ECA Academy
Your GMP/GDP Information Source

Speakers

Marieke van Dalen
formerly Aspen Oss,
Freelance Consultant,
The Netherlands

Ms van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. She has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands, as Global Regulatory Specialist. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.

Beatrice A. Harder Engelhard
Siegfried AG,
Switzerland, Head of Regulatory Affairs

Ms Harder is a Pharmacist with a PhD in in Natural Sciences from ETH in Zurich. She worked as a Quality Reviewer at Regulatory Authorities, and she has more than 20 years of experience in the pharmaceutical industry in Analytical R&D as well as in Regulatory Affairs, covering both drug products and APIs. Since December 2024, she is Head of Regulatory Affairs at Siegfried AG in Switzerland for drug substances globally.

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.

Yujia Wang
Siegfried AG,
Switzerland
Regulatory Affairs

Ms Wang studied Organic Chemistry at Tianjin University in China and did research for her PhD at the University of Zurich. She joined Regulatory Affairs at Siegfried AG in Switzerland in 2022, where she applies her scientific expertise to regulatory challenges for multiple countries worldwide. She is particularly involved in the API registration process in China, navigating complex regulatory landscapes to ensure market access and compliance.

China GMP and Registration of APIs

Live Online Training on 23 September 2025 (13:00 – 17:00 h CEST)

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

Key Considerations for QC API Sample Testing in China
Beatrice A. Harder Engelhard | Yujia Wang

- Process of API sample testing in China
- Case studies for sample 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
Tuesday, 23 September 2025, 13:00 – 17:00 h CEST

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 € 690
APIC Members € 740
Non-ECA Members € 790
EU GMP Inspectorates € 690
The fee is payable in advance after receipt of invoice.

Registration
Please register online at **www.gmp-compliance.org under the number 21944.**

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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