27th APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

23 - 24 October 2024

in Vienna, Austria

or live online

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- Sustainable API companies
- Update from FDA, EMA and EDQM
- 10 interactive Parallel Sessions with hot topics of the API Industry

APIC ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

a sector group of cefic

In cooperation with ECA Academy Your GMP/GDP Information Source

Objectives of the Conference

The APIC/CEFIC Global GMP & Regulatory API Conference is Europe's leading API event. Many major stakeholders from Authorities and the Industry are joining this Conference each year. Speakers from EDQM, EMA, FDA, from Industry and Industry Associations will discuss the latest developments in the field of GMP and Regulatory Compliance.

The APIC Steering Committee has decided once again to offer this year's APIC/CEFIC Global GMP & Regulatory API Conference as a hybrid event. The lectures will be held live in Vienna and streamed online so that you may choose freely how you wish to participate.

During the Conference updates from recent European and global authorities' initiatives, activities and interpretations like EDQM's support for initiatives to handle shortages, the update from EMA's Quality Working Party and FDA's expectations how to implement the Data Integrity requirements are provided. Hear from industry speakers sharing their approaches and best practices on all API related topics.

The Parallel Sessions are no workshops – they are practically oriented and supposed to support you in your daily work.

Wednesday | 23 October

The first day of the Conference provides, besides the first set of Parallel Sessions with various GMP and RA topics, updates about EDQM's activities, the EU Critical Medicines Act and the latest status of PFAS (per- and polyfluoroalkyl substances).

Update from the EMA Quality Working Party

Monika Mayr, EMA

- Recent reorganisation of the QWP (and reasons behind it)
- Current priorities and the workplan of the QWP
- Ongoing guidance work, including on control of nitrosamines and the revision of the guideline on chemistry of active substances

CEP 2.0 - Perspective of MA Holder

Karina Boszko, Polpharma API

- Pros and Cons for FDF manufacturer
- Challenges in using CEP 2.0
- Cooperation with EDQM regarding CEP 2.0

PFAS - From hero to zero

Erik Kateman, Aspen Oss

- Introduction
- Properties
- Uses
- Restriction proposal
- Challenges

1	**Session A**	2

How does the EU pharmaceutical package impact the EU variation classification and procedural guidance's?

Hilde Vanneste, Janssen Pharmaceutica

- What initiatives has the EU pharmaceutical package triggered to make API's for medicines more available, accessible and affordable?
- How can API industry improve, innovate and supply qualitative and compliant API's in a worldwide environment within this EU pharmaceutical package ?
- What next steps would API industry like to see regarding the EC variation regulation 1234/2008 and corresponding guidelines evolve anno 2024?

Differences in the focus of inspections by non-EU authorities

Stéphanie Girard, SEQENS

- Main deficiencies observed in recent inspections
- Expectations from different regulators
- Examples of findings classified by quality systems

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

3 **Session B** 4

Global DMF challenges

Marieke van Dalen, MARA Consultancy

- The CTD: one file fits all?
- Regional differences
- New developments

Prevention of (Cross-)Contamination in Non-Sterile API Manufacturing Processes

Nagesh Samineni, Johnson & Johnson Private Limited

- Current key issues
- Detection and control procedures
- Establishing prevention Culture

The critical medicines act: an enabler for the open strategic autonomy of the EU pharmaceutical supply chain?

Maggie Saykali, Cefic

- Role of API producers in ensuring the resilience and security of supply of the European pharmaceutical supply chain and in responding to fluctuations in demand.
- Innovation as a key competitiveness enabler for EU manufacturers
- Current EU landscape: initiatives to support the pharmaceutical supply chain at EU and national level
- The EU Critical Medicines Act: the ultimate answer to Industry's needs?

Update from the EDQM

Hélène Bruguera, EDQM

- 60 years of contribution to public health protection
- Updates and roadmap of the Ph. Eur.
- Updates and roadmap for the CEP procedure
- How does EDQM support initiatives to handle shortages

Thursday | 24 October

The API world is changing rapidly. On the second day, the focus will be on the second set of Parallel Sessions about e.g. ICH M4Q(R2), Recycled raw materials in API manufacturing, API Registration in China, Process-Equipment-Related Leachables (PERLs) and the new guidance document of APIC about aspects of cleaning validation in API plants.

5 **Session C** 6

ICH M4Q(R2): designing the Common Technical Document for the future

Veronika Schwarz, Sandoz

Rudy Peeters, Janssen Pharmaceutica

- Making the Common Technical Document ready for new concepts, technologies and complex modalities
- Increasing the level of global harmonization for regulatory submissions
- Preparing regulatory submissions for Structured Product Quality Submissions (SPQS)
- Showing you how your future dossiers will look like

New APIC Guidance on aspects of cleaning validation in API plants

Simon Rieder, Siegfried

- Simplifying the calculation of cleaning limits with the toxicity approach
- Cleaning Validation Strategies: risk assessment, continuous production, cleaning validation life cycle

7 **Session D** 8

Microbiological Quality Control of APIs

Marcel Goverde, MGP Consulting

- How to comply with ICH Q7 for microbiological quality of APIs
- Acceptance Criteria and objectionable organisms for APIs
- What are "appropriate microbiological test" for API release testing?
- Reduction of API testing using ICH Q6

Recycled raw materials in API manufacturing process for a greater sustainability

Guillaume Muller, Siegfried Evionnaz

- Regulations and Guidelines associated
- Determine which process and raw materials are eligible to recycled materials
- Case study (Business benefits against quality restrictions)

API Registration in China: Recent Industry Experience

Fabian Schwarb, Siegfried

- Evolving Regulatory Framework
- Registration Procedures and Requirements
- Industry Experience and Case Studies

A new era in the assessment of Process-Equipment-Related Leachables (PERLs)

Wim Van Rossom, UCB Biopharma

- Scope of USP <665> and USP <1665> for pharmaceutical manufacturers
- Risk assessment approach under USP <665>/<1665>
- Guidance for extractables testing under USP <665>/<1665>
- E&L risk evaluation for manufacturing components in rest of the World

Development and regulatory challenges for Peptides

Srikanth Thallapally, Sandoz

Andreja Vuckic, Lek Pharmaceuticals

- Differences in regulatory requirements between US and Europe
- Need for setting guidelines for Impurities thresholds in ICH
- Life cycle management process and challenges
- Importance of DMF (API supplier) role in drug product approval

A sustainable API company: the long and winding road

Joris Gilberts, Aspen Oss

- Reduce resource usage in existing production processes
- Sustainable API synthetic routes
- Circularity in API production: reality or science-fiction?
- Sustainability is more: Social and Governance topics

Data Integrity Assurance: Have You Implemented Sustainable Practices and Controls?

Ruth Moore, US FDA

- ALCOA+ requirements and effective Data Governance.
- Risk Assessment for Data Criticality and Gap Analysis to Identify Vulnerabilities.
- Case Studies from recent Warning Letters to API Manufacturers that highlight violative practices persist despite numerous published guidance documents.

Social Event | 23 October

The social event has become a tradition and was well appreciated during the past conferences in well-known places. We will continue this tradition in Vienna and invite all participants and speakers to an entertaining evening outside the hotel followed by a dinner.

APIC
ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

About APIC

APIC's membership consists of companies from different pharmaceutical industry sectors, all involved in the manufacture of APIs. This provides an ideal basis for developing and communicating a balanced, holistic view on API-related regulations and guidelines. APIC's focus is on worldwide Quality, Good Manufacturing Practice (GMP) and Regulatory matters relating to APIs and Intermediates. Through the years APIC has developed into a high-profile industry association with an excellent, worldwide reputation.

Steering Committee

We would like to express our sincere gratitude to the members of the steering committee for developing the Conference:

Ilaria Duo, *Siegfried Evionnaz SA*
Rainer Fendt, *BASF*
Stéphanie Girard, *SEQENS*
Pieter van der Hoeven, *Cefic*
Sabina Jurca, *Sandoz*
Graça Mata, *Hovione FarmaCiencia SA*
Luisa Paulo, *Hovione*
Danny De Scheemaecker, *Pharmaron Manufacturing Services*
Anthony Storey, *Pfizer*
Hilde Vanneste, *Janssen Pharmaceutica*
Stefaan van de Velde, *Ajinomoto Bio-Pharma Services*
Vicky Waddington, *Sterling Pharma Solutions*
Karolien Verheyde, *Ajinomoto Bio-Pharma Services*

Anne Günster, *CONCEPT Heidelberg*
Oliver Schmidt, *CONCEPT Heidelberg*

Speakers

The following speakers will share their experiences at this year's Global GMP & Regulatory API Conference:

Karina Boszko
Polpharma API BU, Poland

Hélène Bruguera
EDQM, France

Marieke van Dalen
MARA Consultancy, The Netherlands

Joris Gilberts
Aspen Oss B.V., The Netherlands

Stéphanie Girard
SEQENS, France

Marcel Goverde
MGP Consulting GmbH, Switzerland

Erik Kateman
Aspen Oss B.V., The Netherlands

Monika Mayr
EMA, The Netherlands

Ruth Moore
US FDA

Guillaume Muller
Siegfried Evionnaz SA, Switzerland

Rudy Peeters
Janssen Pharmaceutica NV, Belgium

Simon Rieder
Siegfried AG, Switzerland

Nagesh Samineni
Johnson & Johnson Private Limited, India

Maggie Saykali
Cefic, Belgium

Fabian Schwarb
Siegfried AG, Switzerland

Veronika Schwarz
Sandoz GmbH, Austria

Srikanth Thallapally
Sandoz Private Limited, India

Wim Van Rossom
UCB Biopharma SRL, Belgium

Hilde Vanneste
Janssen Pharmaceutica NV, Belgium

Andreja Vuckic
Lek Pharmaceuticals d.d., a Sandoz company, Slovenia

APIC Industry Best Practice documents

APIC developed a number of guidances on GMP and Regulatory Affairs, e.g. "Guidance on aspects of cleaning validation in active pharmaceutical ingredient plants" or "How to do – Interpretation of ICH Q7 document & « Review form »".

All APIC guidance documents are available for free download on the APIC/CEFIC website: https://apic.cefic.org/publications/

Conference Dates
Wednesday, 23 October 2024, 09.00 - 17.30 h
Thursday, 24 October 2024, 09.00 - 16.30 h
All times mentioned are CEST.

Registration – for taking part onsite in Vienna only
Tuesday, 22 October 2024, 19.00 - 20.00 h or
Wednesday, 23 October 2024, 08.00 - 09.00 h

Venue – for taking part onsite in Vienna only
Austria Trend Parkhotel Schönbrunn
Hietzinger Hauptstr. 10-14
1130 Vienna, Austria
Phone: +43 (1) 878 04 0
parkhotel.schoenbrunn@austria-trend.at

Technical Requirements – for taking part online only
We will stream the 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.

Fees (per delegate plus VAT)
Book both conference days for the price of € 1,680.-.

For the APIC Pre-Conference Session "From theory to practice: implementing API process knowledge" a special fee of 990,- Euro (regular fee: 1090,- EUR) will be granted to participants who also register for the APIC Conference.

Discounts
APIC Members 10%,
ECA Members 5%,
Inspectorates 25%.

Please note that discounts cannot be combined!

Accommodation – for taking part onsite in Vienna only
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.

Registration
Via the attached reservation form, by e-mail or by fax message, or 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.

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

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69007 Heidelberg
Germany

27th Global GMP & Regulatory API Conference, 23-24 October 2024 in Vienna or live online

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

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: How does the EU pharmaceutical package impact the EU variation classification and procedural
☐ guidance's?
Session 2: Differences in the focus of inspections by non-EU authorities
Parallel Session B
☐ Session 3: Global DMF challenges
☐ Session 4: Prevention of (Cross-)Contamination in Non-Sterile API Manufacturing Processes
Parallel Session C
☐ Session 5: ICH M4Q(R2): designing the Common Technical Document for the future
☐ Session 6: New APIC Guidance on aspects of cleaning validation in API plants
Parallel Session D
☐ Session 7: Microbiological Quality Control of APIs
☐ Session 8: Recycled raw materials in API manufacturing process for a greater sustainability
Parallel Session E
☐ Session 9: API Registration in China: Recent Industry Experience
☐ Session 10: A new era in the assessment of Process-Equipment-Related Leachables (PERLs)

☐ **I also register for the Pre-Conference Session "From theory to practice: implementing API process knowledge" at the special rate of 990 € plus VAT.**

☐ Mr ☐ Ms ☐ Mx 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)

CF/RI/21062024

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
- 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.