024

Understand the Relevance of your IT

Highlights

- The Technology behind your IT
- Requirements for the 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 and their Influence on the Pharmaceutical Industry

Programme

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 Live Online Training 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?
- What the heck does qualification and validation actually mean
- Applicable regulatory framework
- Typical weaknesses

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: Scrum^{4LS} 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

- Critical thinking
- Risk based approach
- CSA (Computer Software Assurance)

Introduction to Cloud Computing

- Deployment models
- Service models
- Areas of concern

Leveraging Supplier Involvement

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

IT Trends and Challenges

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: 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


CERTIFICATE

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.

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.

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Reservation Form (Please complete in full)

IT for Non-IT Professionals
Live Online Training on 27/28 February 2024

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 %.

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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 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
Tuesday, 27 February 2024, 09.00 h – 18.00 h
Wednesday, 28 February 2024, 08.30 h – 17.30 h

All times mentioned are CET.

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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.

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.

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