- Efficiency in Audit Planning and Performance
- Multicultural Communication
- Conflict Management

The GMP Auditor

Initial and Continuous Professional Training for GMP Auditors

11 – 13 November 2015, Vienna, Austria

SPEAKERS:

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

Afshin Hosseiny, Ph.D.
Tabriz Consulting

Stefan Reintgen
Team Connex

LEARNING OBJECTIVES:

- Expectations of the Authorities
- Various Audit Types
- Risk-based Audit Planning
- Categorisation of Audit Findings
- Leadauditor Skills and technical Knowledge
- Communication Skills
- Conflict Solving
- Suppliers from China, India and South America
- Audit Simulation Workshop with role plays and video feedback

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „ECA Certified GMP Auditor“. Please find details at www.gmp-certification.eu

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Learning Objectives

In this advanced 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

Background

Initial and continuous professional training for auditors and lead-autitors 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
- Risk-based audit planning
- Audit plan and audit team
- Audits in China, India and South America
- Categorisation of audit findings
- Leadauditor 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.

Please note: The number of participants is limited.

Target Group

New and experienced GMP-Auditors from Pharmaceutical and API Industry.

Moderator

Dr Afshin Hosseiny

Social Event

On 11 November you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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
- Setting out audit objectives
- Selecting the audit team
- Assigning objectives to the audit team
- Performing audit and monitoring progress
- Summarising findings and feedback to the auditee
- Follow up and closing the loop

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.

How to become a good Leadauditor
- Auditor skills
- Auditor technical knowledge requirements
- Auditor training

Audit Types
- Manufacturing site GMP audits
- Wholesalers and distribution centres
- Due diligence audits
- Pre-inspection audits
- Examples of audit findings

Interactive Sessions: 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.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "Certified GMP Auditor". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates.
Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Speakers

Dr Christian Hösch
GMP-Inspector, Ministry of Health and Consumer Protection, Hamburg, Germany
Dr Hösch worked in the pharmaceutical industry as Head of Production before he became GMP-inspector in 2001. At the Health Authority in Hamburg he is the head of the unit "pharmaceutical manufacturers" and is mainly responsible for inspecting manufacturers of medicinal products and APIs worldwide. He is also a member of the ZLG Expert Groups Quality Assurance and Inspections.

Afshin Hosseiny, Ph.D.
Tabriz Consulting Ltd., U.K.
Dr Hosseiny is Managing Director of Tabriz Consulting Ltd., formerly Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. He is a QP via permanent provision with detailed working knowledge of European and FDA regulatory requirements with over 20 years of experience of auditing pharmaceutical manufacturing sites across Europe and USA, as well as preparation for and fronting of EU and FDA regulatory inspections. He is a member of the UK standards committee for development of the ISO GMP standards for packaging components and a visiting lecturer at the London Metropolitan University.

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, where he enjoyed the benefits of Quality Management in his Sales + Marketing responsibilities. Thanks to his international assignments he contributes a profound intercultural understanding.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full) + 49 6221 84 44 34

The GMP Auditor
11 – 13 November 2015, Vienna, Austria

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No, if applicable

Street/P.O. Box

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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week 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 January 2012)

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

Wednesday, 11 November 2015, 9.00h – 18.00h
(Registration and coffee 8.30h - 9.00h)
Thursday, 12 November 2015, 9.00h – 17.30h
Friday, 13 November 2015, 8.30h – 15.00h

Venue

Austria Trend Hotel Park Royal Palace
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 89 11 0
Fax +43 (1) 89 110-9090

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The course fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.

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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Ms Nicole Bach (Organisation Manager) at +49-62 21 / 84 44 22, or per e-mail at bach@concept-heidelberg.de