ECA ACADEMY

Comply with the new EU GDP Guideline

The Responsible Person for Good Distribution Practices (GDP)

Speakers:

Dr Afshin Hosseiny
Chair of the ECA Expert Working Group on GDP, Tabriz Consulting

Dr Martin Egger
Pharmaserv

Dr Daniel Müller
GMP/GDP Inspector

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

in cooperation with

QP ASSOCIATION

20-21 May 2015, Lisbon, Portugal

Highlights

- The New EU GDP Guideline
- Role of the RP in Batch Release
- Roles and responsibilities of the Responsible Person
- GMP/GDP Inspections
- Control temperature distribution
- Track & Trace
- Case Study: Management of a GMP warehouse and distribution of medicinal products with a 3PL-Approach
- GDP Audits
- Roles and Responsibilities of a RP and a QP in a Warehouse and Distribution environment
- How to manage 3PL service providers

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

The Responsible Person for Good Distribution Practices (GDP)

20-21 May 2015, Lisbon, Portugal

Objectives

Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) are closely linked. A new GDP Guideline published by the European Commission will bring comprehensive changes for everyone involved in the distribution of Medicinal Products.

The enhanced role of the Responsible Person for GDP will be highlighted at this event. The specific responsibilities and tasks of the Responsible Person will be discussed as well as the close link between QA and the QP of the Medicinal Product Manufacturer.

Background

In 2013, the European Commission's Directorate General for Health and Consumer Policy (DG SANCO) published the new 'Guideline on Good Distribution Practice of Medicinal Products for Human Use'. Through its GMP/GDP Inspectors Working Group the European Medicine Agency worked on the revision of the guideline which was first published in 1994.

The guideline was 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" defines tasks and responsibilities of the Responsible Person are defined. This Responsible Person should be continuously contactable. General requirements like organisational chart, job descriptions and training requirements are new or outlined in much more detail.

Target Group

The Training Course is of particular interest to management and personnel from Pharmaceutical Companies as well as from Distributors and Service Providers involved in wholesale distribution of medicinal products for human use.

Moderator

This training course will be moderated by Dr Afshin Hosseiny

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

The New EU GDP Guideline

- The counterfeit directive and pharma supply chain overview
- New/additional requirements
- Regulatory expectation for implementation
- Inspection approach

View of a European GMP/GDP Inspector

Role of the RP in batch release

- What does Batch Release mean to a Responsible Person?
- Responsible Person (RP) vs. Qualified Person (QP) role in batch release
- Basic requirements for the role of Responsible Person (RP) in batch release

Roles and responsibilities of the Responsible Person

- Qualifications requirements for RP
- Duties of a RP
- How to discharge your duties

GMP/GDP Inspections

- GDP Inspections
- Frequent Findings
- Expectations with regard to the Responsible Person

View of a European GMP/GDP Inspector

Track and Trace

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

Control temperature distribution

- How to manage cold chain products
- How to manage 15 – 25°C requirements
- Temperature monitoring or control – what is the best option for the product?

GDP Audits

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

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

The roles and responsibilities of wholesalers

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

Roles and responsibilities of an RP and a QP in a warehouse and distribution environment where value added logistic activities, like re-labelling, etc. take place

- Responsible Person/Qualified Person
- Pharmaceutical versus Nutritional products
- Good Distribution/Manufacturing Practice
- Product Finishing activities
- Product Diversions
- Product Action, like QA holds
- Handling of Returned and Damaged goods
- Complaint Handling

How to manage 3PL service providers

- Selection process
- Approval process
- Contracts and monitoring

Speakers

DR AFSHIN HOSSEINY,
GDP WORKING GROUP
Afshin Hosseiny is Chair of the ECA Working Group who is currently preparing a guidance document on GDP. He is also Member of the ECA Advisory Group 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 MARTIN EGGER,
PHARMASERV, GERMANY
Martin Egger joined Pharmaserv in 2002 as the Head of Quality Management and was responsible until 2008. Since 2005, he additionally has been in charge of Logistics at Pharmaserv.

DR DANIEL MÜLLER,
GMP/GDP INSPECTORATE LOCAL GOVERNMENT, GERMANY
Daniel Müller started working in the pharmaceutical industry in 1998. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate in Tübingen.

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.

About ECA

The European Compliance Academy (ECA) was founded on the 1st of January 1999 as an independent membership association and is today the leading European association with regard to pharmaceutical Quality Assurance and GMP/GDP compliance. Close to 4.000 members from all over Europe and abroad represent more than 60 countries.

The ECA has initiated several working groups. Among others the Good Distribution Practice Group which was founded in March 2013. 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. Membership is available at no costs at http://www.good-distribution-practice-group.org

About the European QP Association

The European Qualified Person (QP) Association was founded on 7 July 2006 by the European Compliance Academy's (ECA) Advisory Board Members. With this unique association the ECA wants to provide QPs in Europe with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach.

More information about the QP Association and a membership application form are available at www.qp-association.eu.

ECA Certified GDP Compliance Manager

The European Commission has published the revised EU Good Distribution Practice (GDP) Guideline in March 2013. The completely revised document contains comprehensive requirements for all stakeholders involved such as logistic service providers, wholesalers, storage facilities and for the manufacturer of the medicinal products. Chapter 2 of the EU GDP Guideline defines that Personnel involved in GDP activities should "receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme." Furthermore the GDP Guide states that "a record of all training should be kept, and the effectiveness of training should be periodically assessed and documented."

The certification programme of the ECA Academy aims to provide the necessary knowledge for personnel involved in GDP activities.


Mr John Smith
ECA Certified
GDP Compliance Manager

Courses and Conferences acknowledged
To receive the certificate, the applicant must attend two training courses. After attending the second course, the applicant can pass an exam. If the applicant passes the GDP exam he/she obtains the certificate "ECA Certified GDP Manager"

- The Responsible Person for GDP
- GMP meets GDP
- GDP – how to get you there
- Further optional courses will be offered in future

Please find the current dates for the above mentioned events at www.gmp-certification.org

Lufthansa Mobility Partner

Special offer with Lufthansa – up to 20% discounted travel for all ECA Events Attendees

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming you at one of our next events – and we already wish you a pleasant flight!

Conference Folder

You cannot take part in this event? Just order the documentation at the price of € 380.- + VAT+ postage and packing at www.gmp-comliance.org.
Please note: In order to ensure that the documentation is complete, the conference folder will not be available until two weeks after the event.

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, 20 May 2015, 09:00 h– 17:30h
(Registration and coffee 08:30 h – 09:00 h)
Thursday, 21 May 2015, 09:00 h – 16:00 h

Venue
Lisbon Marriott Hotel
Avenida dos Combatentes 45
Lisbon, 1600-042
Portugal
Phone +351 21 7235400
Fax +351 21 7264281

Accomodation
CONCEPT HEIDELBERG has reserved a limited numger 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 and European 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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info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Oliver Schmidt (Operations Director) at
+49-62 21/84 44 23, or per e-mail at
schmidt@concept-heidelberg.de.

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

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

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

+49 6221 84 44 34

Registration form (please complete in full)

The Responsible Person for Good Distribution Practices (GDP)
20-21 May 2015, Lisbon, Portugal

☐ 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 HEIDELBERGwill 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).

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.