ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers

Dr Christian Hösch
GMP-Inspector, Ministry of Justice and Consumer Protection, Hamburg, Germany

Stefan Reintgen
Team Connex, Germany

Charis Schmidt
Entourage, Germany

Thomas Schmidt
CSL Behring, Switzerland

The GMP-Auditor

Initial and Continuous Professional Training for GMP Auditors

14 – 16 June 2023 | Copenhagen, Denmark

Highlights

- Expectations of the Authorities
- Risk-based Audit Planning
- Categorisation of Audit Findings
- What makes a good Auditor
- Communication Skills and Conflict Solving
- Distant Assessments/ Hybrid Audits
- Suppliers from China, India and South America
- Audit Simulation Workshop with Role Plays and Video Feedback
- Audit Report Writing

- Efficiency in Audit Planning and Performance
- Global Auditing
- Communication and Conflict Management

Programme

Objectives

In this training course you will learn

- How to plan and conduct audits efficiently
- How to face various audit challenges
- What communication techniques are needed
- How you can avoid and solve conflicts

Background

Initial and continuous professional training for auditors is of utmost importance as the authorities expect highly qualified personal performing audits. Therefore, ECA has developed the programme at hand to give you a detailed overview about important matters to consider and to discuss important tasks and challenges like:

- Expectations of the authorities
- Audit types
- Risk-based audit planning
- Audit plan and audit team
- Audits in China, India and South America
- Categorisation of audit findings
- Auditor skills and technical knowledge requirements
- Communication Skills
- Conflict solving

In a special Audit Simulation Workshop with role plays and video feedback, you will be able to deepen your skills and knowledge.

Target Audience

GMP-Auditors from Pharmaceutical and API Industry.

Moderator

Wolfgang Schmitt (on behalf of ECA)

Programme

How to Optimise the Audit Programme

- Community project: evaluation of supplier audits in Europe
- Who needs to be audited
- Things to consider when setting up a risk-based audit programme
- GMP Certificates and CEPs
- Third Party, Joint- and Shared Audits
- Expectations of the authorities
- Examples: what can go wrong

How to Plan an Audit

- Preparing your audit programme
  - Criteria for setting priorities
  - Resource planning
- Setting and agreeing audit objectives
- Selecting auditor team and assigning objectives to auditors
- Defining roles in an audit team
- Performing the audit and monitoring progress
- Summarising the findings and how to feedback to auditees
- Follow up and closing the loop

Workshop: Categorisation of various Audit Findings

Based on typical audit situations and real case studies, proposals on how to evaluate the given examples will be developed in small working groups. Possible follow-up activities will be discussed.

Distant Assessments and the Combination with on-site Audits

- Distant Assessments as part of the overall supplier qualification system
- Possibilities and limits of Distant Assessments
- Distant Assessments in combination with on-site audits
- Tips for technical implementation

The Auditor – what makes you a good Auditor

- Auditor training
- How to become a good auditor
- Essentials auditor skills
- Auditor pitfalls and how avoid them

Interactive Sessions on: Communication Skills

1. The challenge of appropriate communication
2. How to recognise, understand and solve conflicts
3. Body Language
4. Questioning Techniques

Suppliers from China, India and South America

- How to prepare audits abroad
- Challenges and pitfalls
- Typical compliance issues: what to look for
- Cultural particularities

Audit Simulation Workshops

- Role plays
- Video Feedback

Selected working groups will simulate pre-defined audit situations. The experience and performance will be evaluated and discussed with the team.

Audit Report Writing

- How to take proper audit notes
- Best practices for audit report writing
  - Using standardised report templates
  - How to generate a clear and concise list of findings
  - Phrases that should be avoided
  - Purpose and conclusion
- When is a report final?
- Timelines for finalisation, distribution, feed-back and follow-up
- Difference between internal and external audit report

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.

Speakers

Dr Christian Hösch
Ministry of Justice and Consumer Protection, Hamburg, Germany

At the Health Authority in Hamburg Dr Hösch is the head of the unit "pharmaceutical manufacturers" and is mainly responsible for inspecting manufacturers of medicinal products and APIs worldwide.

Stefan Reintgen
Team Connex AG, Germany

As Trainer and Consultant Stefan Reintgen focuses on the topics of Leadership, Communication and interpersonal relations. His prior experience includes working for BASF and Celanese.

Charis Schmidt
Entourage, Germany

Charis Schmidt is Management Consultant at Entourage in Munich. Before that she was Quality Auditor at Vetter Pharma.

Thomas Schmidt
CSL Behring, Switzerland

Thomas Højsholm Schmidt is Associated Director and Lead Auditor at CSL Behring AG in Switzerland. Before that, he was a GMP Lead Auditor at LEO Pharma A/S in Denmark for over 12 years.

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

Reservation Form (Please complete in full)

The GMP-Auditor | 14 – 16 June 2023, Copenhagen, Denmark

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.
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Date
Wednesday, 14 June 2023, 9.00h – 18.00h
(Registration and coffee 8.30h - 9.00h)
Thursday, 15 June 2023, 9.00h – 17.30h
Friday, 16 June 2023, 8.30h – 15.30h

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark

On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on-site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate, plus VAT)
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes lunch on all thee 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.

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.

Conference language
The official conference language will be English.

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