



Speakers



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



Afshin Hosseiny, Ph.D.
Tabriz Consulting, U.K.



Stefan Reintgen
Team Connex, Germany



Thomas Højsholm Schmidt
Leo Pharma, Denmark

The GMP Auditor

Initial and Continuous Professional Training for GMP Auditors



Live Online Training on 16/17 November 2021



Highlights

- Expectations of the Authorities
- Risk-based Audit Planning
- Categorisation of Audit Findings
- Leadauditor Skills and technical Knowledge
- Remote Audits and Distant Assessments
- Communication Skills and Conflict Solving
- Suppliers from China, India and South America
- Audit Report Writing

Each Delegate will get a free HBDI®
(Herrmann Brain Dominance Instrument) Test

Objectives

In this Live Online 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
- Best practices for audit report writing

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
- How to deal with travel restrictions
- Risk-based audit planning
- Audit plan and audit team
- Audits in China, India and South America
- Categorisation of audit findings
- Audit report writing
- Communication Skills
- Conflict solving

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

Remote Audit/ Distant Assessment

- What are the regulations saying?
- Remote Audit or Distant Assessment?
- Benefits, limits, risks
- Integration in Supplier Qualification System
- Comparative study to what extent findings in an on-site audit would also be made in a distant assessment

Case Studies: Categorisation of various Audit Findings

- Examples of audit situations and findings
- How to evaluate the given examples
- Possible follow-up activities

What makes a good Auditor?

- Auditor skills
- Auditor technical knowledge requirements
- Auditor training



Participant comments from the last Live Online Training in March 2021

"Very good and experienced speakers."
Ioana Ionita-Turcu, Switzerland

"Excellent training and a great help for my work as an auditor. The practical cases reviewed allow all participants to see the possible valid options."
Eva Planas, Siegfried Barbera S.L, Spain

"Interesting presentations, experienced speakers."
Gyöngyi Gosztonyi, Teva Pharmaceuticals Works Plc., Hungary

"Very good / relevant topics."
Betzaida Castilla, Quality & Compliance Consulting Solutions LLC, USA

"Great training session."
Attila Kerekes, Bioeel Ltd., Romania

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 you hear - not verifying the facts
- Poor record keeping – no evidence to refer to
- Not knowing the requirements
- Lack of understanding the process
- Poor communication and reporting of findings

Communication Skills

- The challenge of appropriate communication
- HBDI® (Herrmann Brain Dominance Instrument)
- How to recognise, understand and solve conflicts
- Body Language
- 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 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

Speakers



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

At the Consumer Protection in Hamburg Dr Hösch is the head of the unit "Pharmacy II" 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.



Thomas Højsholm Schmidt
Leo Pharma, Denmark

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.



Question and Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

Each delegate will get a free HBDI® (Herrmann Brain Dominance Instrument) test.

Understanding oneself better leads to a better understanding of others and to better audits. The HBDI model will be discussed in the course; participation in the test is voluntary.



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.



The GMP Auditor | Live Online Training on 16/17 November 2021

Participation in the HBDI Test: Yes - I will attend the HBDI Test - free of charge. Yes - I agree that my name and e-mail address will be forwarded to Team Connex AG, Altdorf Germany in order to receive the access link to the test programme Axon.
 No - I am not interested in the HBDI Test.

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)

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 %
 - Cancellation until 1 week prior to the conference 50 %
 - Cancellation within 1 week 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 can-

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 <https://www.gmp-compliance.org/privacy-policy>). 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 of the Live Online Training

Tuesday, 16 November 2021, 9.00h – 18.00h

Wednesday, 17 November 2021, 9.00h – 17.30h

All times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and 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.

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.

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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

CONCEPT HEIDELBERG

P.O. Box 10 17 64 | D-69007 Heidelberg

Telefon +49 (0) 62 21 / 84 44-0

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

E-Mail: info@concept-heidelberg.de

www.concept-heidelberg.com

For questions regarding content please contact:

Mr Wolfgang Schmitt (Operations Director) at +49 (0) 62 21 / 84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de

For questions regarding organisation please contact:

Ms Isabell Neureuther (Organisation Manager), at +49 (0) 62 21 / 84 44 49 or per e-mail at neureuther@concept-heidelberg.de