

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

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







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, 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.

You can benefit from the Early Bird offer and register for the conference now and decide later how you participate.

During the Conference, updates from recent European and global authorities' initiatives, activities and interpretations like EDQM's support for initiatives to handle shortages and FDA's expectations on how to implement the Data Integrity requirements are provided. Hear 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).

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.

Session B

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

Adel Stiti, SEQENS

- Simplifying the calculation of cleaning limits with the toxicity approach
- Cleaning Validation Strategies: nitrosamines, sterile APIs, continuous production, new technologies, cleaning validation life cycle

7 Session D 8

Title to be announced

To be announced

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

- 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.



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

Luisa Paulo, Hovione

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
Nessa Fennelly, IBEC
Stéphanie Girard, SEQENS
Pieter van der Hoeven, Cefic
Sabina Jurca, Sandoz
Graça Mata, Hovione FarmaCiencia SA

Danny De Scheemaecker, Janssen Pharmaceutica

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



Nagesh Samineni Johnson & Johnson Private Limited, India



Hélène Bruguera EDQM, France



Maggie Saykali Cefic, Belgium



Marieke van Dalen *MARA Consultancy, The Netherlands*



Fabian Schwarb Siegfried AG, Switzerland



Joris Gilberts *Aspen Oss B.V., The Netherlands*



Veronika Schwarz Sandoz GmbH, Austria



Stéphanie Girard SEQENS, France



Adel Stiti SEQENS, France



Erik KatemanAspen Oss B.V., The Netherlands



Srikanth ThallapallySandoz Private Limited, India



Ruth Moore US FDA



Wim Van Rossom UCB Biopharma SRL, Belgium



Guillaume Muller Siegfried Evionnaz SA, Switzerland



Hilde Vanneste Janssen Pharmaceutica NV, Belgium



Rudy Peeters Janssen Pharmaceutica NV, Belgium



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/

27th Global GMP & Regulatory API Conference | 23 - 24 October 2024 | Vienna, Austria or Live Online

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.-. Register by June 30 and benefit from 100,- EUR Early-Bird Discount.

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.

CONCEPT HEIDELBERG P.O. Box 10 17 64 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 question 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:	27 th Global GMP & Regulatory API Conference, 23-24 October 2024 in Vienna or live online will
	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
CONCEPT HEIDELBERG P.O. Box 10 17 64 Fax +49 (0) 6221/84 44 34	□ Session 7: Title to be announced □ 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)
69007 Heidelberg Germany	 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

General terms and conditions
f 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
2. Cancellation until 3 weeks prior to the conference 10 %,
2. Cancellation until 3 weeks prior to the conference 55 %,
3. Cancellation until 3 weeks prior to the conference 50 %
4. Cancellation until 3 weeks prior to the conference 50 %
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- 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 discontairfare 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.

Phone / Fax

E-mail (please fill in)

City

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 informe 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).

Zip Code

Privacy Policy: By registering for this event, laccept 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 hittp://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.

Country