



Speakers



Alfred Hunt
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GMP/GDP Inspector



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The Responsible Person for Good Distribution Practices (GDP)

17/18 April 2024 | Hamburg, 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

In cooperation with



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

Roles and Responsibilities of the Responsible Person

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

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

Management of Export and Import

- Annex 21: Importation of medicinal products
- What does batch release mean?
- Export and import to and from UK

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.

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

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 security
- What is available and how to implement



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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17/18 April 2024, Hamburg, Germany

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date

Wednesday, 17 April 2024, 09:00 h – 18:00 h
(Registration and coffee 08:30 h – 09:00 h)

Thursday, 18 April 2024, 08:30 h – 15:30 h

Venue

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone +49 40 22 63 62 0
Email hamburg@barcelo.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 message. Or you register online at www.gmp-compliance.org.

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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