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

GMP Auditor Practice

An advanced Auditor Course with many practical Examples

Live Online Training on 21/22 October 2020

Highlights

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

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)

Programme 21 October 2020

09.00 – 09.10 h
Welcome & Introduction

09.10 – 10.45 h
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

10.45 – 11.00 h Break

11.00 – 12.15 h
How to Audit Production of Solid Dosage Forms

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

12.15 – 12.45 h
Q&A Session

12.45 – 13.45 h Break

13.45 – 15.00 h
How to Audit Production of Sterile Dosage Forms

- Key essentials and points to consider
- Case studies

15.00 – 15.15 h Break

15.15 – 16.30 h
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"

16.30 – 17.00
Q&A Session

Programme 22 October 2020

08.30 – 08.35 h
Welcome & Introduction

08.35 – 09.45 h
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

09.45 – 10.00 h Break

10.00 – 11.15 h
How to Perform Quality Control Laboratory Audits

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

11.15 – 12.30 h
How to Audit Microbiological Laboratories

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

12.30 – 13.00 h
Q&A Session

13.00 – 14.00 h Break

14.00 – 15.15 h
How to Perform an API Site Audit (chemical)

- Dedicated vs. multiple purpose facility
- Material dispensing
- Cross-Contamination
- Process and cleaning validation
- Utilities

15.15 – 15.30 h Break

15.30 – 16.45 h
How to Perform an API Site Audit (biotech)

- Cell banks
- Inoculation
- Fermentation
- Harvest
- Purification

16.45 – 17.00 h
Q&A Session

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.

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Reservation Form (Please complete in full)

GMP Auditor Practice - Live Online Training on 21/22 October 2020

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)

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If you cannot attend the conference you have two options:
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Date of the Live Online Training

Wednesday, 21 October 2020, 9.00h – 17.00h
Thursday, 22 October 2020, 8.30h – 17.00h
All times mentioned are CEST.

Technical Requirements

For our 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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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 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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