ECA Academy
Your GMP/GDP Information Source

Speakers

Marieke van Dalen
Global Regulatory Specialist
Aspen Oss, The Netherlands

Francois Vandeweyer
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Freelance Consultant, Belgium

China GMP and Registration of APIs

Live Online Training on 07 December 2021 from 13:30 - 16:30 h CET

Highlights

- Chinese GMP – General Topics
- Chinese Drug GMP – On Site Inspection Focus Points
- Chinese GMP Annexes with Focus on Biologicals
- Chinese Quality Management and Equipment Strategy to Compete with the West
- Health Authorities in China
- The Chinese Drug Master File System
- Bundled Review
- Specifics for the Chinese API Drug Master File
- Common Deficiencies

Objectives / Background

In a relatively short period of time, China has become the leading global supplier of APIs in terms of volume. China is the world's leading producer and exporter of active pharmaceutical ingredients (APIs) by volume, accounting for 20% of total global API output. According to WHO China produces over 2000 APIs, with annual production capacity exceeding 2 million tons.[1]

China first introduced GMP in 1988, and the latest GMP regulations are the 2010 revised edition of Good Manufacturing Practice for Pharmaceutical Products (with effect from 1 March 2011). While CFDA is responsible for developing regulations and standards for GMP, it is mainly provincial and local authorities that are responsible for inspection and certification.[1]

The understanding of GMP and Registration Procedures for APIs are thus important to know. This Live Online Training provides an overview of the legal requirements regarding APIs in China.

[1]Source: WHO Report https://www.who.int/phi/publications/2081China020517.pdf?ua=1

Target Audience

This online training has been developed for all who are dealing with API Sourcing, Manufacturing, Quality Assurance and Regulatory Affairs.

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Programme

API Registrations in China
Marieke van Dalen

- Health authorities in China
- The Chinese Drug Master File system
- Bundled review
- Specifics for the Chinese API Drug Master File
- Common deficiencies

China's Current View on Drug GMP
Francois Vandeweyer

- Chinese GMP – general topics
- Chinese Drug GMP – on site inspection focus points
- Chinese GMP annexes with focus on Biologicals
- Chinese quality management and equipment strategy to compete with the West

Speakers

Marieke van Dalen
Global Regulatory Specialist
Aspen Oss, The Netherlands

Ms van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with almost 35 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in the Japantask force, Emerging markets task force and the Japan task force. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, ICH etc.

Francois Vandeweyer
formerly Janssen Pharmaceuticals
Freelance Consultant,
VDWcGMP Consultancy, Belgium

Mr Vandeweyer joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit. Starting from 1995 he joined the QA department. Several Senior Manager responsibilities. 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019 he is a freelance consultant.

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GERMANY

Reservation Form (Please complete in full)

China GMP and Registration of APIs, Live Online Training on 07 December 2021, 13:30 h – 16:30 h

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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Date of the Live Online Training

Tuesday, 07 December 2021,
13:30 h – 16:30 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 490
APIC Members € 540
Non-ECA Members € 590
EU GMP Inspectorates € 490
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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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