



Speakers



Dr Christian Hösch
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Charis Schmidt
Entourage, Germany



Thomas Schmidt
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The GMP-Auditor

Initial and Continuous Professional Training for GMP Auditors

15 – 17 May 2024 | Berlin, Germany



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

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 personnel 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

Social Event

On 15 May, 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.

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

Reservation Form (Please complete in full)

The GMP-Auditor | 15 – 17 May 2024, Berlin, Germany

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

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GERMANY

E-Mail (Please fill in)

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If you cannot attend the conference you have two options:

- We are happy to welcome a substitute colleague at any time.
- 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 %
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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 can-

cellation 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

Wednesday, 15 May 2024, 9.00h – 18.00h
(Registration and coffee 8.30h - 9.00h)
Thursday, 16 May 2024, 9.00h – 17.30h
Friday, 17 May 2024, 8.30h – 15.30h

Venue

HYPERION Hotel Berlin
Prager Straße 12
10779 Berlin
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E-Mail: hyperion.berlin@h-hotels.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 conference fee is payable in advance after receipt of invoice and includes dinner on 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.

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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