

Speakers



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Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification



Live Online Training on 02 May 2022, 14:00 – 17:00 h



Highlights

- Temperature-Controlled Transports of Medicinal Products
 - Insulated packaging for small and large quantities
 - Road transport and air freight of cold chain products (2 – 8 °C)
 - Transport and storage at ultra-frozen range (-70 °C)
- Vehicle Qualification
 - Qualification of temperature-controlled vehicles (IQ/OQ/PQ)
 - Regulatory landscape
 - Matrix approach for larger fleets
 - Vehicle mapping case study
- Questions and Answers Session

Objectives

This Live Online Training aims to give participants a comprehensive yet compact overview of expectations concerning the transportation of products requiring special conditions. The focus will be on the requirements for the transport of **temperature-sensitive products**.

General aspects of **road transport and air freight at cold chain (2 – 8 °C) and at ultra-frozen (-70 °C) conditions** will be discussed. Furthermore, **vehicle qualification** and the effective **mapping of vehicles** will be covered. A **Q&A session** ensures interaction and that all questions are answered.

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.

The **distribution of temperature-sensitive pharmaceuticals** is extremely challenging. The **EU GDP-Guidelines** (Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use) require that 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, taking into account seasonal variations. 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.

With the approvals of **various COVID-19 vaccines** in many countries at the beginning of 2021, the question came into focus on how to safely transport the serum from manufacturing facilities to storage and distribution centres, and then onwards to local healthcare facilities and vaccination centres. However, this question does not only arise for COVID-19 vaccines, but also for **all temperature-sensitive products in general**.

The specific packaging, transport, handling and storage requirements as well as the transport routes may differ depending on the type of pharmaceutical product. of the various COVID-19 vaccines are partly still open. The transport routes may also depend on the future production sites. In any case, transport companies must take special safety precautions for the transport of temperature-sensitive pharmaceuticals. The products are often not only very valuable, but also particularly sensitive. Damages can quickly lead to a total loss, as in case of doubt, the entire load must be destroyed. In addition, there are risks such as interruption of the cold chain. Therefore, the products may only be distributed with controlled packaging solutions and in special vehicles that are appropriately qualified and whose temperature is monitored permanently.

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 distribution and supply of temperature-sensitive pharmaceutical products.

It will be of interest in particular for personnel from the following departments:

- Quality Assurance
- Validation
- Engineering
- Logistics
- Cold Chain
- Regulatory Compliance

Moderator

Dr Markus Funk

Programme

Welcome and Introduction

(Dr Markus Funk)



Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

Chapter 2.4. (Training)

[...] Personnel dealing with any products which require more stringent handling conditions should receive specific training. Examples of such products include [...] temperature-sensitive products.

A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

Temperature-Controlled Transports of Medicinal Products

(Peter Kralinger)

- Insulated packaging for small and large quantities
- Road transport and air freight of cold chain products (2 – 8 °C)
- Transport and storage at ultra-frozen range (-70 °C)

Vehicle Qualification

(Kane Edgeworth)

- Qualification of temperature-controlled vehicles (IQ/OQ/PQ)
- Regulatory landscape
- Matrix approach for larger fleets
- Vehicle mapping case study

Questions and Answers Session

(Peter Kralinger and Kane Edgeworth)

- Participants are invited to ask questions



Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

Chapter 9.4. (Products requiring special conditions)

In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances, the wholesale distributor should maintain a safe and secure supply chain for these products in accordance with requirements laid down by the Member States concerned. There should be additional control systems in place for delivery of these products. There should be a protocol to address the occurrence of any theft.

[...]

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.

If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions.

[...]

The process for delivery of sensitive products and control of seasonal temperature variations should be described in a written procedure.



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.



Kane Edgeworth

Biomap Ltd, UK

Kane Edgeworth is Director at Biomap, providing validation & temperature monitoring solutions for the Life Sciences industry. Before that, he was UK Operations Director at one of the world's largest data logger manufacturers.

Agenda

14:00 – 14:10 h	Welcome and Introduction
14:10 – 15:10 h	Presentation 1 (Temperature-Controlled Transports of Medicinal Products)
15:10 – 15:20 h	Break
15:20 – 16:20 h	Presentation 2 (Vehicle Qualification)
16:20 – 16:30 h	Break
16:30 – 17:00 h	Questions and Answers Session



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Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification Live Online Training on 02 May 2022, 14:00 – 17:00 h

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Date of the Live Online Training

Monday, 02 May 2022, 14:00 – 17:00 h

All times mentioned are CEST.

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Organisation and Contact

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

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