ECA Certified QA Manager Course*

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

The GMP Leadauditor

Continuous Professional Training for GMP Auditors

5 – 7 October 2011, Prague, Czech Republic

SPEAKERS:

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

Afshin Hosseiny, Ph.D.
Tabriz Consulting

Stefan Reintgen
Team Connex

Wolfgang Schmitt
Concept Heidelberg

LEARNING OBJECTIVES:

- Expectations of the Authorities
- Various Audit Types
- Risk-based Audit Planning
- Audit Plan and Audit Team
- 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
EUROPEAN COMPLIANCE ACADEMY

* This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager". 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

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 broaden 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 5 October 2011 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
- Different types of conversational partners
- Analysing conversational behaviour
- Multicultural aspects

2. How to recognise, understand and solve conflicts
- Conflict prevention
- Conflict free communication
- Solving communicative problems
- 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:

- Communication as the tool
- Questioning techniques and body language
- 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.

Speakers

Dr Christian Hösch

Ministry of Social- and Family Affairs, Health and Consumer Protection, Hamburg, Germany

Dr Hösch worked in the pharmaceutical industry as Head of Production before he became GMP-inspector at the local authority in Braunschweig 2001. He changed to the authority in Hamburg in 2004 and is responsible for inspecting manufacturers of medicinal products and APIs worldwide. He is also a member of the ZLG Expert Groups Quality Assurance and Biotechnology.

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.

Wolfgang Schmitt

Concept Heidelberg, Germany

Before Wolfgang Schmitt started as Director Operations at Concept Heidelberg in 2006, he worked for Abbott (the former Knoll AG, Germany). Wolfgang Schmitt was Head of Quality Management at SOLIQS (Abbott's global Drug Delivery Business Unit) and later an Associate Director and Qualified Person at Abbott's Global Pharmaceutical Research and Development QA, where he was responsible for GMP/GLP-Compliance.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "Certified QA Manager". 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

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.

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:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ 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)

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

D-69007 Heidelberg
GERMANY

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)!

Date

Wednesday, 5 October 2011, 9.30h – 18.00h
(Registration and coffee 9.00h - 9.30h)
Thursday, 6 October 2011, 9.00h – 18.00h
Friday, 7 October 2011, 8.30h – 15.00h

Venue

Dorint Don Giovanni Prague
Vinohradská 157A
130 20 Prague 3
Czech Republic
Tel.: +420 2 6703 1111
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Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT (does not include ECA Membership).
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
The course 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 event. Please use this form for your room reservation or be sure to mention "VA 6872 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 4 September 2011 . 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

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