



Speakers



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



Stefan Reintgen
Team Connex, Germany



Charis Schmidt
Entourage, Germany



Thomas Højsholm Schmidt
CSL Behring, Switzerland

The GMP-Auditor

Initial and Continuous Professional Training for GMP Auditors



Live Online Training on 21 - 23 November 2023



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)



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.

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

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

Case Studies: Categorisation of various Audit Findings

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

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

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



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.

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.



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 Højsholm 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.



Participant comments from previous Live Online Training courses:

"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

"The course is very well structured, the material is excellent" | Fabiana Frech, Switzerland

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 | Live Online Training on 21 - 23 November 2023

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)

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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 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 %
 - Cancellation within 2 weeks 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 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 July 2022). Court of jurisdiction is Heidelberg. German law shall apply.

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 of the Live Online Training

Tuesday, 21 November 2023, 11.00h – 16.15h
 Wednesday, 22 November 2023, 9.00h – 16.30h
 Thursday, 23 November 2023, 9.00h – 13.30h
 All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 EUR 1,790.-
 APIC Members EUR 1,890.-
 Non-ECA Members EUR 1,990.-
 EU GMP Inspectorates EUR 995.-
 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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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