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
RegSmart Life Science

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 23/24 February 2021

Highlights

- Relevant GMP and GDP Requirements and Guidelines
- Best Practices in Storage and Transportation
- Cold Chain 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

All participants will receive a Roadmap to
Good Distribution Practice:
- Overview of the designated Responsibilities
- Checklist for the implementation of GDP principles

Programme

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 Day 1 - 23 February 2021

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 1-8°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).

Programme Day 2 - 24 February 2021

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

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

Supply Chain Security

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

Import and Export under new Circumstances

- New and possible future regulations impacting import and export (e.g. Annex 21, MRA)
- Political developments impacting import and export (e.g. Brexit, trade embargos)

Final Discussion

Q&A sessions

Q&A sessions after each presentation ensure interaction and that your questions are answered.

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
RegSmart Life Science AB, Sweden

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. Most recently Emil comes from the Swedish Medical Products Agency, 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. Emil is a board member of the European GDP Association.

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 23/24 February 2021

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)

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If you cannot attend the conference you have two options:
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Date of the Live Online Training
Tuesday, 23 February 2021, 9.00 h – 16.30 h
Wednesday, 24 February 2021, 9.00 h – 16.30 h
All times mentioned are CET.

Technical Requirements
For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 1,490
European GDP Association Members € 1,490
APIC Members EUR 1,590
Non-ECA Members EUR 1,690
EU GMP/GDP Inspectorates EUR 845
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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