

The GMP Auditor

Initial and Continuous Professional Training
for GMP Auditors

SPEAKERS:



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



Afshin Hosseiny, Ph.D.
Tabriz Consulting



Stefan Reintgen
Team Connex



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

06 – 08 November 2019, Prague, Czech Republic

LEARNING OBJECTIVES:

- Expectations of the Authorities
- Risk-based Audit Planning
- Categorisation of Audit Findings
- Leadauditor Skills and technical Knowledge
- How to avoid mistakes
- Communication Skills
- Conflict Solving
- Suppliers from China, India and South America
- Audit Simulation Workshop with role plays and video feedback



Learning Objectives

In this training course you will learn

- How to plan and conduct audits efficiently
- How to face the various 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 the 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
- Leadauditor 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.

Please note: The number of participants is limited.

Target Group

GMP-Auditors from Pharmaceutical and API Industry.

Moderator

Wolfgang Schmitt

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 program
 - 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.

How to become a good Leadauditor

- Auditor skills
- Auditor technical knowledge requirements
- Auditor training

Top 10 Mistakes Auditors make and how to avoid them

- Poor planning
- Understanding the local culture and language
- Being led by the hosts
- Following hobby horses (wasting time)
- Focus on minor issues missing the big problems
- Accept what they hear - not verifying the facts
- Poor record keeping – no evidence to refer to
- Not knowing the requirements
- Lack of understanding the process they are auditing
- Poor communication and reporting of findings
- Including Examples of audit findings:
 - As reported
 - As it should have been reported

Interactive Sessions: 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.



Participant's comment on the 2016 course:

"All was perfect (with a nice design). Thank you very much for this course."

Dr. Bratoljic-Melkay, Janssen Vaccines AG



Speakers



Dr Christian Hösch

Ministry of Health 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.



Afshin Hosseiny, Ph.D.

Tabriz Consulting Ltd., U.K.

Dr Hosseiny is Managing Director of Tabriz Consulting Ltd., formerly Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. He is a member of ECA's Board of Directors and Chairman of the European GDP Association.



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.

Social Event


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



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



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

The GMP Auditor

06 - 08 November 2019, Prague, Czech Republic

Mr. Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order No, if applicable

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

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

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg

GERMANY

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, in-

structors, 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 January 2012)

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 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

Wednesday, 06 November 2019, 9.00h - 18.00h
(Registration and coffee 8.30h - 9.00h)

Thursday, 07 November 2019, 9.00h - 17.30h

Friday, 08 November 2019, 8.30h - 15.00h

Venue

Corinthia Hotel Prague

Kongresova 1

14069 Prague, Czech Republic

Phone + (0) 420 261 191 111

email prague@corinthia.com

Fees (per delegate plus VAT)

ECA Members € 1,790

APIC Members € 1,890

Non-ECA Members € 1,990

EU GMP Inspectorates € 995

The course fee is payable in advance after receipt of invoice and includes conference documentation, 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 event. 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

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

CONCEPT HEIDELBERG

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For questions regarding content:

Mr Wolfgang Schmitt (Operations Director) at

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w.schmitt@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc.:

Ms Isabell Neureuther (Organisation Manager),

at +49(0)6221 / 84 44 49 or per e-mail at

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