ECA Academy
Your GMP/GDP Information Source

GDP for APIs

Meet the requirements of the Guidelines on GDP for APIs

SPEAKERS:

Fred Bauer
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Dr Rainer Gnibl
GMP Inspectorate, Germany

Dr Martin Melzer
Chemgineering Business Design, Germany

Dr Bernd Renger
Bernd Renger Consulting, Germany

4 – 5 December 2018, Berlin, Germany

PROGRAMME:

- EU Legislation on distribution of APIs
- Quality System Elements for API Distributors
- API distribution and Application of Risk Management Principles
- The role of agents and traders within the supply chain
- Risk analysis of transportation routes
- Implementation of GDP – Case study
- Authority's expe,ctations
- Conducting GDP audits at API suppliers' sites

This education 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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Objectives

This course is intended to provide guidance on the provisions laid down in the EU GDP guidelines for APIs. You will get to know the key aspects of these guidelines and you will learn about

- What has to be considered regarding GDP-compliant storage and transportation of APIs
- How the exchange of information between agents, traders and pharmaceutical manufacturers should work
- Which risk assessment approaches are suitable and should be applied
- What authorities expect regarding GDP-compliant storage, transportation and distribution of APIs

Background

In March 2015, the "Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use" were published in the Official Journal of the European Union.

Since September 2015, the provisions of these Guidelines have been obligatory. The driving force behind these Guidelines is the combat against falsified drug substances and drug products. It is intended to control the entire supply chain and thus to mitigate the risk associated with complex distribution pathways. From now on, distributors are required e.g. to have a complete deviation management in place and to maintain a change management system as well as a CAPA system based on risk assessments. Moreover, a GMP-compliant complaint and recall management has to be established and a well trained staff has to ensure that all the requirements of the guidelines are met. In several sections of the Guidelines, it is pointed out that a thorough training of the employees is important.

Target Audience

This education course is designed for all persons from companies involved in the distribution and supply of pharmaceutical products. The course will be of interest to managers and executives from the pharmaceutical industry, API manufacturers as well as distributors and traders.

Programme

EU Legislation on Distribution of APIs

- Directive 2110/83/EC and 2011/62/EU (Falsified Medicines Directive)
  - Which authorizations/registrations are required?
  - Supervisions and sanctions
- EU GDP Guideline for APIs (Overview)
- EU GMP Guideline Part II
- Annex 15
- Annex 16

Quality System Elements for API Distributors

- Manufacture, Importation, Distribution – what does your company do?
- Elements of the Quality System for API Distributors
- Technical Standards for Distribution of API

Application of Risk Management Principles in Planning and Surveillance of the API Distribution

- Responsibilities, INCOTERMS, QA-Agreements
- Key elements in planning and monitoring distribution routes
- Risk-based qualification of distribution routes/ risk mitigation activities

Workshop
„Risk Analysis of Transportation Routes – Practical Exercise"

In this workshop participants will work on specific cases regarding transportation of APIs by performing risk assessments for different scenarios.

GDP and the role of agents and traders within the supply chain

- Types of intermediates
- Key points of an agent's quality system
- Communication and exchange of information with the pharmaceutical manufacturer
- Traceability of APIs and how to document it according to the new GDP guidelines
- Key aspects of quality agreements

Conducting GDP audits at API suppliers' sites – key points to be considered

- Preparing a GDP audit
- Key factors of success
- GDP audits at suppliers' sites in Far East – what has to be considered?
- Frequent findings in audits

Implementation of GDP at an API manufacturer's site – case study

Authority's expectations and other API GDP topics

- Hot spots from EU GDP Guideline for APIs
- Outsourcing of GDP activities
- API import: Written Confirmation
- QP Declaration
- GDP necessary or not?

Social Event

In the evening of the first course day, 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

Fred Bauer
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Fred Bauer started his professional career as Corporate Auditor and Quality Manager at Milupa. Since 2007 he is Senior Lead and Corporate Auditor in the Global Quality Services department of Boehringer Ingelheim in Germany.

Dr Rainer Gnibl
GMP Inspector for EMA and local Government, Germany
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University of Erlangen-Nürnberg.

Dr Martin Melzer
Chemgineering Business Design GmbH, Germany
Dr Martin Melzer is Senior Consultant GMP Compliance. Before that he was GMP -Inspector in a German Field Inspectorate in Hannover. During that time he was representing the German inspectorates in EMA and PIC/S Working Groups for the preparation of the new GDP-Guidelines.

Dr Bernd Renger
Bernd Renger Consulting, Germany
Dr Bernd Renger started at Hoechst AG. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna and Vetter Pharma-Fertigung. He was a member of the European Compliance Academy (ECA) Advisory Board and is Immediate Past Chair of the European QP Association.

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

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

Reservation Form (Please complete in full)

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Title, first name, surname

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Important: Please indicate your company's VAT ID Number **Purchase Order No, if applicable**

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GERMANY

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1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date

Tuesday, 4 December 2018, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 5 December 2018, 9.00 – 12.15 h

Venue

Titanic Hotel Chaussee Berlin
Chaussee Straße 30
10115 Berlin, Germany
Phone +49 30 311 6858-0
Email info.tcb@titanic-hotels.de

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA 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 first day, business lunch on second day and all refreshments.

Accommodation

CONCEPT 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 language

The official conference language will be English.

Organisation and Contact

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

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