ECA Academy
Your GMP/GDP Information Source

A new ECA Forum to foster Discussions and mutual Exchange in small Working Groups

GMP-Auditor Forum

Release of ECA´s new GMP-Auditor Handbook

25/26 June 2024 | Barcelona, Spain

Highlights

Presentations:

- ECA's GMP Auditors Reference Handbook
- Current Developments
- Auditor Training
- Inspector Preferences

Round Table Discussions:

- Information Gathering
- Special Challenges
- Checklists
- Interpreters
- Supplier Qualification (Consequences of the Chinese Anti-Espionage Law)
- Difficult Auditees

Objective

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

A team of experts have developed a new **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. Authorities emphasise the need for on-site audits. However, hybrid versions and complete distant assessments also play an important role in the supplier qualification toolbox.

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. This means 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 new GMP Auditor Forum format aims to present and discuss current topics and promote mutual exchange of opinions and experiences.

Target Audience

This course is designed for both new and experienced GMP auditors who want to network and broaden their overall knowledge.

Moderator

Afshin Hosseiny
Chairman of ECA

Programme

Introduction to the new ECA GMP-Working Group and the GMP Auditors Reference Handbook

- Brief history
- Members
- Output so far
- Possibilities for information sharing

How good Auditors should be trained

- Content and Design
- Internal and external training
- Experience needed
- Behavior needed

Current Developments

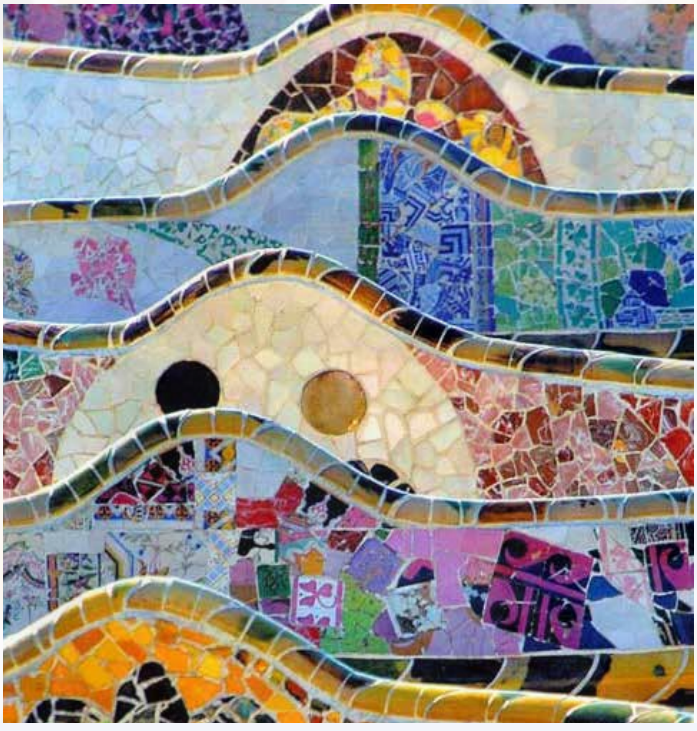
- What's new in the world of auditing
- Inspection trends
- Current ways of auditing and the future of audits: Onsite, remote, hybrid
- Agents' business practices, roles in the market

What are the Inspectors looking for?

- How do GMP inspectors evaluate a company's audit programme
- Inspection methodologies/concepts/approaches
- Expectations for audit days and number of auditors in an audit vs. scope of the audit, type of products and activities to be covered
- Audit Reports

Auditing in the Middle East and Asia

- How EU-GMP regulations are implemented (with a focus on the new Annex 1)
- What auditors from EU could expect
- Experiences made being a female auditor in some parts – and how to overcome these



Parallel Sessions (Round Table Discussions)

External Information – how to use it

- Where to get the information
- Third Party Audit Reports - sources, validity of the reports
- Inspection Reports, 483s, Warning Letters
- What to learn from it

Special Challenges

- What to do if Supplier does not allow for an Audit? Or only remote?
- What to do if Supplier does only allow for a one-day Audit?
- Supplier is not willing to be audited according to API requirements although product is used as API

The Use of Checklists

A checklist should not be a substitute for proper planning and audit performance. Discuss advantages of using a well-prepared checklist and its limits.

The Use of Interpreters

- How to get good interpreters
- Challenges and pitfalls
- Experience sharing

Supplier Qualification in a changing World

Consequences of the Chinese Anti-Espionage Law

How to deal with difficult Auditees

- Limited information provided
- Documents not provided or very late
- Tour is not well organised
- Passive and uninterested representatives
- SME unavailability

Speakers

David Abraham
QRS-Associates, UK
Chairman of the ECA GMP-Auditor Working Group

David Abraham is Principal Consultant and Director at QRS-Associates LTD with extensive experience in both business and Quality Management. David is also Chairman of the new ECA Working Group for GMP-Auditors.

Jyotsna Agnihotry
Flavine, Germany
Head of Quality Operations

Jyotsna Agnihotry is responsible for the implementation of the Flavine Quality Management System. She is an experienced lead auditor with a proven track record in overseeing and managing comprehensive internal & external audit processes.

Dr Afshin Hosseiny
ECA
Chairman of the ECA Executive Board (Foundation Board)

Afshin Hosseiny is Chairman of the ECA Executive Board and an independent consultant also conducting audits of manufacturing sites across Europe and USA. Before that, Afshin was Director of Quality Assurance for the Global Supply Network of GSK.

Ian Holloway
Form. MHRA, UK
former GMP/GDP/GCP Inspector

Ian Holloway was GMP/GDP/GCP inspector at the MHRA. Before that, he was Head of the Defective Medicines Report Centre at MHRA.

Maryam Davoudi Keleshteri
CinnaGen, Iran
Valildation Manager

Maryam Davoudi Keleshteri has more than 10 years experience in the field of biological and chemical products. Before that Maryam Davoudi Keleshteri was as Head of External Audit and Inspection.

Dr Felix Kern
Merck, Germany
Associate Director and Head of Compliance

Felix Kern is Associate Director and Head of Compliance Launch and Technology Center. Felix is a member of the new ECA Working Group for GMP-Auditors.

Ágnes Kis
form. GMP-Inspector at OGYÉI, Hungary
Compliance Consultant

Before starting to work as a consultant, Ágnes Kis worked as GMP-Auditor at Roche and Novartis. Before her industrial career, Ágnes Kis was 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. Ágnes is a member of the new ECA Working Group for GMP-Auditors.

Katja Manthey
Life Molecular Imaging, Germany
Quality Assurance Manager

Katja Manthey is QA Manager at Life Molecular Imaging GmbH, Global Quality Assurance Management of Contract Manufacturers, License Holders, and Suppliers. Previously, she has worked in various quality functions across the pharmaceutical industry in Germany, Australia, and Singapore. Until recently, she has been an active member of the executive committee of the Singapore ISPE.

Thomas Højsholm Schmidt
CSL Behring, Switzerland
Associated Director and Lead Auditor

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

Dr Ingrid Walther
Pharma Consulting Walther
Consultant and Auditor

Dr Ingrid Walther is an independent consultant and has more than 25 years of professional experience, including in the areas of R&D, QA/QC, auditing and management of strategic projects.

Date
Tuesday, 25 June 2024, 9.00h – 17.45h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 26 June 2024, 8.30h – 15.30h

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 € 1,690
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.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.

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w.schmitt@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Helm (Organisation Manager) at
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helm@concept-heidelberg.de

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.

ECA´s new Good Practice Guide: 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.

We decided early on that we would focus on the most important chapters first, rather than waiting until a full guide was produced. This way we could shorten the time to delivery and also have the opportunity to collect feedback and improve content. The first versions of the chapters have different formats and styles as different volunteer teams were involved in their creation. In the future, we will work on further standardisation and add additional chapters. We would appreciate it if you would let us know what else is important to you.
Members of the new GMP-Auditor Association will get free access to an online version.

Membership will be free! We will keep you informed.

NEWS

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.

To subscribe, simply scan the QR code on the right or visit www.gmp-compliance.org/gmp-newsletter

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GERMANY

Reservation Form (Please complete in full)

GMP-Auditor Forum | 25/26 June 2024, Barcelona, Spain

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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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). 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.