ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

The Responsible Person for Good Distribution Practices (GDP)

24/25 March 2021 | Vienna, Austria

Speakers

Prabjeet Dulai
GDP & Quality Matters

Dr Martin Egger
Pharmaserv

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

In cooperation with

QP ASSOCIATION

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

Dr Markus Funk

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.

Programme

The EU GDP Guidelines

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

Roles and Responsibilities of the Responsible Person

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

The Role of the RP in Approval Deliveries/ Products for Distribution

- What does batch release mean?
- Responsible Person (RP) vs. Qualified Person (QP)
- What the Responsible Person (RP) needs to know about batch release

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

Experiences from GMDP Inspections

- Frequent Findings
- Expectations with regard to the Responsible Person

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

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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CONCEPT HEIDELBERG
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GERMANY

Reservation Form (Please complete in full)

The Responsible Person for Good Distribution Practices (GDP), 24/25 March 2021, 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.
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- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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Date
Wednesday, 24 March 2021, 09:00 h – 18:00 h
(Registration and coffee 08:30 h – 09:00 h)
Thursday, 25 March 2021, 08:30 h – 15:30 h

Venue
Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10 - 0
Email info.parkroyalpalace.vienna@radissonblu.com

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, 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.

GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

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