



## Speakers



Dr Christian Hösch  
GMP Inspector



Stefan Reintgen  
Team Connex



Charis Schmidt  
Ferring



Thomas Schmidt  
CSL Behring

# The GMP-Auditor

Initial and Continuous Professional Training  
for GMP Auditors

21 - 23 May 2025 | 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

## 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)



### Participants' comments:

*"Well structured and presented, a wealth of information and industry experiences learned",*  
Ahistha Chanerika,  
FineChemicalsCorporation (Pty) Ltd, South Africa

## Programme

### How to Optimise the Audit Programme

- Part I: Who needs to be audited
  - Legal basis for audits
  - Community project: Evaluation of supplier audits in Europe
- Part II: The Audit Programme
  - How to set up a risk-based audit programme
  - Expectations from a GMP Inspectors point of view
- Part III: How to optimise the Programme
  - Third Party, Joint- and Shared Audits
  - EU-GMP Certificates and CEPs
- Part IV: What can go wrong

### How to Plan an Audit

- Audit program to audit plan
- Setting audit scope
- Selecting the auditor/team
- Defining roles in the audit team
- Gathering Information
- Preparing an audit plan/agenda
- Interactive part



### 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 skills
- Auditor technical knowledge
- Auditor training
- Mistakes auditors make



## 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 21 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.

## Speakers



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

Dr Christian Hösch is the head of the unit “pharmaceutical manufacturers” and is mainly responsible for inspecting manufacturers of medicinal products and APIs worldwide. Christian also actively supports the Board of Directors of the ECA GMP-Auditor 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.



**Charis Schmidt**  
Ferring, Germany

Charis Schmidt is Team Lead Sterile Production. Before that, she was Quality Auditor at Vetter Pharma.



**Thomas Schmidt**  
CSL Behring, Switzerland

Thomas Højsholm Schmidt is Associated Director and Corporate Lead Auditor at CSL Behring AG in Switzerland. Before that, he was GMP Domain Expert and GMP Lead Auditor at LEO Pharma A/S in Denmark. Thomas is a member of the Board of Directors of the ECA GMP-Auditor Association.

### 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.

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

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Reservation Form (Please complete in full)

The GMP-Auditor | 21 - 23 May 2025, 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

CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg  
GERMANY

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.
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 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](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, 21 May 2025, 9.00 h – 18.00 h  
(Registration and coffee 8.30 h - 9.00 h)  
Thursday, 22 May 2025, 9.00 h – 17.30 h  
Friday, 23 May 2025, 8.30 h – 15.30 h

## Venue

Radisson Blu Scandinavia Hotel  
Amager Boulevard 70  
2300 Copenhagen S  
Denmark  
Tel +45 (0) 33 96 50 00

## Fees (per delegate, plus VAT)

ECA Members € 2,290  
APIC Members € 2,390  
Non-ECA Members € 2,490  
EU GMP Inspectorates € 1,245

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 – **or search and register directly at [www.gmp-compliance.org](http://www.gmp-compliance.org) under the number 21576.**

## 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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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](mailto:w.schmitt@concept-heidelberg.de)

For questions regarding reservation, hotel, organisation etc. please contact:

Ms Isabell Helm (Organisation Manager), at  
+49 (0) 62 21 / 84 44 49 or per e-mail at  
[helm@concept-heidelberg.de](mailto:helm@concept-heidelberg.de)