ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

Kane Edgeworth
Biomap

Dr Zvonimir Majic
Teva Pharmaceutical Industries

Sue Mann
Sue Mann Consultancy

Emil Schwan
Swedish Medical Products Agency

Supported by the
European GDP Association

ECA GDP ASSOCIATION
An ECA Foundation Interest Group

GDP for Beginners

Storage - Transportation - Cold Chain

Live Online Training on 31 January/01 February 2024

Highlights

- Relevant GMP and GDP Requirements and Guidelines
- Best Practices in Storage and Transportation
- Cold Chain Management and its Validation
- Shipping Stability
- Temperature Mapping
- Deviation Handling: Pharma Shipment without a Data Logger
- Import and Export
- Understanding the Supply Chain
- Supply Chain Security
- New: GDP Role Play, acted out by the Speakers

All participants will receive:
- Pre-course reading material
- A Roadmap to Good Distribution Practice:
  - Overview of the designated Responsibilities
  - Checklist for the implementation of GDP principles

Objectives

During this course, **well experienced speakers** will share their **expert knowledge** about all relevant aspects regarding the current **GMP and GDP requirements and current developments** in storage, transportation and Cold Chain Management of medicinal products. You will learn how these requirements evolve and how they can be **implemented efficiently**.

Background

Globalisation, counterfeiting problems and the expectations regarding pharmaceutical **storage, transport and cold chain management** are forcing the pharmaceutical industry to challenge their current practices. Companies have to increase their effort and validation activities as one prerequisite for safe and secure storage and transportation of their medical products over boarders and through various climatic conditions.

Directives, Guides, Guidelines and initiatives from various regulatory bodies lead the way in this development and define expectations and requirements, where Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) are closely linked.

§ **EU-GDP Guidelines**
"Compliance with these Guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products."

Target Audience

This education course is designed for all managers, supervisors and other staff members who are involved in pharmaceutical storage, transportation, cold chain and distribution activities and the control of those activities.

Moderator

Dr Markus Funk

Programme

Welcome and Introduction

European Regulatory Requirements and Guidance

- What are the rules and regulations?
- Who is responsible for maintaining product quality in the supply chain
- Cold Chain and ambient storage and transportation
- The revised EU Guidelines on Good Distribution Practice (GDP)
- Who needs a Responsible Person (RP)?

Introduction to the Roadmap to Success

- Background and comments
- Delineation of responsibilities
- Introduction to the checklist

Case Study on Temperature Mapping Warehouse, Vehicle & Cold Storage Case Studies

- Protocol preparation
- Seasonal variations
- Impact tests
- Results and reporting

Roadmap to Good Distribution Practice

All participants receive a Roadmap to Good Distribution Practice containing:

- An overview of the designated Responsibilities for Senior Management, Responsible Person and Authority
- A checklist for the implementation of GDP principles

Understand your Supply Chain

- Selection of the supply route
- Process mapping of a supply chain
- Developing a QMS for supply chain (Policies, SOPs, documentation & Training)

Best Practices in Storage

- Defining your specification
- How to set up an adequate storage facility
- 15-25 °C and 2-8 °C storage

§ **EU-GMP Guidelines**
"Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored." (3.19)

§ **EU-GDP Guidelines**
"An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions" (3.2.1). "If temperature-controlled vehicles are used, ... temperature mapping under representative conditions should be carried out" (9.4).

GDP Role Play (acted out by the Speakers)

During this session, there will be Q&A role play between an auditor and an auditee acted out by the speakers. After each question answered, a short reflection will be provided by an inspector on regulatory standpoint.

Cold Chain Management and its Validation

- Validation of transport and hold time
- Validation vs. monitoring
- Qualification of various transport routes
- Data collection and evaluation

Best Practices in Transport and Logistics

- How to implement the requirements and stay efficient
- Managing 15-25 °C and 2-8 °C transportation
- Challenges that different modes of transportation introduce to pharmaceuticals

Supply Chain Security

- Anti-counterfeiting strategies
- What the agencies can do
- What industry can do
- Compliance issues

Shipping Stability

- What should industry do and deliver
- Using stability data to assist in supply chain design
- What is the necessary data to discuss excursions
- Discussion of possible deviations and excursions

Deviation Handling: Pharma Shipment without a Data Logger

- How to support product release in case of missing data loggers in road, air or ocean shipments
- Data accessibility and validity
- Record types and supporting documents
- Investigation report and CAPA

Import and Export under new Circumstances

- Regulations impacting import and export (e.g. Annex 21, MRA)
- Political developments impacting import and export (e.g. Brexit, trade embargos)

Q&A sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

Speakers

Kane Edgeworth
Biomap, U.K.

Kane Edgeworth is Director at Biomap, providing temperature monitoring solutions for the Life Sciences industry. Before that, he was Operations Manager at Sensitech UK Ltd.

Dr Zvonimir Majic
Teva Pharmaceutical Industries Ltd., Croatia

Dr Zvonimir Majic is Director Global Quality Logistics. He has Ph.D. in Transportation and Logistics and is certified Quality and Risk Manager (EOQ - European Organization for Quality), Process Design Manager and a Lead Auditor for ISO and EU OPS norm. He is a member of the European steering committee of PDA's SCIG and IATA CEIV consultant.

Sue Mann
Sue Mann Consultancy, UK

Sue Mann is a Pharmacist and a Qualified Person, and has spent over 35 years in the industry in various roles including technical support, clinical trial supplies and quality assurance/management. She has worked with both commercial and investigational medicinal products and most major dosage forms. She is presently a pharmaceutical consultant working for Pharmaceutical and Biopharmaceutical companies.

Emil Schwan
Swedish Medical Products Agency

Emil Schwan is a pharmacist with experience from performing GMP and GDP inspections, formulation development, manufacturing of medicinal products and pharmaceutical quality systems. Emil has been chief designer for medicinal products of several dosage forms. Emil comes from the Swedish Medical Products Agency (MPA), where he spent eight years as a pharmaceutical inspector. As an inspector he inspected sites in Sweden and in countries outside EU, e.g. China, India, USA. He has knowledge in GMP and GDP for both medicinal products and active pharmaceutical substances. After working as a Senior Consultant for RegSmart Life Science AB, he returned as an inspector with the MPA in November 2021.

Participants' comments of February 2019 course:

„Very important subjects discussed! I loved all presentations."
Katharina Bubb, Paula Sanches (PharmD), Grifols Portugal, Lda.
„Very good – lots of learnings that will be used."
John Turner, GW Pharmaceuticals, UK
„Every speaker was inspiring."
Niko Pelkonen, FinVector Oy, Finland

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Reservation Form (Please complete in full)

GDP for Beginners
Live Online Training on 31 January/01 February 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:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
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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, 31 January 2024, 9.00 h – 17.30 h
Thursday, 01 February 2024, 9.00 h – 17.00 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 EUR 1,690
European GDP Association Members EUR 1,690
APIC Members EUR 1,790
Non-ECA Members EUR 1,890
EU GMP/GDP Inspectorates EUR 945
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.

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