ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

## Speakers

**Dr Martin Egger**
Pharmaserv

**Alfred Hunt**
Hunt Pharma Solutions

**Dr Daniel Müller**
GMP/GDP Inspector

**Dr Laura Ribeiro**
OCP Portugal

**Jonathan Riley**
Takeda UK

**Dr Torsten Schmidt-Bader**
moveproTec, Germany

In cooperation with

QP ASSOCIATION

# The Responsible Person for Good Distribution Practices (GDP)

## 03/04 May 2023 | Vienna, Austria

## Highlights

- The EU GDP Guidelines
- Roles and Responsibilities of the Responsible Person
- What to learn from GMP/GDP Inspections and Audits
- Management of Export and Import
- Storage and Transport:
  - Warehouse Management
  - Controlled Temperature Distribution
  - Security in the Supply Chain
- Working with 3PL Service Providers

**GDP Compliance Toolkit**
All participants will receive a Roadmap to Good Distribution Practice containing:

- An Overview of the designated Responsibilities
- A Checklist for the Implementation of GDP Principles

## Objective

The EU-GDP Guidelines require that wholesale distributors have to appoint a Responsible Person (RP) for GDP. There has been a lot of discussion about the duties of the RP. Therefore, the ECA Foundation's GDP Working Group has developed this training course. In this course, the role and responsibilities of the Responsible Person for GDP will be highlighted and discussed.

## Background

In 2013 the "Guidelines on Good Distribution Practice of Medicinal Products for Human Use" were published. The Guidelines were revised to take into account advancements of practices for an appropriate storage and distribution of medicinal products in the European Union.

In Chapter 2 "Personnel", tasks and responsibilities of the RP are defined. RPs should fulfil their responsibilities personally and should be continuously contactable. The RP should have appropriate competence and experience as well as knowledge of and training in GDP. He or she may delegate duties but not responsibilities. The RP should carry out their duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.

## Target Audience

The Training Course is of particular interest to Responsible Persons but also management and quality personnel from pharmaceutical companies, wholesalers, distributors and service providers involved in distribution of medicinal products.

## Moderator

Dr Markus Funk

### The European GDP Association

A GDP Working Group was founded in March 2013 by the ECA Foundation Board. The objective of the group is to support all stakeholders involved in Good Distribution Practice (GDP) by providing them information about the implementation of GDP. In August 2016, the European GDP Group was reorganised to become the European GDP Association. More information can be found here:

www.good-distribution-practice-group.org

## Programme

### The EU-GDP Guidelines

- The counterfeit directive and the introduction of the EU GDP Guidelines
- GDP requirements for the pharmaceutical supply chain
- Regulatory expectations for implementation

### Roles and Responsibilities of the Responsible Person

- Qualifications requirements for RPs
- Duties and delegation
- How to discharge your duties

### Experiences from GMDP Inspections

- Inspections of the competent authorities
- Typical GDP inspection findings

### Management of Export and Import

- Annex 21: Importation of medicinal products
- What does batch release mean?
- Export and import to and from UK

### The Roles and Responsibilities of Wholesalers and 3PL Service Providers

- Services offered
- How to manage different clients and their requirements
- Pick and pack – best practices
- How to stay in compliance

### GDP Audits

- How to plan the audit
- Approach to GDP audits
- Reporting deficiencies
- Examples of recent audit findings

### What you need to know about 3PL Service Providers

- Co-operation
- How 3PL service providers are organised
- Contracts and qualification

### Case Study: Management of a GMP Warehouse and Distribution of Medicinal Products with a 3PL-Approach

- Outsourcing in Pharma Logistics – current trends & benefits
- Determining the scope of Outsourcing
- Processes, roles & responsibilities
- Monitoring of critical data
- Reporting of the performance & controlling of the 3PL

## Controlled Temperature Distribution

- How to manage cold chain products
- How to manage 15 – 25 °C requirements
- Air freight, sea freight, road transport and the last mile

## Roles and Responsibilities of an RP and a QP

- Responsible Person vs. Qualified Person
- GDP vs. GMP
- Product finishing activities
- Product diversions
- Handling of returned and damaged goods
- Complaint Handling

## Security in the Supply Chain – what is expected and how Industry is approaching it

- FMD and its role in supply security
- How can track and trace improve supply chain security
- What is available and how to implement


### 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
- Checklist for the implementation of GDP principles

# Social Event

On the evening of the first day of the training course, 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.

### Dr Martin Egger
Pharmaserv Logistics, Germany

Martin Egger is Managing Director at Pharmaserv Logistics. He is also a member of the Board of Directors of the European GDP Association.

### Alfred Hunt
Hunt Pharma Solutions, Ireland

Alfred Hunt is a consultant. From 2008 until 2015 he was an Inspector with the Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board (IMB). He was also key member of the European Medicines Agency (EMA) drafting group which developed the revised EU GDP Guidelines (2013/C 343/01).

### Dr Daniel Müller
GMP/GDP Inspectorate, Local Government, Germany

Currently Daniel Müller is head of the GMP Inspectorate at the local competent authority in Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA and overseas inspections.

### Dr Laura Ribeiro
OCP Portugal

Laura Ribeiro is Director Quality and Regulatory Affairs, managing a team of Responsible Persons and being responsible for the quality management system and continuous improvement of the company. She is also a member of the Board of Directors of the European GDP Association.

### Jonathan Riley
Takeda UK Limited

Jonathan Riley is a QA professional with over 20 years quality management experience including GMP, GDP, GLP and GCP in contract research, pharmaceuticals, clinical trials and chemicals manufacturing.

### 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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GERMANY

Reservation Form (Please complete in full)

## The Responsible Person for Good Distribution Practices (GDP), 03/04 May 2023, Vienna, Austria

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 %.

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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 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, 03 May 2023, 09:00 h – 18:00 h
(Registration and coffee 08:30 h – 09:00 h)
Thursday, 04 May 2023, 08:30 h – 15:30 h

### Venue
Doubletree by Hilton Vienna Schonbrunn
(former Radisson Blu Park Royal Palace Hotel Vienna)
Schlossallee 8 | 1140 Vienna | Austria
Phone +43 (1) 89 11 0

### Fees (per delegate, plus VAT)
European GDP Association Members EUR 1,590
ECA and European QP Association Members EUR 1,590
APIC Members EUR 1,690
Non- Members EUR 1,790
EU GMP Inspectorates EUR 895
The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

### 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 message. Or you register online at www.gmp-compliance.org.

### Conference language
The official conference language will be English.

### 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.

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