GMP-Auditor Forum

A Conference for GMP-Auditors to Exchange Experience

23/24 June 2026 | Barcelona, Spain

ECA Academy
Your GMP/GDP Information Source

300€ Discount for GMP-Auditor Association Members

Presentations

- ECA's GMP-Auditors Reference Handbook
- Global Inspection and Audit Experience
- Auditing AI Applications
- Auditor Rights and Limits

Interactive Sessions

- Difficult Audit Situations
- Self-Inspections
- Digital Proficiency
- The Use of AI
- Observation Categorisation
- Auditing new Facilities
- Hybrid and Distant Assessments

Objectives

In this format, GMP-Auditors can discuss current topics and exchange opinions and experiences with other auditors in moderated interactive session. The presentations will address specific topics deemed important for GMP-Auditors.

A team of experts has been developing the ECA Good Practice Guide "GMP Auditors Reference Handbook". The guide considers feedback from GMP inspectors, the pharmaceutical industry and suppliers as well as practical experiences from real project cases. Experts working on this guide will be present so participants will have the opportunity to discuss current challenges around GMP Auditing.
All members of the Association will have the possibility to download the current version of the guide free of charge.

Background

Manufacturers are obliged to carry out GMP audits at their suppliers' and contract manufacturers' premises or have them carried out by suitably qualified and trained external auditors. Auditors play a very important role in the pharmaceutical industry and in the life cycle of pharmaceutical products. Their training and experience, and thus also a mutual exchange, is immensely important here.

What makes a good auditor?

An auditor must certainly have extensive specialist knowledge of the GMP regulations and their implementation. But an auditor must also have the necessary technical and practical expertise to sufficiently understand and question the audited processes.
To do this, an auditor must be unbiased and independent, know appropriate questioning techniques and be able to apply them. It also requires patience, the ability to listen, persistence and determination. Unfamiliar and new situations must not become a problem.

The ECA Certified GMP-Auditor certification programme consists of three modules that provide GMP auditors with specialised knowledge and soft skills, including conflict resolution. And auditors gain experience in their daily professional practice. This additional GMP-Auditor Forum format aims to present and discuss current topics and promote mutual exchange of opinions and experiences.

Target Audience

This Forum is designed for both new and experienced GMP-Auditors who want to network and broaden their overall knowledge.

Moderator

Wolfgang Schmitt
(On behalf of ECA)

Programme

Introduction to the ECA GMP-Auditor Association and the updated GMP-Auditors Reference Handbook

- Brief history
- New chapters and attachments
- Possibilities for information sharing

40 Years of Audit, Inspection and MHRA Experience

- Personal highlights of an experienced inspector

Discussion: How an Auditor can use AI

- How to use AI in audit planning and reporting
- Considerations and challenges

When Audits go wrong: Rights and Limits of the Auditor

- Limitations of authority — auditors are not regulators
- Rights and duties of the auditee
- Misconduct: what can "go wrong" during an audit?
- Legal consequences of misconduct (breach of contract, crossing legal boundaries, lying, intrusive behaviour, defamation, etc.)
- Documentation of misconduct
- What to do when criminal behaviour is revealed during an audit?

Auditing Global Supply Chains with cultural and regional Differences

- How auditing styles and expectations differ in Asia, EU, US, and how to adapt without compromising standards
- How auditors can manage ethical dilemmas
- How experienced auditors detect hidden problems through body language, resistance, or "too-perfect" documentation
- Different expectations of auditors in different countries: How can a uniform audit approach be applied in different subsidiaries?

Presentation and interactive Session: How to audit AI Providers and AI Applications

- Regulatory Background
- How to audit AI providers
- How to audit AI applications at a manufacturer
  - Types of AI applications in GMP
  - Key audit focus areas
  - Prompting, testing, documentation and records

Parallel Sessions (Experience Sharing and Discussions)

You will be able to attend **2 of these sessions** per day. Please choose the ones you like to attend when you register.

Day 1

How to deal with difficult Situations in Audits

- Recognizing and managing difficult audit situations
- Strategies for managing difficult situations
- Handling specific scenarios (with examples)

Successful Self-Inspections and Internal Audits

- Preparing, conducting, reporting
- Common pitfalls and how to avoid them
- Promoting a culture of continuous improvement

Stay up to Date: Digital Proficiency needed

- Digital proficiency and the ability to audit digital data and its analysis
- How to audit:
  - Paperless eQMS
  - Electronic batch records
  - Digital life cycle management

Day 2

Categorising/Summarising Observations

- Observation writing
- Categorising and summarising observations
- Common pitfalls and misunderstandings

How to audit brand new Facilities without a Quality History

- How to prepare
- Key audit focus areas
- Documentation and evidence expectations
- Auditor approaches and strategies

How to utilise Hybrid and Distant Assessments in the Audit Plan

- Strategic Integration into Audit Planning
- Planning a Hybrid or Distant Assessment
- The usage of e-auditing tools (e.g. smart glasses, dashboards), virtual tours and other interactive remote auditing models
- Documentation and reporting

Speakers

David Abraham | QRS-Associates, UK
Principal Consultant and Director at QRS-Associates Ltd with extensive experience in both business and Quality Management. Chairman of the ECA GMP-Auditor Association Board of Directors.

Ian Holloway | Form. MHRA, UK
Consultant and former GMP/GDP/GCP inspector and Head of the Defective Medicines Report Centre at MHRA. Member of the ECA GMP-Auditor Association Board of Directors.

Dr Felix Kern | Merck, Germany
Associate Director and Head of Compliance Launch and Technology Center. Member of the ECA GMP-Auditor Association Board of Directors.

Ágnes Kis | Form. GMP-Inspector at OGYÉI, Hungary
Former GMP-Auditor at Roche and Novartis, former Senior GMP/GDP Inspector for the Hungarian National Institute of Pharmacy and Nutrition (OGYÉI) and expert member in various working groups at EMA, PIC/S and the European Commission. Member of the ECA GMP-Auditor Association Board of Directors.

Dr Hanneke Later-Nijland | Genome Lawyers, The Netherlands
Lawyer and pharmacist, specialised in EU and national regulatory life sciences law. Former inspector for Clinical Trials and Pharmacovigilance with the Dutch Inspectorate for Healthcare (IGJ).

Markus Roemer | comes compliance services, Germany
Consultant, Auditor, Speaker and Trainer

Beatriz Sanchez | Kyowa Kirin, USA
Senior Director, Global Head GMP/GDP/GQP Audit with 10+ years QP & RP Experience in the EU.

Thomas Højsholm Schmidt | CSL Behring, Switzerland
Associated Director and Corporate Lead Auditor in Global Quality Systems & Compliance at CSL Behring AG located in Switzerland. Before that, 12 years at LEO Pharma A/S in Denmark as GMP domain expert and GMP Lead Auditor. Member of the ECA GMP-Auditor Association Board of Directors.

Dr Ingrid Walther | Pharma Consulting Walther, Germany
Independent consultant with many years of professional experience in R&D, QA/QC, auditing and management of strategic projects. Member of the ECA GMP-Auditor Association Board of Directors.

Social Event

On the evening of the first day of the conference, 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.

The GMP-Auditor Association

ECA's GMP-Auditor Association promotes dialogue among GMP-Auditors in the pharmaceutical industry. Its goals are:
1. Professional development and networking
2. Information exchange
3. Advocacy and Representation

By collaborating, networking, and sharing experiences, GMP-Auditors can contribute to the continuous improvement of pharmaceutical quality assurance within their organizations and help ensure the safety and efficacy of pharmaceutical products.
Membership is free! (https://gmp-auditor.gmp-compliance.org/)

The GMP-Auditors Reference Handbook
In the course of establishing the new ECA Working Group and moving towards becoming an Association, it became apparent that ECA wanted to produce a guide for its members; a GMP-Auditors Reference Handbook.
This handbook is frequently revised and updated aiming to give auditors a sound reference for their auditing activities.
Members of the GMP-Auditor Association will get free access to an online version.

Date
Tuesday, 23 June 2026, 9.00h – 17.45h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 24 June 2026, 8.30h – 15.45h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n | 08014 Barcelona, Spain
Phone: +34 93 503 53 00
E-Mail: sants@barcelo.com

Fees (per delegate, plus VAT)
GMP-Auditor Association Members EUR 1.990€
ECA Members EUR 2.090€
APIC Members EUR 2.190€
Non-ECA Members EUR 2.290€
EU GMP Inspectorates EUR 1.145.-
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both 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 when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Per e-mail or online at:
https://gmp-auditor.gmp-compliance.org/

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.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Wolfgang Schmitt (Director Operations) at
+49 (0)62 21/84 44 39 or per e-mail at
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