ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

## Speakers

**Alfred Hunt**
Hunt Pharma Solutions, Ireland

**Dr Daniel Müller**
GMP/GDP Inspector, Germany

**Jonathan Riley**
Takeda UK

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

In cooperation with

QP Association

# The Responsible Person for Good Distribution Practices (GDP)

## 21/22 May 2025 | Munich, Germany

## Highlights

- The EU GDP Guidelines
- Roles and Responsibilities of the Responsible Person
- What to learn from GMP/GDP Inspections and Audits
- Controlled Temperature Distribution
- Management of Export and Import
- Validation of Computerized Systems
- Security in the Supply Chain
- Workshop on Deviation Management

**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. Today, the Association represents more than 4,300 professionals from across the globe. 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

### What is the RP and Wholesaling

- Qualification and experience requirements for RP
- The Role of RP in management of export & import
- Annex 21: Importation of medicinal products
- Export & import to and from EU

### Experiences from GMDP Inspections

- Inspections of the competent authorities
- Typical GDP inspection findings

### 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

### GDP Audits

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

### Roles and Responsibilities of the RP

- Qualifications requirements for RPs
- Responsible Person vs. Qualified Person
- GDP vs. GMP
- Duties and delegation
- How to discharge your duties
- Handling of returned and damaged goods
- Complaint Handling

### Validation of Computerized Systems under GDP Regulation

- Validation requirements – regulatory overview
- GAMP oriented validation approach of GDP critical systems

### Case Study: Validation of a new Warehouse and Material Management System

- Wholesaler in Germany

### Workshop: Deviation Management

During this workshop participants will learn and discuss how to ensure that the deviation system is being correctly used and implemented.

## Security in the Supply Chain

- Counterfeit / falsified pharmaceuticals – a real threat!
- What is pharma industry doing about it?
- Recent developments
- How can track & trace support anti-counterfeiting requirements


### 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.

## Speakers

### 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.

### 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)
21/22 May 2025, Munich, Germany

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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**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.
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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, 21 May 2025, 09:00 h – 18:00 h
(Registration and coffee 08:30 h – 09:00 h)
Thursday, 22 May 2025, 08:30 h – 15:30 h

## Venue
HYPERION Hotel München
Truderinger Str. 13, 81677 München | Germany
Phone: +49 89 4110900
E-Mail: Hyperion.Muenchen@h-hotels.com

## Fees (per delegate, plus VAT)
European GDP Association Members € 1,690
ECA and European QP Association Members € 1,690
APIC Members € 1,790
Non- Members € 1,890
EU GMP Inspectorates € 945
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 – or search and register directly at www.gmp-compliance.org under the number 21746.

## 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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