ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

Prabjeet Dulai
GDP & Quality Matters

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Chair of the European GDP Association

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Dr Laura Ribeiro
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In cooperation with

QP Association

The Responsible Person for Good Distribution Practices (GDP)

Live Online Training on 30/31 March 2022

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

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. 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

This Live Online Training 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

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

Programme Day 1 - 30 March 2022

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

Roles and Responsibilities of the Responsible Person

- Qualifications requirements for RPs
- Duties and delegation
- How to discharge your duties
- What the Responsible Person (RP) needs to know about batch release

Experiences from GMDP Inspections

- Inspections of the competent authorities
- Typical GDP inspection findings

Management of Export and Import

- 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

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

GDP Audits

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

Participants' comments of March 2021 Live Online Training:

"I received a lot of useful information and advises of the lecturers. They were all very well prepared."
Eva Hace, Vitamed d.o.o., Slovenia

Programme Day 2 - 31 March 2022

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

- Responsible Person vs. Qualified Person
- GDP vs. GMP
- Product finishing activities
- Product diversions
- Handling of returned and damaged goods
- Complaint Handling

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

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
- What is available and how to implement

Question & Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

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: www.good-distribution-practice-group.org.

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

The Responsible Person for Good Distribution Practices (GDP), Live Online Training on 30/31 March 2022

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 %
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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). 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 of the Live Online Training

Wednesday, 30 March 2022, 09:00 h– 17:15 h
Thursday, 31 March 2022, 09:00 h – 16:15 h
All times mentioned are CEST.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

European GDP Association Members EUR 1,590.-
ECA and European QP Association Members EUR 1,590.-
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.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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