



## Speakers



Prabjeet Dulai, GDP & Quality Matters



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# 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

In cooperation with



### 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

## Programme

### The EU-GDP Guidelines

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- 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

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

### Experiences from GMDP Inspections

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- Inspections of the competent authorities
- Typical GDP inspection findings

### Management of Export and Import

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- 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

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

### GDP Audits

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- 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

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- 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

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- 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.



**Prabjeet Dulai**  
GDP & Quality Matters Ltd.

Prabjeet Dulai is a Consultant Responsible Person at GDP & Quality Matters Ltd. Before working as a consultant she was the RP and Senior Supply Chain Pharmacist for the UK Ministry of Defence.



**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.

### 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](http://www.good-distribution-practice-group.org)

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

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

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ZIP Code

Country

Phone / Fax

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CONCEPT HEIDELBERG  
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Fax +49(0) 62 21/84 44 34  
  
D-69007 Heidelberg  
GERMANY

#### 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 2 weeks prior to the conference 10 %
  - Cancellation until 1 week prior to the conference 50 %
  - Cancellation within 1 week 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.

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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 January 2012).

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](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, 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

Radisson Blu

Park Royal Palace Hotel Vienna

Schlossallee 8 | 1140 Vienna | Austria

Phone +43 (1) 89 11 0

Email: [info.parkroyalpalace.vienna@radissonblu.com](mailto:info.parkroyalpalace.vienna@radissonblu.com)

## Fees (per delegate, plus VAT)

European GDP Association Members EUR 1.590

ECA and European QP Association Members EUR 1590

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](http://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.

CONCEPT HEIDELBERG

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