ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GMP Auditor

Speakers

Dr Christian Hösch
GMP Inspector

Stefan Reintgen
Team Connex

Charis Schmidt
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Thomas Højsholm Schmidt
CSL Behring

The GMP Auditor

Initial and Continuous Professional Training for GMP Auditors

Live Online Training on 15 - 17 October 2025

Highlights

- Expectations of the Authorities
- Risk-based Audit Planning
- Categorisation of Audit Findings
- Auditor Skills
- Distant Assessments as Part of Hybrid Audits
- Communication Skills and Conflict Solving
- Suppliers from China, India and South America
- Audit Report Writing

With a View on Hybrid Audits

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 personnel 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

Hybrid Audits: 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
- 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.

Participant comments from previous Live Online Training courses:

"Great presentations, with relevant key points. Very good case studies. Thank you!" | Sofia Couceiro, Greatsoul, Portugal
Very relevant for all types and scope of audit." Andy Dann, NHS, U.K.
"The variation in presenters and shift between getting info and participating actively was very good" | Mie Kramer Madesen, Region Hovedstadens Apotek, Denmark
"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

Speakers

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

At the Consumer Protection in Hamburg Dr Christian 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
Ferring, Germany

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

Thomas Højsholm Schmidt
CSL Behring, Switzerland

Thomas Højsholm Schmidt is Associate Director and Corporate Lead Auditor in Global Quality Systems & Compliance at CSL Behring AG. Before that, he was 12 years at LEO Pharma A/S in Denmark as GMP Domain Expert and GMP Lead Auditor. Thomas is a Board Member of the new ECA Working Group for GMP-Auditors.

Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

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GERMANY

Reservation Form (Please complete in full)

The GMP Auditor | Live Online Training on 15 - 17 October 2025

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)

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 %.

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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 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).
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 of the Live Online Training

Wednesday, 15 October 2005, 11.00h – 16.15h
Thursday, 16 October 2025, 9.00h – 16.30h
Friday, 17 October 2025, 9.00h – 13.30h
All times mentioned are CEST.

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 1,990.-
APIC Members EUR 2,090.-
Non-ECA Members EUR 2,190.-
EU GMP Inspectorates EUR 1,095.-
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 – or search and register directly at www.gmp-compliance.org under the number 21928. To avoid incorrect information, please give us the exact address and full name of the participant.

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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