The Responsible Person for Good Distribution Practices (GDP)

Comply with the new EU GDP Guidelines

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

11/12 March 2020, Berlin, Germany

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

This course is recognised for the ECA GMP Certification Programme „Certified GDP Compliance Manager". Please find details at www.gmp-certification.eu

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11/12 March 2020, Berlin, Germany

Objectives

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

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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
- 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

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

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 11 March 2020, 09:00 h– 18:00h
(Registration and coffee 08:30 h – 09:00 h)
Thursday, 12 March 2020, 08:30 h – 15:30 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

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.

Conference 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.

Registration
Via 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.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content please contact:
Mr Wolfgang Schmitt (Operations Director) at +49(0)62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at +49(0)62 21/84 44 22, or per e-mail at bach@concept-heidelberg.de.

Social Event
On the evening of the first conference 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.

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

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P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

+49 6221 84 44 34

Registration form (please complete in full)

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

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order No. (if applicable)

Street / P.O. Box

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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- 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.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of 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,

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WA/0407/2019