ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers

Energy Kristina Hansen
Novo Nordisk, Denmark

Ágnes Kis
form. GMP-Inspector at OGYÉI, Hungary

Christof Langer
OSConsulting, Austria

Thomas Højsholm Schmidt
CSL Behring, Switzerland

GMP-Auditor Practice

An advanced Auditor Course with many interactive Sessions and practical Examples

08 – 10 October 2024 | Barcelona, Spain

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
  - Microbiological Laboratories
  - Engineering and Facility Management

Objectives

You will have the possibility to learn and intensively discuss

- how to focus on specific GMP related aspects
- how to act and react in an audit

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 practice-oriented course which is also part of ECA's Certified GMP Auditor Programme.

Target Audience

This course 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)

Social Event

On the evening of the first course day, 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

The Root Cause of Poor Personnel Related Discrepancies

- Introduction – humans are rational!
- An explanation for undesirable behaviour
- Utilising behaviour science models to change behaviour
- The 3BMethod

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"

Testimonials:

„Fantastic course – I really enjoyed the interactive structure & greatly appreciate social activity"
Anthony Cummins, Sebela Pharmaceuticals, Ireland

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 Perform Quality Control Laboratory Audits

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

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 Audit Microbiological Laboratories

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

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

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 seminar in detail and with which you document your training.

Energy Kristina Hansen
Novo Nordisk, Denmark
Senior QA Specialist

Energy Kristina Hansen has many years of experience in current measures towards internal and external audit and inspection within Life Sciences, HealthCare, and Warehousing. As a consultant for MilCor Consulting she also gives courses, presentations, and lectures related to improving employee behaviour within the workplace.

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
CSL Behring, Switzerland
Associated Director and Lead Auditor

Thomas Højsholm Schmidt is Associated Director and Lead Auditor in Global Quality Systems & Compliance at CSL Behring AG located in Switzerland. Before that, he was 12 years at LEO Pharma A/S in Denmark as GMP domain expert and GMP Lead Auditor. Thomas is a member of the new ECA Working Group for GMP-Auditors.

NEWS

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 on the right or visit www.gmp-compliance.org/gmp-newsletter

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

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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP-Auditor Practice | 08 – 10 October 2024, Barcelona, Spain

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 %.

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.
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 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

Tuesday, 08 October 2024, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 09 October 2024, 8.30 h – 17.45 h
Thursday, 10 October 2024, 8.30 h – 15.00 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone: +34 93 503 53 00
Email: sants@barcelo.com

Fees (per delegate, plus VAT)

ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
The course fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on all three days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG 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.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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CF/27112023