ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

GDP for Beginners

Storage - Transportation - Cold Chain

14 – 16 May 2025, Vienna, Austria

Two-day training + one-day airport tour

Highlights

- Relevant GMP and GDP Requirements and Guidelines
- Best Practices in Storage, Transportation and Cold Chain Management
- Temperature Mapping
- Deviation Handling
- Import and Export
- Supply Chain Security

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

Airport tour at Vienna Airport in cooperation with DHL

DHL

Objectives

During day 1 and day 2 of 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.

On Day 3, participants will benefit from a guided tour of the DHL Campus and Vienna Airport, providing exclusive insights into the operations and specialized handling of Life Sciences and Healthcare shipments.

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."

§ **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).

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 + Day 2)

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

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)

Airport Tour in co-operation with DHL on Day 3

- Guided tour of the DHL Campus and Vienna Airport, providing insights into operations and facilities.
- Exclusive access to an international logistics hub, offering a behind-the-scenes look at the specialized handling of Life Sciences and Healthcare shipments.

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
IATA Senior Consultant for Healthcare, Croatia

Dr Zvonimir Majic is former Global Director for supply chain quality assurance and GDP in Teva Pharmaceutical Industries Ltd. He has a 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 co-authored several Technical reports on GDP and also published several articles of special products logistics and quality assurance in supply chain.

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. He 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. After working as a Senior Consultant for RegSmart Life Science AB, he returned as an inspector with the MPA in November 2021.

Social Event

On 14 May 2025, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

If the bill-to-address deviates from the specifications on the right, please fill out here:

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GDP for Beginners | 14 – 16 May 2025, Vienna, Austria

For participants of the airport tour:

☐ *I consent to the transfer of my personal data (including name, address, company, date of birth, and email address) to DHL Group and Vienna Airport for security verification. A valid ID document is required for the security check prior to the airport tour, and a copy must be submitted in advance. After registration, we will contact you with further information.*

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 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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
Wednesday, 14 May 2025, 9.00 h – 17.45 h
(Registration and coffee, 8.30 – 9.00 h
Thursday, 15 May 2025, 8.30 h – 16.30 h
Friday, 16 May 2025, 9.00 – approx. 15.00 h

Venue
NH Vienna Airport Conference Center
Einfahrtsstraße 1-3
1300 Vienna / Schwechat, Austria
Phone: +43 (1) 701510
E-Mail: nhviennaairport@nh-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 2,290
European GDP Association Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP/GDP Inspectorates € 1,245
The conference fee is payable in advance after receipt of invoice and includes lunch and dinner on day 1, lunch on day 2 and a business snack on day 3.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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 21611.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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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