ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

Kane Edgeworth
Biomap

Dr Afshin Hosseiny
Tabriz Consulting

Dr Zvonimir Majic
Teva Pharmaceutical Industries

Emil Schwan
Swedish Medical
Products Agency

Supported by the
European GDP Association

ECA GDP ASSOCIATION
An ECA Foundation Interest Group

GDP for Beginners

Storage - Transportation - Cold Chain

4 - 5 February 2020 | Prague, Czech Republic

Highlights

- Relevant GMP and GDP Requirements and Guidelines
- Best Practices in Storage and Transportation
- Cold Chain and its Validation
- Shipping Stability
- Quality Risk Management
- Import and Export
- Supply Chain Security
- Workshop on Understanding the Supply Chain

All participants will receive a Roadmap to
Good Distribution Practice:
- Overview of the designated Responsibilities
- Checklist for the implementation of GDP principles

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 of medicinal products. 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.

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

Target Audience

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

Social Event

In the evening of the first course day, 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

Moderator

Dr Markus Funk

Programme

Regulatory Requirements and Guidance

- What are the rules and regulations?
- Who is responsible for maintaining product quality in the supply chain
- Cold Chain and ambient storage and transportation
- The revised EU Guidelines 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

- All participants receive 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
- How to set up an adequate storage facility
- 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 Guidelines**
"Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored." (3.19)

§ **EU-GDP Guidelines**
"An initial temperature mapping exercise should be carried out on Zthe 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: 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)

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

Supply Chain Security:

- Anti-counterfeiting strategies
- What the agencies can do
- What industry can do
- Compliance issues

Import and Export under new Circumstances

- New and possible future regulations impacting import and export (e.g. Annex 21, MRA)
- Political developments impacting import and export (e.g. Brexit, trade embargos)

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 Zvonimir Majic Teva Pharmaceutical Industries Ltd., Croatia

Dr Zvonimir Majic is Director Global Quality Logistics. He has Ph.D. in Transportation and Logistics and is certified Quality and Risk Manager (EOQ - European Organization for Quality), Process Design Manager and a Lead Auditor for ISO and EU OPS norm. He is a member of the European steering committee of PDA's SCIG and IATA CEIV consultant.

Emil Schwan, Medical Products Agency, Sweden

Emil Schwan is Pharmaceutical Inspector at the Drug Inspectorate of the MPA and a member of the PIC/S Working Group on GDP.

Participants' comments of February 2019 course:

„Very important subjects discussed! I loved all presentations." Katharina Bubb , Paula Sanches (PharmD), Grifols Portugal, Lda.

„Very good – lots of learnings that will be used."
John Turner, GW Pharmaceuticals, UK

„Every speaker was inspiring."
Niko Pelkonen, FinVector Oy, Finland

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GDP for Beginners, 4-5 February 2020 Prague, Czech Republic

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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German law shall apply. Court of jurisdiction is Heidelberg.

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 https://www.gmp-compliance.org/privacy-policy). 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, 04 February 2020, 9.00 h - 17.45 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 05 February 2020, 8.30 h – 15.30 h

Venue
InterContinental Praha
Pařížská 30
110 00 Prague 1, Czech Republic
Phone +420-296631111
E-Mail prague@icprague.com

Fees (per delegate, plus VAT)
ECA Members € 1,490
European GDP Association 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/POG 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon +49(0) 62 21/84 44-0
Telefax 49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:
Dr Markus Funk (Director Operations) at
+49(0) 62 21/84 44 40, or per e-mail at
funk@concept-heidelberg.de..

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