ECA Academy
Your GMP/GDP Information Source

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 over 35 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she actively participates and/or (co-)chairs in a number of task forces. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI 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.

Ellen Zandvoort
Aspen Oss, Customer & Regulatory Support Officer, The Netherlands

Ms Zandvoort has a background in Biochemistry and more fundamental research at the University of Groningen in The Netherlands. After leaving the lab behind she entered the pharmaceutical industry. She gained experience with diverse aspects of the industry; from human to animal health, from analytical development and dossier writing to labeling and packaging. At Aspen she's involved in the registration of APIs in many countries worldwide and providing regulatory support to customers for registration of their drug products, with a focus on the regulatory requirements, including QC testing, in China.

China GMP and Registration of APIs

Live Online Training on 02 November 2023 from 13:00 - 16:30 h CET

Send us your questions related to China GMP and registration of APIs!

Highlights

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

Programme

Objectives / Background

China first introduced GMP in 1988, and since then the GMP regulations are revised and updated several times. Most of the existing GMP requirements and guidance documents were updated by the so called National Medical Products Administration (NMPA), China's new Drug Regulatory Authority since 2018, and replace former guidelines published by the CFDA (China Food and Drug Administration). In 2021, the NMPA published a new guideline in regard on the inspection system and GMP certificates, which influenced the certification procedure tremendously.

Also in 2021, the NMPA issued new guidelines with information relevant for changes in registrations of drug products, for administrative and for technical processes. To keep track with the mandatory guidance documents of the regulatory authority as well as the understanding of the GMP requirements and registration procedures for APIs are the prerequisites to register APIs in China.

This Live Online Training provides an overview of the regulatory and GMP requirements regarding APIs in China.

Target Audience

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

Take advantage of the experiences of our speakers and send us your **questions related to China GMP and registration of APIs** in China prior to the Live Online Training. Your questions are welcome and will be answered as comprehensively as possible by the experts during the Q&A sessions.

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

QC Testing: a China Specific Requirement
Ellen Zandvoort

- The procedure for QC testing
- Common observed hurdles with QC testing

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 and the new Annex 13 for IMPs
- Chinese quality management and equipment strategy to compete with the West

Date of the Live Online Training
Thursday, 02 November 2023, 13:00 h – 16:30 h CET

Technical Requirements
We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 590
The fee is payable in advance after receipt of invoice.

Registration
Please 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.

Ordering Recordings
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact
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