

- 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 Chemgineering 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



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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:

Distribution Practice

Before being audited: Conducting a GAP Analysis

Preliminary considerations – what are the requirements? What are the expectations?

All participants will receive

- the current GDP-Guidelines as a handy Paperback

- an SOP on Self-Inspection

- Conducting your own GAP Analysis
- Action plan & processing
- How to keep the achieved status

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

Chemgineering 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.

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.



Reservation Form: CONCEPT HEIDELBERG P.O. Box 10 17 64 69007 Heidelberg Germany				Reserv + 49 62	ation F 221 84 4	orm: 44 34	@ e-mail: info@concept	-heidelberg.de
n Form (Please complete in full) Audit mber 2015, Budapest, Hungary	□ Ms.	sumame	icate your company's VAT ID Number		Zip Code Country	E-Mail (please fill in)	t you have to inform us in writing. The cancellation fee calculated according to the point of time at which we message. In case you do not appear at the event with informed us, you will have to pay the full registration favore not made the payment yet. Only after we have re payment, you are entided to participate in the confere payment will not be confirmed)! (As of January 2012)	DateTuesday, 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 hVenueHilton Budapest City Center Váci út 1-3. 1062 Budapest, Hungary Phone +36 1 288 5500 Fax +36 1 288 5500 Fax +36 1 288 5500Dees (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. Begistration Via the attached reservation form, by e-mail or by fax message. Or you register online at
Reservation Form The GDP Audit 17-18 November 2	Mr.	Title, first name, surname	Company Important: Please ind	Street/P.O. Box	City	Phone/Fax	notice or to cancel an event. will be notified a soon as pr se paid. CONCEPT HEIDELBEF infare penalties or other costs of thout deductions within 10 c agistration and above fees are ppearance. If you cannot take	www.gmp-compliance.org. Conference language The official conference language will be English. Organisation and Contact
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Easy Registration