Meet the requirements of the new Guidelines on GDP for APIs

How to implement the new GDP requirements for APIs

7 – 8 April 2016, Berlin, Germany

SPEAKERS:

Rainer Gnibl
EU-GMP Inspector, Local Government

Karl Metzger
gmPlan, Germany

Volkmar Schimming
VS Consulting, Germany

PROGRAMME:

- GDP compliant storage and transportation of APIs
- The role of agents and traders within the supply chain
- Traceability of APIs and how to document it
- Risk assessment approaches regarding storage and transportation of APIs
- Authority's expectations
- Conducting GDP audits at API suppliers' sites
- Implementation of GDP at API manufacturers

ECA ACADEMY

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 new 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

GDP compliant storage and transportation of APIs

- Which specific requirements are to be implemented?
- Risk-based approach for transportation qualification
- Supplier qualification

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

Risk assessment regarding storage and transportation of APIs

- Why is it important to perform risk assessments
- Risk assessment approaches
- What you should avoid when performing a risk assessment

Workshop „Quality risk management in API distribution"

In this workshop participants will work on specific cases regarding storage and transportation of APIs by performing risk assessments for different scenarios and by defining corrective and preventive actions.

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?

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 API manufacturers – practical experience

- Identifying requirements and gaps
- Risk assessments
- Qualification of facilities, equipment and service providers
- Contractual arrangements
- Frequent problems and pitfalls

Speakers

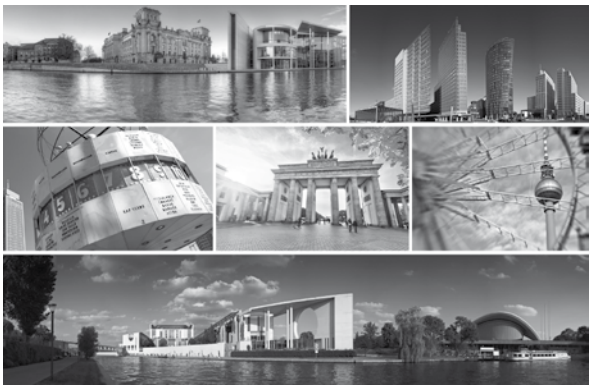
Dr Rainer Gnibl
GMP-Inspector for EMA and local Government, Germany
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer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

Karl Metzger,
gmPlan GmbH, Germany
Mr Metzger is Managing Partner of gmPlan GmbH. He is APIC certified ICH Q7 Auditor and has more than 15 years experience in global auditing of chemical, biotechnological and pharmaceutical manufacturers. Previous to his current position, he held appointments with BASF Pharma, Concept Heidelberg, Euroengineering and finally with Welding as Management responsible for the company's integrated Management System and deputy QP for APIs. Furthermore, Karl was vice chairman of FECC's 'Good Trade and Distribution Committee'.

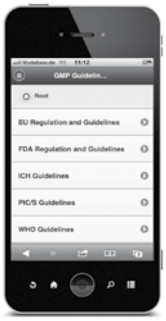
Dr. Volkmar Schimming,
VS Consulting, Germany
Dr Schimming is freelance consultant and APIC Certified ICH Q7 Auditor. Before he started with his own business he was Quality Manager and Corporate Auditor at Alfred E. Tiefenbacher in Hamburg. Before that he worked at Merckle/Ratiopharm, where he held the same positions.

Social Event

On 7 April, 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.



Use the GMP App at no costs!



The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Date

Thursday, 7 April 2016, 9.30 – 18.00 h
(Registration and coffee 9.00 – 9.30 h)
Friday, 8 April 2016, 8.30 – 13.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 21 27 – 0
Fax +49 (0)30 21 27 – 799

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 both days and all refreshments.
VAT is reclaimable.

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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