



## Speakers



Dr Rainer Kahlich  
GMP/GDP Inspector, Germany



Robert Kayum  
DD, UK



Peter Kralinger  
Carrymed, Austria



Dr Torsten Schmidt-Bader  
moveproTec, Germany

Supported by the  
European GDP Association



An ECA Foundation Interest Group

# Ambient Transport and Cold Chain

Temperature controlled Transports of Medicinal Products



Live Online Training on 06/07 November 2024



## 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
- Two Case Studies
- Q&A Sessions
- Workshop to discuss the most important Questions

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, the distribution remains extremely challenging. The approvals of various COVID-19 vaccines in many countries at the beginning of 2021 illustrated the importance of distribution of temperature-sensitive medicinal products – and the challenges involved.

With the implementation of the revised EU-GDP Guidelines (Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use) it became clear that control is needed also for all other products, e.g. for those which need to be stored at so-called ambient temperature conditions. Consequently, the temperature should be monitored during storage and transport.



### EU-GDP Guidelines, Chapter 9 – Transportation

*“It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport.*

*Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.*

*[...]*

*For temperature-sensitive products, qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature-controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and customer.*

*If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals. Temperature mapping under representative conditions should be carried out and should take into account seasonal variations.”*

## Target Audience

This Live Online Training was developed for managers, executives, Responsible Persons (RP's), technical staff and other employees from companies involved in the 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 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



### 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



**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.



**Robert Kayum**  
DD, UK

Robert Kayum is currently Group Head of Quality Assurance at DD. He has more than 15 years' experience as an RP, with a wealth of knowledge and experience in various aspects of GDP. Approaching 30 years of global experience, Robert has previously worked with Softbox Systems, Envirotainer, OBG Pharmaceuticals, Unipart/NHS Supply Chain, MSI Reproductive Choices, Kammac, Masters Speciality Pharma and has consulted to organisations such as McKinsey and Eurazeo. Robert specialises and especially enjoys temperature control packaging, quality excellence (culture) and GxP quality focused strategy.



**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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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 July 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

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## Date of the Live Online Training

Wednesday, 06 November 2024, 9.00 h – 17.00 h

Thursday, 07 November 2024, 9.00 h – 16.30 h

All times mentioned are CET.

## Technical Requirements

We use Webex for our live online training courses and webinars. At [www.gmp-compliance.org/training/online-training-technical-information](http://www.gmp-compliance.org/training/online-training-technical-information) you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)

ECA Members € 1,690

European GDP Association Members € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

The fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax – **or search and register directly at [www.gmp-compliance.org](http://www.gmp-compliance.org) under the number 21381.**

## 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.

## You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings).

## Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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