

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

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

The GDP Audit

17-18 November 2015, Budapest, Hungary

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)

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

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:

- until 2 weeks prior to the conference 10 %

- until 1 week prior to the conference 50 %

- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, in-

structors, 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

Tuesday, 17 November 2015, 9.30 h – 17.30 h

(Registration and coffee 9.00 h – 9.30 h)

Wednesday, 18 November 2015, 8.30 h – 15.00 h

Venue

Hilton Budapest City Center

Váci út 1-3.

1062 Budapest, Hungary

Phone +36 1 288 5500

Fax +36 1 288 5500

Fees (per delegate plus VAT)

ECA Members € 1,490

APIC Members € 1,590

Non-ECA Members € 1,690

EU GMP Inspectorates € 845

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.

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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P.O. Box 10 17 64

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For questions regarding content:

Mr Wolfgang Schmitt (Operations Director) 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.:

Ms Marion Weidemaier (Organisation Manager) at +49(0) 62 21 / 84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.



All participants will receive:

- the current GDP-Guidelines as a handy Paperback
- an SOP on Self-Inspection
- a Checklist for GDP-Compliance

The GDP Audit

How to conduct and pass GDP Audits and Inspections

17-18 November 2015, Budapest, Hungary

SPEAKERS:

Birgit Bigga
Hermes Pharma GmbH

Michael Fleischer
World Courier

Mag. pharm. Andreas Kraßnigg
*Austrian Agency for Health and
Food Safety (AGES)*

Dr Martin Melzer
Chemengineering Business Design GmbH

LEARNING OBJECTIVES:

- Regulatory Requirements and Expectations
- Audit Management (from Preparation to Follow-Up)
- Typical Audit Findings
- Conducting a GAP Analysis
- Communication and Conflict Solving



The GDP Audit

17-18 November 2015, Budapest, Hungary

Learning Objectives

The **EU GDP Guidelines** have been extensively revised to take into account the changing nature of the globalised supply chain. One important aspect is auditing partners in the supply chain. But who needs to audit which service provider and how? And who will be inspected by the authorities? And how can I prepare myself?

In this training course you will learn

- How to plan and conduct audits efficiently
- How to prepare yourself when being audited
- How to face the various challenges
- What communication techniques are needed
- How you can avoid and solve conflicts

Background

The revised GDP-Guidelines highlight the need for an **effective quality management system and appropriate controls** for all partners and service providers in the distribution chain (like manufacturers, wholesalers, warehouses and transport and logistics providers).

Qualification of these partners, like for example with audits, is a core element to implement the GDP requirements.

Initial and continuous **professional training for auditors** 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 of GDP audits.

On the other hand you will learn how to prepare your company to pass an inspection or customer audit and how to assure the most positive outcome.

Target Audience

This education course is designed for all managers, supervisors and other staff members who are involved in audits of pharmaceutical storage, transportation, cold chain and distribution activities.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg

Programme

Regulatory Part:

Overview: Regulatory Requirements and Guidance

- EU-GMP Guidelines
- EU-GDP Guidelines
- Other Guides
- Who needs to audit?
- Expectations of the Authorities

Regulatory Inspections and typical GDP Deviations

- GDP inspections
 - Who will be inspected
 - Different kinds of inspections
 - Approach
 - Classification of audit findings
- Examples of frequent observations and typical audit findings:
 - Storage
 - Transport
 - Wholesalers

General Part:

Audit Management in Distribution

Part 1: Planning the Audit

- Evaluation of the distribution chain/ Risk based planning
- Audit planning and resource planning
- Auditor training and qualification

Part 2: Conducting the Audit

- Aide Memoire vs. Checklist (benefits and risks)
- Audit strategy during the audit
- Audit report and classification of findings

Part 3: Audit Follow-Up

- Follow-up of corrective/ preventive actions (CAPA)
- Development of Key Quality Performance Indicators (KQPI)
- CAPA efficiency evaluation in the follow-up audit

Practical Part:

Auditing and Qualifying Service Providers

- A look behind the scenes: what can go wrong
- Challenges
- Examples and possible solutions

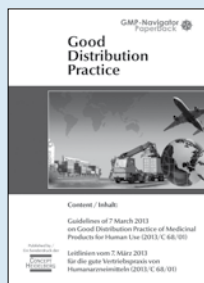
Communication Skills

- The challenge of appropriate communication
- How to recognise, understand and solve conflicts
- Body Language
- Questioning Techniques

Workshop:

Before being audited: Conducting a GAP Analysis

- Preliminary considerations – what are the requirements? What are the expectations?
- Conducting your own GAP Analysis
- Action plan & processing
- How to keep the achieved status



All participants will receive

- the current GDP-Guidelines as a handy Paperback
- an SOP on Self-Inspection
- a Checklist for GDP-Compliance

Social Event

On 17 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.



Speakers



Birgit Bigga

Hermes Pharma GmbH, Austria

Birgit Bigga has 30 years experience within the pharmaceutical industry (e.g. in validation, documentation and training). Since 15 years, she is also working as a freelance coach in communication training and conflict solving.



Michael Fleischer

World Courier, Germany

Michael Fleischer is Global Director and responsible for the GDP compliance of all World Courier sites worldwide. Before that he was Customer Service Trainer and Temperature Control Specialist.



Mag. pharm. Andreas Kraßnigg

Austrian Agency for Health and Food Safety (AGES)

Mag. pharm. Andreas Kraßnigg is Head of Inspections at the Austrian Agency for Health and Food Safety (AGES) and the Austrian Federal Office for Safety in Health Care (BASG).



Dr Martin Melzer

Chemengineering Business Design GmbH, Germany

Dr Martin Melzer is Senior Consultant GMP Compliance. Before that he was GMP -Inspector in a German Field Inspectorate in Hannover. During that time he was representing the German inspectorates in EMA and PIC/S Working Groups for the preparation of the new GDP-Guidelines. He was heading the GDP Expert Group of the German GMP inspectors from 2008 up to 2011. Before that he was working at Solvay Pharmaceuticals GmbH and a company of the Diapharm Group.