ECA
European Compliance 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

Checklist
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

12-13 December 2013, Heidelberg, Germany

Highlights

- The New EU GDP Guideline
- Impact of the new GDP regulations on industry
- 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

in cooperation with

QP Association

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

The Responsible Person for Good Distribution Practices (GDP)

12-13 December 2013, Heidelberg, Germany

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

On 7 March 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

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.

Programme

The New EU GDP Guideline

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

Impact of the New GDP regulations on Industry

- What are the challenges for the industry in implementing the new requirements
- Potential issues with implementation
- How best to proceed and become compliant

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,
TABRIZ CONSULTING, U.K.
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 DANIEL MÜLLER,
GMP 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.

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.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 200 EUR discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**.

About the European QP Association

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.

GMP Certification Programme

This course is recognised within the GMP Certification Programme for the module "ECA Certified QA Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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
Thursday, 12 December 2013, 09:00 h– 17:00 h
(Registration and coffee 08:30 h – 09:00 h)
Friday, 13 December 2013, 09:00 h – 16:00 h

Venue
Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49 (0)6221 908 0
Fax +49 (0)6221 908 660

Accomodation
CONCEPT HEIDELBERG has reserved a limited numger of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.
Room Rate: € 125,00 including breakfast

Conference fees
ECA and European QP Association Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
Non-Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- per delegate plus VAT
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
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
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.:
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
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Registration form (please complete in full)

The Responsible Person for Good Distribution Practices (GDP)
12-13 December 2013, Heidelberg, 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 of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**