



## Speakers



Prabjeet Dulai  
GDP & Quality Matters



Dr Rainer Kahlich  
GMP/GDP Inspector



Peter Kralinger  
Carrymed



Dr Torsten Schmidt-Bader  
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Supported by the  
European GDP Association



# Ambient Transport and Cold Chain

Temperature controlled Transports of Medicinal Products



Live Online Training on 10/11 November 2021



## 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
- Q&A Sessions

Regulatory Requirements and Practical Implementation

## 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	-

## Target Audience

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

## Moderator

Dr Markus Funk

## 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



### Discussion:

#### 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?



### Case Studies:

#### A global Approach to the Control of Transport 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

## 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.



**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.

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## Date of the Live Online Training

Wednesday, 10 November 2021, 9.00 h – 17.00 h

Thursday, 11 November 2021, 9.00 h – 17.00 h

All times mentioned are CET.

## Technical Requirements

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European GDP Association Members € 1,590

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Non-ECA Members € 1,790

EU GMP Inspectorates € 895

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## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## 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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