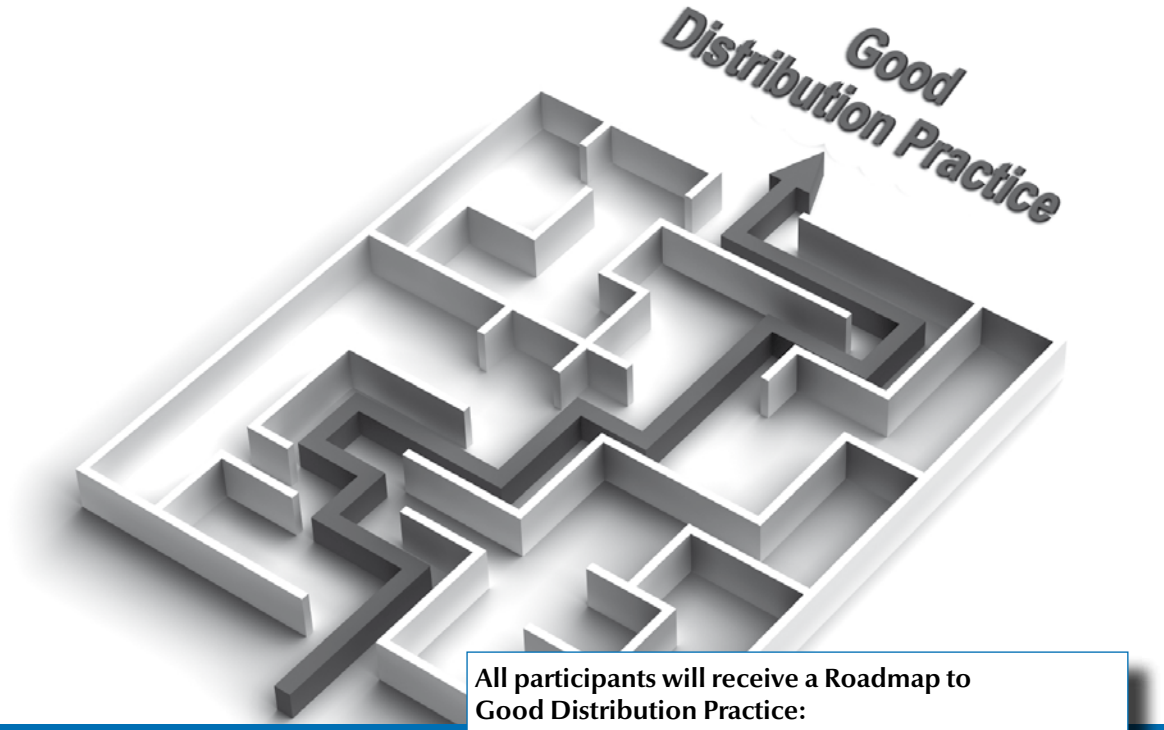

All participants will receive a Roadmap to Good Distribution Practice:

- Overview of the designated responsibilities
- Checklist for the implementation of GDP principles

GDP: How to get you there

A 2-day Tutorial with practical Advice

19-20 February 2015, Heidelberg, Germany

SPEAKERS:

Simone Dietz
Grieshaber Logistics Group AG, Germany

Ursula Green
McGee Pharma International, Ireland

Dr Afshin Hosseiny
Tabriz Consulting, U.K.

Rico Schulze
GMP/GDP Inspectorate, Germany

LEARNING OBJECTIVES:

- Gap Analysis and Risk Assessment
- Implementation Planning
- Key Areas of new Regulations:
  - Quality Management and Organisation
  - Premises and Equipment
  - Transport Vehicles
  - Documentation
  - Supplier Selection and Qualification
  - Complaints, Recalls and returned Products
  - Contracting

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified GDP Compliance Manager". Please find details at www.gmp-certification.eu

GDP: How to get you there

19-20 February 2015, Heidelberg, Germany

Objectives

This education course provides practical guidance through workshops on how to perform gap analysis, prepare plans for implementing systems and procedures to bring your organisation in compliance with the GDP regulations.

Background

The globalisation of the pharmaceutical supply chain has created new challenges for manufacture and supply of medicinal products in various markets, resulting in reduced control and increased security risk to the products.

The **EU GDP Guidelines** have been extensively revised to take into account the changing nature of the globalised supply chain. The new requirements have been effective since September 2013. These requirements highlight the need for an effective quality management system supported by risk assessment and appropriate controls. Do you think you are compliant with the new requirements?

This two day tutorial has been designed to bring you up-to-date with the current regulatory thinking and standards for Good Distribution Practice (GDP) and to provide you with **tools and guidance** to help you with **identifying the gaps** in your quality systems compared to the new requirements and **planning and implementing the actions required.**

Target Audience

Managers and executives from companies involved in the distribution and supply of pharmaceutical products.

Moderator

Wolfgang Schmitt, Concept Heidelberg

Programme

Introduction

The new GDP Guidelines: What is it all about?

- Background to development and revision of the new EU GDP Guidelines
- Well-known or new: A summary of the most important changes
- A look into the crystal ball: What is the impact on industry and other stakeholders?

A step-wise Approach: Workshops and interactive Sessions

Quality Management System (QMS)

- What is a QMS and why do we need it?
- What does an effective QMS look like?
- How to develop and implement an effective QMS

Transportation

- Key requirements for transportation of medicines
- How to develop and implement a sGDP-compliant and cost effective transportation network.

Premises & Equipment

- What is a for medicinal products
- How would you plan and implement facility improvement ensuring compliance with the current requirements

Operations

- Qualification of suppliers and customers
- Receipt, storage and return of medicinal products
- Export markets
- Deviation and Complaint Management in a wholesaler facility
- How to conduct a gap analysis, develop plans and implement the new requirements

Personnel

- Competency requirements for GDP personnel
- Overview of the role and responsibilities of the Responsible Person
- Necessary documentation
- Training matrix and managing continuous training

Outsourced Activities

- What is an outsourced activity?
- How to set priorities to audit, approve and manage service providers
- How to develop and manage contracts and agreements

Case Study

GDP – how we got there

- How we approached the new requirements
- Challenges and best practice

Lessons learned and Action Planning

Summary and Take Away Message

- Developing a take home action plan for the delegates

Social Event

The ECA Academy and CONCEPT HEIDELBERG cordially invite you for a social event on Thursday evening in Heidelberg. This will be an excellent opportunity to share your experiences and discuss the hot topics of the day with your colleagues and the speakers.

Speakers

Simone Dietz
Grieshaber Logistics Group AG
Simone Dietz is Director Quality & Regulatory Affairs and is in charge of enforcing GDP in seven subsidiaries in Germany, Switzerland and France. She is a pharmacist by education and has also worked on a research project in the area of "pharmaceutical drug delivery systems" at the College of Pharmacy, University of Texas, USA.

Ursula Green,
McGee Pharma International, Ireland
As a consultant, Ursula Green has delivered a number of GDP projects to various clients over the past few years. Before that she was Production Manager with Fannin Compounding Limited, Dublin. Ursula Green is a member of the Advisory Board of the ECA GDP Working Group.

Afshin Hosseiny, Ph.D.
Tabriz Consulting Ltd., U.K.
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd and Qualified Person. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of Glaxo SmithKline. He is Chairman of the ECA GDP Working Group.

Rico Schulze
GMP/GDP Inspectorate,
Local Authorities Dresden, Germany
Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is a GMP and GDP Inspector at the Local Inspectorate in Dresden. He is the head of the German Inspectors' Expert Group on Radiopharmaceutical and a member of the Expert Group on GDP.

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GDP: How to get you there

19-20 February 2015, Heidelberg, Germany

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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)! (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.

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

Date

Thursday, 19 February 2015, 9.00 h – 18.00 h
(Registration and coffee 8.30h – 9.00h)
Friday, 20 February 2015, 8.00 h – 15.45 h

Venue

Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49(0)6221 908 0
Fax +49(0)6221 908 660

Heidelberg – Optimal Accessibility via Frankfurt

Airport Shuttle Service: Airport shuttle services bring you promptly and reliably from the airport to your hotel. Info: www.hls-online.de or www.ics-logistik.de.
Train: You can get on the train at the Airport Station. A train leaves up to three times per hour and it usually takes less than one hour to get to Heidelberg.

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 event. 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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69007 Heidelberg, Germany
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w.schmitt@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at
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