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Speakers

Peter Kralinger
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COVID-19 Vaccines and Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification

Live Online Training on 04 March 2021, 10:00 – 13:00 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

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 **COVID-19 vaccines** and other **temperature-sensitive products**.

General aspects of **road transport and air fright 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, the question arises 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 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 COVID-19 vaccines. The serum is 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 vaccine 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 COVID-19 vaccines and 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)

- 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

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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

10:00 – 10:10 h	Welcome and Introduction
10:10 – 11:10 h	**Presentation 1**
11:10 – 11:20 h	Break
11:20 – 12:20 h	**Presentation 2**
12:20 – 12:30 h	Break
12:30 – 13:00 h	**Questions and Answers Session**

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Reservation Form (Please complete in full)

COVID-19 Vaccines and Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification
Live Online Training on 04 March 2021, 10:00 – 13:00 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

Phone / Fax

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Date of the Live Online Training
Thursday, 04 March 2021, 10:00 – 13:00 h
All times mentioned are CET.

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Fees (per delegate, plus VAT)
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Non-ECA Members € 590
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The conference 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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