ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers

Ágnes Kis
form. GMP-Inspector at OGYÉI, Hungary

Christof Langer
OSConsulting, Austria

Thomas Højsholm Schmidt
Leo Pharma, Denmark

Kristina Smith Hansen
MilCor Consulting, Denmark

GMP Auditor Practice

An advanced Auditor Course with many Practical Examples

Live Online Training on 06 – 08 October 2021

Highlights

- How to audit:
  - Quality Systems
  - Solid Dosage Forms
  - Parenteral Dosage Forms
  - Data Integrity
  - APIs
  - QC Laboratories
  - Microbio Laboratories
  - Engineering and Facility Management

- Understand and discuss:
  - Root Causes in poor personal Behaviour
  - Challenging Personalities in the Audit

Objectives

In this Live Online Training you will have the possibility to learn and intensively discuss how to focus on specific GMP related aspects.

Background

Continuous professional training for auditors and lead auditors is of utmost importance as the authorities expect qualified personal performing audits. And GMP audits of suppliers, contract manufacturers and contract laboratories are a fundamental part of a Quality Management System to assure the quality of a drug product. Only knowledgeable and highly qualified auditors with a profound technical knowledge and good communication skills can guarantee audits that are useful for both the auditing company and the auditee.

Recognising this need for further professional knowledge development, the ECA Academy has set up this Live Online Training as an individual course which is also part of ECA's Certified GMP Auditor Programme.

Target Audience

This Live Online Training is designed for both new and experienced auditors. It can also be seen as an addition to the ECA Course "The GMP-Auditor".

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

This Training Course is recognized for the GMP/GDP Certification Scheme "Certified GMP Auditor"

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

Please find more information at www.gmp-certification.org

Programme

The Root Cause of Poor Personnel Related Discrepancies

- Introduction – humans are rational!
- An explanation for undesirable behaviour
- Utilising behaviour science models to change behaviour
- A brief explanation on Nudging and Behavioural Design

How to Audit Quality Systems

- What should be included in a Quality System's audit
- Pitfalls when auditing Quality Systems
- How to detect Quality System issues

How to Audit Production of Solid Dosage Forms

- Risk-based approach
- Key points to consider
- Exercise with role play

How to Audit Production of Sterile Dosage Forms

- Key essentials and points to consider
- Case studies

How to Audit Data Governance and Data Integrity

- Examples of data governance and data integrity issues
- Implications of data integrity issues
- Auditors role in data integrity governance
- Developing a data integrity audit program – "Hands-on Approach"

How to Audit Engineering and Technical Operations

- HVAC systems
- Water systems
- Utilities
  - Pressured air
  - Clean steam
  - Special gases
- Room qualification
- Facility layouts
- Flow of material and waste

How to perform Quality Control Laboratory Audits

- Sample receipt and registration
- Sample preparation
- Equipment Calibration and Maintenance
- Reporting

How to audit microbiological laboratories

- Where to look at
- Interpretation of microbiological Data
- Examples

How to perform an API Site Audit

- Chemical synthesis
  - Dedicated vs. multiple purpose facility
  - Material dispensing
  - Cross-Contamination
  - Process and cleaning validation
  - Utilities
- Biotechnology
  - Cell banks
  - Inoculation
  - Fermentation
  - Harvest
  - Purification

How to deal with challenging Personalities in the Audit Room

- Introduction: people are strange!
- Top 10 most frustrating, difficult, or annoying personalities in an audit and how to deal with them

Speakers

Ágnes Kis
form. GMP Inspector at OGYÉI, Hungary
Compliance Consultant

Before starting to work as a consultant in July 2018, Ágnes Kis was a global GMP Compliance Auditor for Roche and earlier for Novartis. Before her industrial career, Ágnes Kis was Senior GMP/GDP Inspector for the Hungarian National Institute of Pharmacy and Nutrition (OGYÉI) and expert member in various working groups at EMA, PIC/S and the European Commission.

Christof Langer
OSConsulting, Austria
Managing Director

Christof Langer is a biotechnologist, certified Risk Manager, Lean Six-Sigma Black Belt and independent consultant since 2009. Before that, he was Managing Director at Baxter BioScience (now Shire) in Switzerland and the Czech Republic.

Thomas Højsholm Schmidt
Leo Pharma, Denmark
Principal Quality Professional

Thomas Højsholm Schmidt is Principal Quality Professional and Lead GMP Auditor. Before joining LEO Pharma he held positions at different API Manufactures as Development and Pilot scale Chemist.

Kristina Smith Hansen
MilCor Consulting, Denmark
Founder

Kristina Smith Hansen is a certified quality auditor (GMP/GDP/ISO) and consultant, helping the Food, Pharma, Health, and Manufacturing industries get to the real root cause of their poor personnel related non-conformities by using behaviour science theories and tactics. She also gives courses, presentations, and lectures related to improving employee behaviour within the workplace.

Your Benefits:
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.

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

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GERMANY

Reservation Form (Please complete in full)

GMP Auditor Practice | Live Online Training on 06 – 08 October 2021

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
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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 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 January 2012).
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

Wednesday, 06 October 2021, 09.00h – 17.15h
Thursday, 07 October 2021, 09.00h – 17.00h
Friday, 08 October 2021, 09.00h – 15.30h

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 course 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 a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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

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