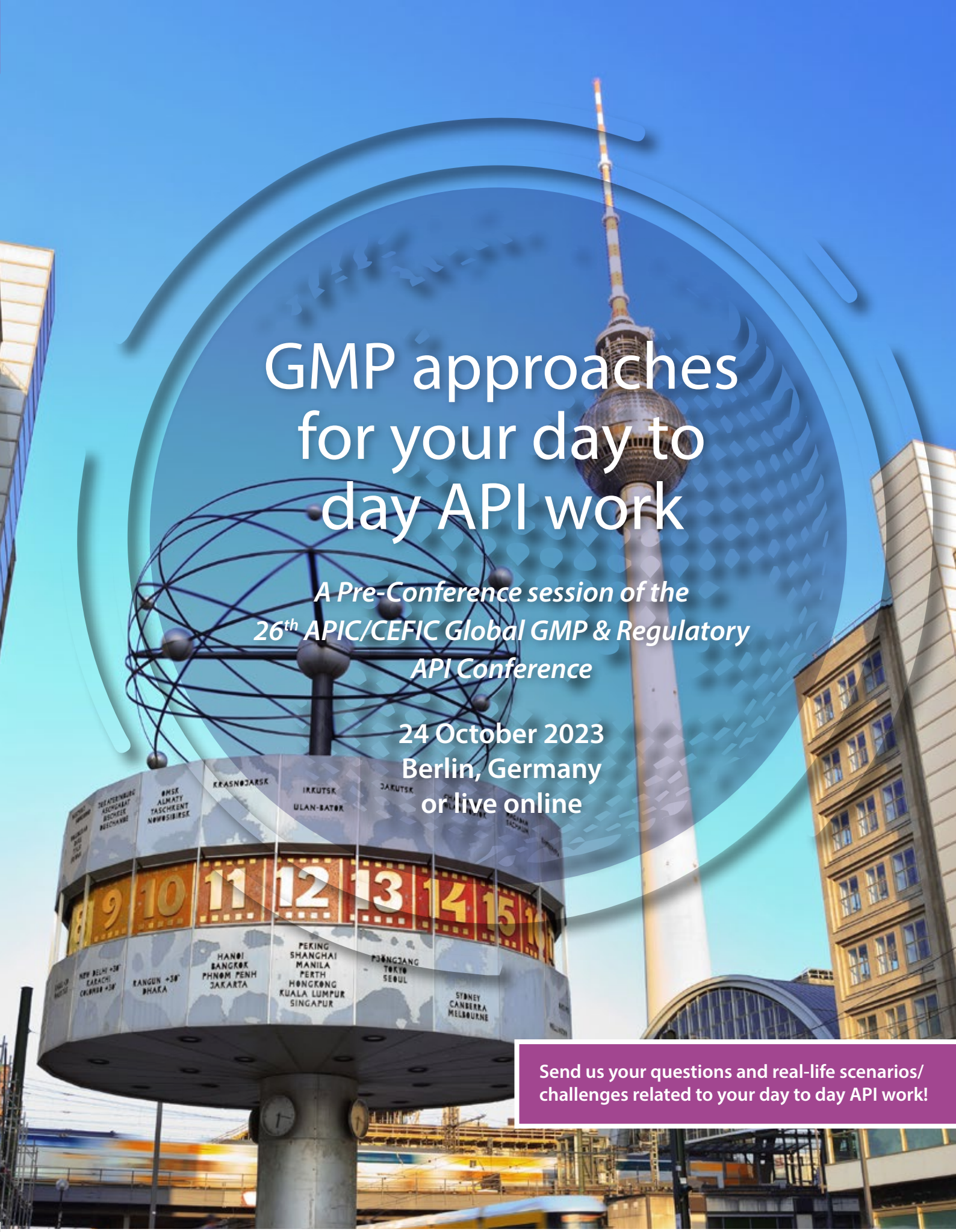

GMP approaches for your day to day API work

A Pre-Conference session of the 26th APIC/CEFIC Global GMP & Regulatory API Conference

24 October 2023
Berlin, Germany
or live online

Send us your questions and real-life scenarios/ challenges related to your day to day API work!

APIC ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

a sector group of cefic

In cooperation with ECA Academy *Your GMP/GDP Information Source*

Overview

Highlights

Practical assistance and experiences for your daily API work – learn from our speakers the latest GMP approaches in the field of:

- Handling foreign particles in APIs and Excipients
- Setting up Stability Studies for APIs
- Auditing Starting Material Manufacturers
- Designing a risk-based environmental monitoring for non-sterile API manufacturing
- Early development stages of APIs

Objectives

This Pre-Conference session provides an overview of the GMP requirements and approaches for the manufacture of APIs based on the experiences of our speakers as well as APIC's guidance documents. During interactive sessions you will get to know:

- Which GMP aspects have to be re-considered during early development stages
- What are the practical consequences for setting up stability studies and handling of foreign particles in APIs
- What has to be taken into account when preparing and conducting a Starting Material Manufacturers' audit

Furthermore, you will have the opportunity to reach clarification on ambiguous issues by bringing your questions up for discussion.

This Pre-Conference session ideally complements the following 26th APIC/CEFIC Global GMP & Regulatory API Conference.

Background

The API world is changing rapidly. Since more than 20 years APIC establishes and prepares Guides and Guidance documents to support the daily API work. Regularly, these documents are revised and updated by the respective Task Forces to reflect the current requirements, developments and experiences gained in the manufacturer and registration of APIs. Comments, questions and remarks by the API industry are always welcome and considered.

Five hot topics out of the long list of topics covered by the guidance documents are selected and will be considered and explained during the Pre-Conference Session. Besides the discussion of e.g. the APIC Guide for auditing registered starting material manufacturers the speakers will share their approaches, experiences and best practices on these API related topics.

Target Audience

This Pre-Conference session is designed for all persons involved in the manufacture of APIs especially for persons from production, quality control, quality assurance, technical and regulatory affairs departments. We are also addressing interested parties from the pharmaceutical industry and GMP inspectorates.

Programme

GMP challenges at early development stages

- GMP in API development - Regulatory Guidance and papers
- Evolution of GMP from development to commercial stage
- Risk Analysis to evaluate the impact of producing APIs at early development stages on your quality system

Practical way forward in handling foreign particles in APIs and Excipients

- Definitions and examples
- Expectations of customers and regulators
- Projects and guidelines
- Way forward and setting acceptance criteria
- Control and improvement strategies

How to audit Starting Material Manufacturers (incl. Case Study)

- Auditing registered starting material manufacturers – an introduction
  - Recent trends
  - Regulatory Guidance and papers
  - Solutions: Risk analysis & The APIC Guide for auditing registered starting material manufacturers
- The APIC Guide for auditing registered starting material manufacturers – Key Aspects and highlights
- Case studies

Take advantage of the **experiences** of our speakers and send us your questions and real-life scenarios/challenges related to your day to day API work prior to the pre-conference session. Your questions and examples are welcome and will be answered as comprehensively as possible by the experts during the Q&A sessions and exchange sessions.

Risk-based environmental monitoring approach in non-sterile API manufacturing

- Designing a risk-based framework
- Structured approach around:
  - Facility design
  - Facility operations
  - Environmental monitoring
- Risk reduction measures

Stability of APIs: retest date vs expiry date

- Setting up stability studies
- Drawing conclusions: retest date vs expiry date

Speakers

Marieke van Dalen
Aspen Oss B.V., 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
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.

Alejandro Sureda Salvadó
Farmhispania Group, Spain

Mr Sureda Salvadó is organic chemist with more than 22 years experience in the API manufacturing in different positions (Production, Analytical Development Technician, Quality Control Manager and Quality Assurance Manager) in Farmhispania, S.A., Menadiona, Kern Pharma and Farmhispania Group. In his current position as Industrial Quality Manager and GMP Compliance Auditor he is responsible for Auditing of suppliers (Key Raw Materials, Registered Starting Materials, Intermediates, Contracted Services), GMP Training, Data Integrity upgrade, Validation and Qualification activities and supporting the Industrial Area (Production, Engineering, Maintenance, EHS) on Deviation investigations, CAPAs and Change Control.

Important Information
The presentations will be made available to you prior to the Pre-Conference session as PDF files. After the event, you will automatically receive your certificate of participation.

Date Pre-Conference session
Tuesday, 24 October 2023, 09.30 - 17.45 h
(Registration and coffee 09.00 - 09.30 h – for taking part onsite in Berlin only)
All times mentioned are CEST.

Venue – for taking part onsite in Berlin only
DoubleTree by Hilton Berlin Ku'Damm
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone: +49 (0) 30/21 27 0
info@doubletreeberlinkudamm.com

Technical Requirements
We will stream the pre-conference and recommend using the latest version of Chrome, Firefox, Edge or Safari to participate. Technical instruction for the livestream will be provided shortly prior to the conference.

Fee
EUR 990.- per delegate plus VAT.

A special fee of 890,- Euro is granted to participants who also register for the 26th APIC/CEFIC Global GMP & Regulatory API Conference.

The registration fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation – for taking part onsite in Berlin only
CONCEPT HEIDELBERG 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.

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

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Ms Anne Günster (Operations Director) at
+49 (0) 6221/84 44 50, or at
guenster@concept-heidelberg.de

For questions regarding organisation etc.:
Ms Sarah Schmidt (Organisation Manager) at
+ 49 (0)6221/84 44 16, or at
s.schmidt@concept-heidelberg.de

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

_____

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

☐ **GMP approaches for your day to day API work,** 24 October 2023 in Berlin or live online

☐ **I also register for the 26th Global GMP & Regulatory API Conference,** 25-26 October 2023 in Berlin or live online

Please choose 5 out of 10 parallel sessions (one choice in Session A, B, C, D and one in Session E):
Parallel Session A
☐ Session 1: API stability studies
☐ Session 2: Navigating the complexities of sterile injectable submissions
Parallel Session B
☐ Session 3: How are health authorities inspections evolving in the world of APIs?
☐ Session 4: ICH M7 – Risk Assessment from API perspective
Parallel Session C
☐ Session 5: How did COVID affect our API industry?
☐ Session 6: Quality Agreements: APIC Guidance and Templates
Parallel Session D
☐ Session 7: Revision of the ICH M4Q guideline: A Regulator's perspective
☐ Session 8: The case for Quality Metrics
Parallel Session E
☐ Session 9: Digitalization in API
☐ Session 10: Recent breakthroughs in ANVISA API requirements and Emerging Markets novelties

I will
☐ **participate on-site in Berlin.**
☐ **participate live online.**
☐ **decide later.**

☐ Mr ☐ Ms Title _____

First name, surname

Company o APIC Member o ECA Member o Inspectorate

Department

Important: Please indicate your company's VAT ID Number P.O. Number if applicable

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.
CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.
Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

ri/16032023