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Speakers

Peter Kralinger
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Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification

Live Online Training on 10 October 2024, 09:00 – 12:30 h

Highlights

- Temperature-Controlled Transports of Medicinal Products
- Vehicle Qualification
- Regulatory Landscape
- Packaging Systems
- Vehicle Mapping Case Study
- Two Questions and Answers Sessions

Strategies to meet Regulatory Expectations

Programme

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 fright at cold chain conditions** will be discussed. Furthermore, **vehicle qualification** and the effective **mapping of vehicles** will be covered. **Q&A sessions** will follow both lectures. Thus, take advantage of this opportunity to ask your questions.

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.

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. For example, how must these vaccines – but also **any other temperature-sensitive product** in general – be transported to get safely from the production sites to the storage and distribution centres and then on to the local vaccination centres?

The specific packaging, transport, handling and storage requirements as well as the transport routes may differ depending on the type of pharmaceutical product. 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 (RPs), 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)

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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)

- Transport process design approach
- Optimization: insulation, freight cost, risk reduction
- Systems
  - Passive cooling
  - Thermohood
  - Containers for wide body aircrafts
- Process risk assessment
- Content of a quality agreement
- Dataloggers

Vehicle Qualification

(Kane Edgeworth)

- Regulatory landscape
- Qualification & validation
  - Definitions
  - Matrix approach
  - Project planning & design
  - IQ/OQ/PQ
  - Calibration
- Vehicle mapping case study

Questions and Answers Sessions

(Peter Kralinger and Kane Edgeworth)

- Participants are invited to ask questions

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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

09:00 – 09:15 h	Welcome and Introduction
09:15 – 10:15 h	**Presentation 1**
10:15 – 10:30 h	**Questions and Answers Session 1**
10:30 – 10:45 h	Break
10:45 – 11:45 h	**Presentation 2**
11:45 – 12:00 h	Break
12:00 – 12:30 h	**Questions and Answers Session 2**

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Reservation Form (Please complete in full)

Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification
Live Online Training on 10 October 2024, 09:00 – 12:30 h

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training
Thursday, 10 October 2024 from 09:00 – 12:30 h
All times mentioned are CEST.

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Fees (per delegate, plus VAT)
ECA Members € 490
European GDP Association Members € 490
APIC Members € 540
Non-ECA Members € 590
EU GMP Inspectorates € 490
The fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at 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.

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

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