ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

Dr Rainer Kahlich
GMP/GDP Inspector, Germany

Robert Kayum
Masters Speciality Pharma, UK

Peter Kralinger
Carrymed, Austria

Dr Torsten Schmidt-Bader
moveproTec, Germany

Supported by the
European GDP Association

ECA 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

Programme

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.

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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 fright, 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
Masters Speciality Pharma, UK

Robert Kayum is currently the Responsible Person/Head of QA at Masters Speciality Pharma, UK. He has 15 years' experience as an RP, with a wealth of knowledge and experience in various aspects of Good Distribution Practice. Approaching 30 years of global experience, Robert has previously worked with Softbox Systems, Envirotainer, OBG Pharmaceuticals, Unipart/NHS Supply Chain, MSI Reproductive Choices, Kammac 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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Reservation Form (Please complete in full)

Ambient Transport and Cold Chain | Live Online Training on 06/07 November 2024

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

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
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- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
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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.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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 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 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.

Organisation and Contact

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

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