All participants will receive a Roadmap to Good Distribution Practice:

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

GMP meets GDP

Storage - Transportation - Cold Chain

29 – 30 September 2015, Prague, Czech Republic

SPEAKERS:

Kane Edgeworth
Biomap

Dr Afshin Hosseiny
Tabriz Consulting

Dr Andreas König
Aenova Holding

Kai-Uwe Riedel
Swedish Medical Products Agency

Emil Schwan
Swedish Medical Products Agency

ECA ACADEMY

LEARNING OBJECTIVES:

- Relevant GMP and GDP Requirements and Guidelines and how to implement them
- Best Practices in Storage and Transportation
- Cold Chain and its Validation
- Shipping Stability
- Security in the Supply Chain
- Quality Risk Management
- Tracking and Tracing
- Workshops on:
  - Understanding the Supply Chain
  - Contracts in the Supply Chain

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

GMP meets GDP

29 – 30 September 2015, Prague, Czech Republic

Objectives

During this course, **well experienced speakers** will share their **expert knowledge** about all relevant aspects regarding the current **GMP and GDP requirements and current developments** in storage, transportation and Cold Chain Management. You will learn how these requirements evolve and how they can be **implemented efficiently**.

Background

Globalisation, counterfeiting problems and the expectations regarding pharmaceutical **storage, transport and cold chain management** are forcing the pharmaceutical industry to challenge their current practices. Companies have to increase their effort and validation activities as one prerequisite for safe and secure storage and transportation of their medical products over boarders and through various climatic conditions.

Directives, Guides, Guidelines and initiatives from various regulatory bodies lead the way in this development and define expectations and requirements, where Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) are closely linked.

"Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products."
(EU-GDP Guidelines)

Target Audience

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

Moderator

Afshin Hosseiny

Social Event

On 29 September, 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

Regulatory Requirements and Guidance

- What are the rules and regulations?
- Who is responsible for maintaining product quality in the supply chain
- Key challenges and criteria to consider
- Cold Chain and ambient storage and transportation
- The revised EU Guideline on Good Distribution Practice (GDP)
- Who needs a Responsible Person (RP)?

The Roadmap to Success

- Background and comments
- Delineation of responsibilities
- Introduction to the checklist

Roadmap to Good Distribution Practice

Each participant receives a Roadmap to Good Distribution Practice containing:

- An overview of the designated Responsibilities for Senior Management, Responsible Person and Authority
- A checklist for the implementation of GDP principles

Best practices in Storage (how to implement requirements and stay efficient)

- Defining your specification
- 15-25°C and 1-8°C storage

Temperature Mapping

- Warehouse, vehicle & cold storage case studies
  - Protocol preparation
  - Seasonal variations
  - Impact tests
  - Results and reporting

EU-GMP Guideline:
"Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored." (3.19)

EU-GDP Guideline:
"An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions" (3.2.1). "If temperature-controlled vehicles are used, ...temperature mapping under representative conditions should be carried out" (9.4)

Workshop Session:

1. Understand your Supply Chain
- Selection of the supply route
- Process mapping of a supply chain
- Developing a QMS for supply chain (Policies, SOPs, documentation & Training)

2. Contracts in the Supply Chain
- GxP contents of Contracts
- How to transfer contents in actions

You can choose one of these 2 workshops offered. Please give your choice when you register for this course.

Cold Chain Management and its Validation
- Validation of transport and hold time
- Validation vs. monitoring
- Qualification of various transport routes
- Data collection and evaluation

Best Practices in Transport and Logistics
- How to implement the requirements and stay efficient
- Managing 15-25°C and 2-8°C transportation
- Challenges that different modes of transportation introduce to pharmaceuticals

Shipping Stability
- What should industry do and deliver
- Using stability data to assist in supply chain design
- What is the necessary data to discuss excursions
- Discussion of possible deviations and excursions

Security in the Supply Chain
- Anti-counterfeiting strategies
- What the agencies can do
- What industry can do
- Compliance issues

Track and Trace and anti-counterfeiting Devices
- What is track and trace?
- Current technologies and best practices
- Anti-counterfeiting devices and management

Speakers

Kane Edgeworth,
Biomap, U.K.
Kane Edgeworth is Director at Biomap, providing temperature monitoring solutions for the Life Sciences industry. Before that, he was Operations Manager at Sensitech UK Ltd.

Afshin Hosseiny, Ph.D.,
Tabriz Consulting Ltd., U.K.
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.

Dr Andreas König,
Aenova Holding, Germany
Dr Andreas König is Senior Vice President Corporate Quality & HSE.at Aenova Holding GmbH. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was head of QC and QA Fresenius Kabi. and later Global Quality Director at Intervet.

Kai-Uwe Riedel,
Medical Products Agency, Sweden
Kai-Uwe Riedel is Pharmaceutical Inspector at the Drug Inspectorate of the MPA. Before that he was Manager Quality Assurance and Qualified Person at Recipharm Karlskoga AB.

Emil Schwan,
Medical Products Agency, Sweden
Emil Schwan is Pharmaceutical Inspector at the Drug Inspectorate of the MPA. Before that he was working in Development at Orexo AB.

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

GMP meets GDP, 29 – 30 September 2015, Prague, Czech Republic
Please choose ONE workshop:
☐ Understand your Supply Chain
☐ Contracts in the Supply Chain

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (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)! (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, 29 September 2015, 9.00 h - 17.45 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 30 September 2015, 8.30 h – 15.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Praha 4
Czech Pepublic
Tel.: +(0) 420 261 191 111
Fax: +(0) 420 261 225 011

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 conference. 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.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany,
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Wolfgang Schmitt (Operations Director)
at ++49-62 21 / 84 44 39 or at
w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager)
at ++49-62 21 / 84 44 22 or per e-mail at
bach@concept-heidelberg.de.