The Responsible Person for Good Distribution Practices (GDP)

11/12 March 2020 | Berlin, Germany

Speakers

Prabjeet Dulai
GDP & Quality Matters

Dr Martin Egger
Pharmaserv Logistics

Dr Afshin Hosseiny
Chair of the European GDP Association

Dr Daniel Müller
GMP/GDP Inspector

Dr Laura Ribeiro
OCP Portugal

Highlights

- The EU GDP Guidelines
- Roles and Responsibilities of the Responsible Person
- What to learn from GMP/GDP Inspections and Audits
- Storage and Transport:
  - Warehouse Management
  - Controlled Temperature Distribution
  - Track & Trace
- 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
Programme

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 new ‘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. Moreover, it should take into account the amendments to the Community Code which have been introduced with Directive 2011/62/EU of the European Parliament and of the Council. It is amending Directive 2001/83/EC on the Community code relating to medicinal products for human use with regard to preventing falsified medicinal products to enter the legal supply chain.

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 may delegate duties but not responsibilities. General requirements like organisational chart, job descriptions and training requirements are new or outlined in much more detail.

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 for human use.

Moderator

Prabjeet Dulai

Social Event

In the evening of the first day of the 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.

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The Responsible Person for Good Distribution Practices (GDP) | 11/12 March 2020, Berlin, Germany
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

Roles and Responsibilities of an RP and a QP (Interactive Session)

- 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

- Track and Trace
- Recent developments
- How can track and trace support anti-counterfeiting requirements
- Current technologies

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

Speakers

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.

Dr Afshin Hosseiny
European GDP Association and Tabriz Consulting, U.K.

Afshin Hosseiny is Chair of European GDP Association. He is also Member of the Executive Board of the ECA Foundation and Managing Director of Tabriz Consulting Ltd. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.

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: http://www.good-distribution-practice-group.org
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GERMANY

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11/12 March 2020, Berlin, 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)

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**Conference language:** English

**Organisation and Contact:**

ECG has entrusted Concept Heidelberg with the organisation of this event.

**Conference and Organisation:**

The official conference language will be English.

**Accommodation:**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form by e-mail or by fax message. On your request online at www.gmp-compliance.org or by phone at +49(0) 62 21/84 44 40 or per e-mail at info@concept-heidelberg.de. For questions regarding reservation, hotel organisation and content please contact: Ms Nicole Bach (Organisation Manager) at +49(0)62 21/84 44 22, or per e-mail at bach@concept-heidelberg.de.

**Date:**

Wednesday, 11 March 2020, 09:00 h – 18:00h

Thursday, 12 March 2020, 08:30 h – 15:30h

Venue:

Steigenberger Hotel Berlin  
Los-Angeles-Platz 1  
10789 Berlin, Germany

**Fees (per delegate plus VAT):**

- ECA Members: € 1,590
- European GDP Association Members: € 1,590
- QP Association Members: € 1,590
- APIC Members: € 1,690
- Non-Members: € 1,790
- EU GMP Inspectorates: € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, break refreshments, lunches on both days, and all refreshments. VAT is reclaimable.

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