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 3-day Tutorial with practical Advice

15 – 17 March 2016, Barcelona, Spain

SPEAKERS:

Heike Gottschalg
Boehringer Ingelheim, Germany

Ursula Greene
McGee Pharma International, Ireland

Dr Afshin Hosseiny
Tabriz Consulting, U.K.

Savvas Koulouridas
Fagron Hellas, Greece

Robert Müller
Boehringer Ingelheim, Germany

Rico Schulze
GMP/GDP Inspectorate, Germany

LEARNING OBJECTIVES:

- Expectations of the Inspectorates
- Gap Analysis and Risk Assessment
- Implementation Planning
- Key Areas of the new Regulations:
  - Quality Management and Organisation
  - Deviations and Complaints
  - Premises and Equipment
  - Personnel
  - Supplier Selection and Qualification
  - Transport
  - 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

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Objectives

This education course provides practical guidance through workshops and interactive sessions 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 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 three day tutorial has been designed to bring you up-to-date with the current regulatory expectations 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

The Inspectors Point of View

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?

GDP Inspection Findings and what to learn from them
- Findings and their ratings
- Examples from manufacturers, wholesalers, storage facilities and transport deviations

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 GDP-compliant and cost effective transportation network.

Premises & Equipment
- What is a must for medicinal products
- How to plan and implement facility improvement ensuring compliance with the current requirements

Operations
- Qualification of suppliers and customers
- Receipt, storage and return of medicinal products
- 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 Studies

GDP – how we got there

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

Contracts in the global Supply Chain

- International laws and systems – how they work and fit together
- Jurisdictions and conflict of law provisions
- Contract law, Technical/ Quality Agreement, Supply Agreement
- 3PL Providers: two bilateral agreements or one tripartite agreement?
- When things go wrong

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 Tuesday evening in Barcelona. 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

Heike Gottschalg
Boehringer Ingelheim Pharma GmbH & Co. KG
Heike Gottschalg is responsible for the Quality Oversight and Compliance for logistics from a global perspective in the Corporate Division Quality within Boehringer Ingelheim. Before that she was responsible for stability studies for new drug products according to ICH and their evaluation. In her Quality Management role she has been responsible for the global implementation of the GDP requirements within Boehringer Ingelheim.

Ursula Greene
McGee Pharma International, Ireland
As a consultant, Ursula Greene 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 Greene 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 GlaxoSmithKline. He is Chairman of the ECA GDP Working Group.

Savvas Koulouridas
Fagron Hellas, Greece
Savvas Koulouridas is a lawyer in profession and founder of Kertus SA, Trikala, now Fagron Hellas, member of Fagron Group, where he works as General Manager. He worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts) and actively participates in setting up the new regulatory framework for the safety of medicinal preparations performed in Pharmacies in Greece.

Robert Müller
Boehringer Ingelheim Pharma GmbH & Co. KG
Robert Müller is responsible for maintaining global standards for shipping and temperature monitoring in the Global Logistics group (Corporate Division Supply Network & Lifecycle Management). Before that he was head of the Shipping & Customs Team. In collaboration with the colleagues of the Global Quality group he has been responsible for the global implementation of the GDP requirements within Boehringer Ingelheim.

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 and performs inspections worldwide. He is the head of the German Inspectors' Expert Group on Radiopharmaceuticals and a member of the Expert Group on GDP.

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Reservation Form (Please complete in full)

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Company Department

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CONCEPT HEIDELBERG
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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)! (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:
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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

Tuesday, 15 March 2016, 10.00h – 18.00h
(Registration and coffee 9.30h – 10.00h)
Wednesday, 16 March 2016, 9.00h – 17.30h
Thursday, 17 March 2016, 8.30h – 15.00h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference 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. 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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