20 YEARS ECA Academy
Your GMP/GDP Information Source

GMP Auditor Workshop

An advanced Auditor Course with many interactive Sessions and practical Examples

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

Miro Zdilar
Teva Pharmaceuticals, Croatia

05-06 September 2019, Berlin, Germany

HIGHLIGHTS:

- Understand and discuss:
  - Root Causes in poor personal Behaviour
  - Challenging Personalities in the Audit
- How to audit:
  - Quality Systems
  - Solid Dosage Forms
  - Parenteral Dosage Forms
  - Data Integrity
  - APIs
  - QC Laboratories
  - Engineering and Facility Management

This Master Class is recognised for the ECA GMP Certification Programme „Certified GMP Auditor“.
Please find details at www.gmp-certification.eu

GMP Auditor Workshop

05-06 September 2019, Berlin, Germany

Learning Goals

In this Workshop you will have the possibility to learn and intensively discuss

- how to focus on specific GMP related aspects
- how to apply appropriate communication skills

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 workshop as an individual course which is also part of ECA's Certified GMP Auditor Programme.

Target Group

This workshop is designed for both new and experienced auditors. It can also be seen as an addition to the ECA Couse "The GMP Auditor".

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

Social Event

On the evening of the first day of the course, you are cordially invited to a social event (city tour and dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Programme

Kick-off: 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

Parallel Sessions:

1) How to audit Production of solid Dosage Forms

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

2) How to audit Production of sterile Dosage Forms

- Key essentials and points to consider
- Case studies

You will be able to attend one of these two parallel sessions.

Please choose the one you like to attend when you register for the Course.

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 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

Parallel Sessions:

3) How to perform Quality Control Laboratory Audits

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

4) 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

You will be able to attend one of these two parallel sessions.

Please choose the one you like to attend when you register for the Course.

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) 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. Her 17+ year history of employment has been within Food, Pharma, Health, and also U.S. Government.

Miro Zdilar | Teva Pharmaceuticals, Croatia Computer Systems Quality Assurance Leader

Miro Zdilar is Computer Systems Quality Assurance Leader, Certified Information Systems Auditor (CISA) and Certified Information Security Manager (CISM) with 20+ years of experience as Audit and Quality Assurance Leader.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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

GMP Auditor Workshop
05-06 September 2019, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **P.O. Number if applicable**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

Parallel Sessions (please choose ONE session)
☐☐ 1) How to audit Production of solid Dosage Forms
☐☐ 2) How to audit Production of sterile Dosage Forms

Parallel Sessions (please choose ONE session)
☐☐ 3) How to perform Quality Control Laboratory Audits
☐☐ 4) How to audit Engineering and Technical Operation

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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 %,
- until 1 weeks prior to the conference 50 %
- 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. 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 responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice. German law shall apply. Court of jurisdiction is Heidelberg.

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)

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 http://www.gmp-compliance.org/eca_privacy.html). 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

Thursday, 05 September 2019, 09.00 h – 18.00 h
(Registration and coffee 8.30h – 9.00 h)
Friday, 06 September 2019, 08.00 h – 15.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

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Mr Wolfgang Schmitt (Director Operations) at +49-62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Neureuther (Organisation Manager) at +49-62 21 / 84 44 49, or per e-mail at neureuther@concept-heidelberg.de.