

Ambient Transport and Cold Chain

Temperature controlled
Transports of Medicinal Products

SPEAKERS:



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09/10 October 2019, Berlin, Germany

HIGHLIGHTS:

- Regulatory Background
- What the Manufacturer can do
- Quality Management: what the Distributor should do
- Cold and Cool Chain strategies
- Strategies for Transport at ambient Conditions
- Appropriate Temperature Control
- Three Case Studies

Supported by the
European GDP
Association



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Objectives

Learn how the experience made in the pharmaceutical Cold Chain can support **strategies for transport at "ambient" conditions**. Challenges and possible solutions will be discussed and examples will demonstrate how the requirements can be put into practice.

Background

It is of key importance that medicinal products are not only made to a high quality in accordance with **Good Manufacturing Practice (GMP)**, but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where **Good Distribution Practice (GDP)** comes into play.

Handling and control of Cold Chain Products (2 – 8°C) have been known for a long time. However, with the implementation of the revised **EU-GDP Guidelines** more control is needed also for all other products, e.g. for those which need to be stored at so called ambient temperature conditions.

But what are the regulatory definitions for "Ambient", "Room Temperature" and "Cold Chain"? This is not harmonised, as this simple summary shows:

	Pharm. Eur.	WHO	USP
Frozen/ deep-freeze	>-15°C	-20°C	-
Refrigerator	2°C – 8°C		-
Cold	8°C – 15°C	2°C – 8°C	<8°C
Cool	8°C – 15°C	8°C – 15°C	8°C – 15°C
Room temperature	15°C – 25°C	15°C – 25°C	temperature prevailing in a work area
Controlled room temperature	-	-	20°C – 25°C excursions between 15°C and 30°C are allowed
Ambient temperature	-	15°C – 25°C or 30°C depending on climatic conditions	-

This is raising quite a few questions for all parties involved in the supply chain. Therefore the European Compliance Academy and the European GDP Association have set up the programme at hand to address and discuss these issues.

Target Audience

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

Programme

Current EU Regulatory Challenges

- EU GDP Guidelines for Medicinal Products and APIs
- The impact of the new GDP guidelines on the cold chain
- EU GDP Chapter 9: Requirements, Clarification and Implementation
 - Principles
 - Well-known or new: transport at storage conditions
 - Transport conditions
 - Responsibilities
 - Risk assessment
 - Using dedicated vehicles or not
 - Containers, packaging and labelling
 - Products requiring special conditions
- EU GMP Guidelines and Annex 15
- Expectations of the agencies
- Trends in GDP Inspections

The complicated Logistics around Medicinal Products and APIs

- Differences in the transport of APIs and medicinal products
- The latest developments in packaging and distribution for temperature sensitive products and materials
- How to find a good transport service provider
- Refrigerated shipment, cold chain management and transport at ambient conditions – avoiding deviations
- Examples and solutions

Quality Management and Operating Procedures

- How to apply quality systems to manage distribution processes
- Necessary elements of the quality management system
- Operating Procedures and how to apply them throughout the supply chain
- Creating an ongoing quality strategy for distribution processes and procedures

The Role of the Manufacturer – from Stability and Packaging to Distribution

- Understanding the needs of the supply chain
- Pulling in three directions – quality, costs and time
- Solutions for packaging and containers
- Information flow along the supply chain: from stability studies to deviation handling

Temperature Control: building up an efficient Supply Chain for Medicinal Products and APIs

- How to perform shipping studies
- How to use risk assessment and management
- Limitations and capabilities of packaging components and containers
- Data logger: when, where and how many?
- Strategies and solutions to meet the regulatory expectations

Application of Cold Chain Standards for ambient Temperature

- Cold and Cool Chain: validation and risk management
 - Strategies and tools to assist in defining validation exercises
 - Risk Assessment and validation master planning
 - Qualification and testing of active systems
- Lessons learned and how the experience made can support strategies for transport at ambient conditions
- Possibilities and boundaries of transport validation in: road transport, air freight, sea transport

The Role of the Qualified Person and the Responsible Person

- The intensified role and responsibilities
- When does the responsibility of the QP end?
- How to handle deviations during storage and transport
- Best practices for co-operation

Case Studies:

A global approach to the Control of Transports at ambient Temperature

- Information needed to perform a sound risk assessment
- How to get all the relevant data
- Qualification and validation: benefits and limits
- Data Management: what to do with all the data

Danger in the Air - how to control Air Transport

- Recent GDP developments in pharma airfreight
- Challenges at airports and how to deal with them
- Best practices
 - Controlling temperature at the airport and on airplanes
 - Optimising and securing load position
 - Communication and co-operation with customs

A Distribution Perspective on Designing and Implementing an Ambient Temperature and Cold Chain Supply Chain

- Understanding the challenges of the supply chain
- Mapping the Supply Chain
- Effectively working with providers to ensure efficiency
- Control and information flow between the partners

Workshop to discuss the most important Questions:

- Do all transports have to be monitored?
- Can we deviate from storage conditions during transport if the manufacturer agrees?
- How can risk assessment give us more flexibility?
- When can I use Mean Kinetic Temperature Calculation (MKT)?
- What has to be done in the case of deviations?
- Who is responsible for the decisions?

Speakers



Prabjeet Dulai, GDP & Quality Matters Ltd., U.K.

Prabjeet Dulai is a Consultant Responsible Person at GDP & Quality Matters Ltd. Before working as a consultant she was the RP and Senior Supply Chain Pharmacist for the UK Ministry of Defence, and prior to this worked as a Pharmacist within the NHS/private hospital sector, retail and pharmaceutical industry.



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.



Dr Rainer Kahlich, Local Government of Baden-Württemberg, Germany

Dr Rainer Kahlich is pharmacist and GMP/GDP Inspector for the Local Government and the EMA and performs GMP/GDP inspections worldwide.



Peter Kralinger, Carrymed Pharma & Transport GmbH, Austria

Peter Kralinger is Managing Director of Carrymed, the first licensed pharma company providing international transport of temperature sensitive pharmaceuticals. Before that he was in charge of the global transportation activities for all manufacturing sites in Europe of a large manufacturer of the pharmaceutical industry.



Dr Torsten Schmidt-Bader, moveproTEC Compliance & Innovation Advisory, Germany

Dr Torsten Schmidt-Bader is Managing Director at moveproTEC and a GMP/GDP lead auditor and compliance advisor. Since 2010 he has been supporting the life science industries and pharma logistic providers with GDP implementation. For SGS ICS, he certified several providers against WHO and EU GDP standards and supported the first airport hub GDP certification.

Social Event



At the end of the first course day, you are invited to take part in an evening program (city tour and dinner). This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.

Easy Registration



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Reservation Form (Please complete in full)

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- until 2 weeks prior to the conference 10 %,

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Date

Wednesday, 09 October 2019, 9.00h - 17.45h
(Registration and coffee 8.30h - 9.00h)
Thursday, 10 October 2019, 8.30h - 15.45h

Venue

TITANIC Hotel Chaussee Berlin
Chausseestrasse 30
10115 Berlin, Germany
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Fees (per delegate plus VAT)

ECA Members € 1,590
European GDP Association Members € 1,590
APIC Members € 1,690
Non-ECA/GDPA Members € 1,790
EU GMP Inspectorates € 895

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 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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