



Academy
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Information Source

GMP meets GDP

Storage - Transportation - Cold Chain

SPEAKERS:



Kane Edgeworth
Biomap



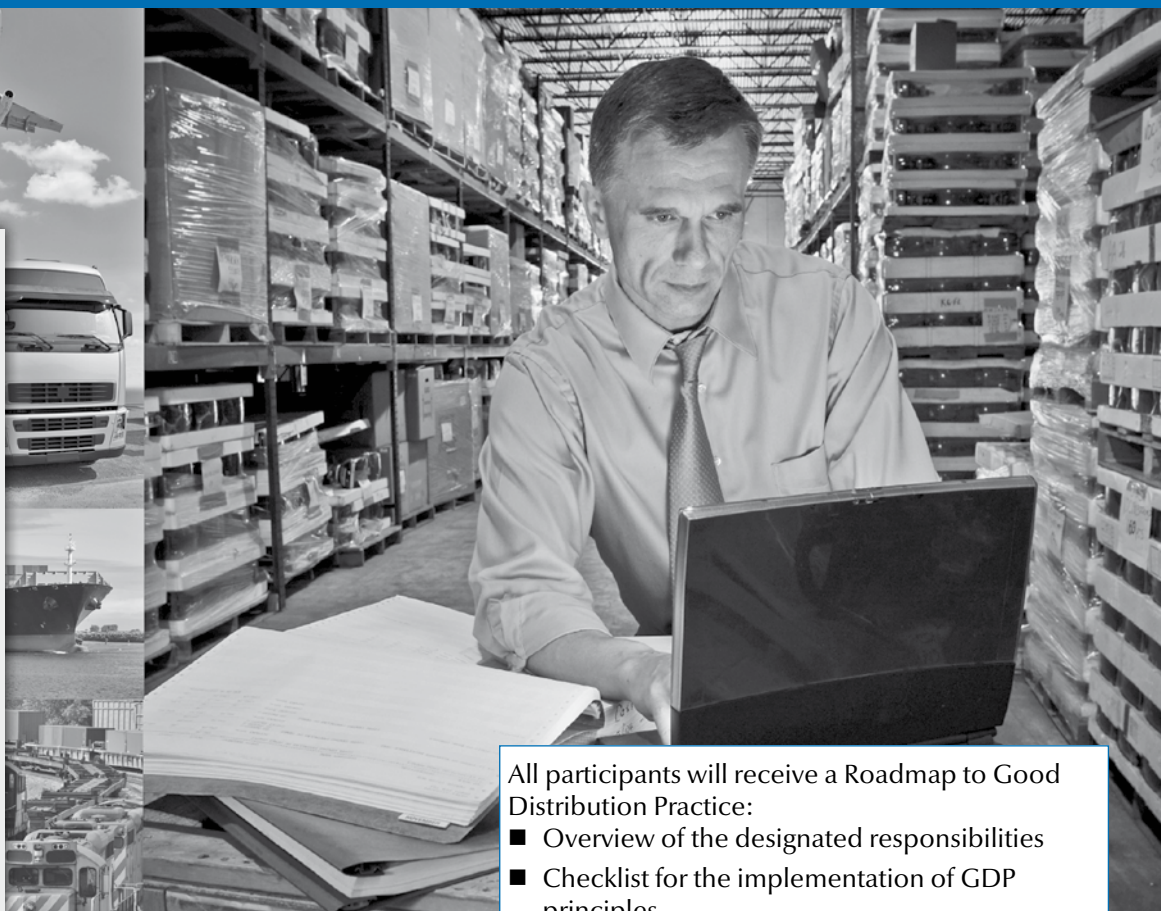
Dr Afshin Hosseiny
Tabriz Consulting



Dr Andreas König
Aenova Holding



Emil Schwan
*Swedish Medical Products
Agency*



All participants will receive a Roadmap to Good Distribution Practice:

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

14-15 November 2017, Berlin, Germany

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
- Quality Risk Management
- Supply Chain Security

Workshop on Understanding the Supply Chain



GMP meets GDP

14-15 November 2017, Berlin, Germany

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 borders 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

Wolfgang Schmitt

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 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 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:

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 (1):

Expectations of the Inspectorates

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

Supply Chain Security (2):

How to minimise Risks

- FMD requirements and the link to GDP
- Timelines for industry
- What the distributors and 3LPs need to know
- What else companies need to do to prevent security risks

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.



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.

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.



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Reservation Form (Please complete in full)

GMP meets GDP

14-15 November 2017, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

CONCEPT HEIDELBERG
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Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Important: Please indicate your company's VAT ID Number

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City

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General terms and conditions

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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 %
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Easy Registration



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Date

Tuesday, 14 November 2017, 9.00 h - 17.45 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 15 November 2017, 8.30 h – 15.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
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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.

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