24th APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

Live Online Conference

26 – 28 October 2021

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- Reshoring of APIs: the EU position
- Brexit – a regulator's perspective
- FDA: First Experiences with QMM API Pilot Program

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 EMA, EDQM, FDA, National Authorities, the Industry and Industry Associations will discuss the latest developments in the field of GMP and Regulatory Compliance.

This year, like the last, is a special year and will certainly be remembered. Therefore the APIC Steering Committee has decided once more to offer the APIC/CEFIC Global GMP & Regulatory API Conference as a Live Online Conference.

The first day of the Conference provides updates from recent authorities' initiatives, activities and interpretations like the update of HPRA about latest Brexit activities, FDA's Quality Management Maturity Program, EMA's outlook for the API industry and the European Union's position on reshoring of APIs. Hear from industry speakers their approaches and best practices on all API related topics.

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

Tuesday | 26 October

EMA Outlook: what changes for APIs?
Speaker to be announced

COVID Vaccine – can the API Industry and Authorities learn from the Speed from Concept to Patient Use?
Jennifer Sloan, Pfizer

- Understanding where time can be saved to expedite approvals
- How these concepts can be applied to the API industry
- The importance of good collaboration between industry and authorities; post approval change management
- How quality and patient safety was maintained while accelerating delivery

Reshoring of APIs: the EU Position
Andrzej Rys, European Commission

Brexit – a Regulator's Perspective
Rita Purcell, HPRA

- Did industry and authorities plan pragmatically for potential drug shortages ?
- If UK was part of the EMA should MRA not have been put in place well before Brexit to aid the transition?
- Was industry prepared for Brexit?
- Learnings from the authorities to aid future events that may impact on drug shortages

APIs and the European Supply Chain: Challenges and Opportunities
Maggie Saykali, Cefic

- The European pharmaceutical supply chain: Updated facts and figures from 2020 survey
- The Covid-19 pandemic: A catalyst for change
- Current regulatory landscape: Challenges and opportunities
- The EU Commission's pharmaceutical strategy: How industry is helping to shape its own future

FDA's Quality Management Maturity Program
Lyle Canida, US FDA

- What is QMM?
- FDA's QMM Pilot Program
- Incentivizing Industry toward higher QMM

Important Information
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.

Wednesday | 27 October

The second day of the Live Online Conference provides, besides three Parallel Sessions with various GMP and RA topics, updates about EDQM's and ANVISA's activities and PMDA's inspection procedures.

1 Session A 2

Regulatory Hurdles and Opportunities

Marieke van Dalen, Aspen Oss B.V. and
Hilde Vanneste, Janssen Pharmaceutica

- Feedback from APIC's meetings with authorities
- Experiences with new regions

ICH Q13 – Achieving Regulatory Harmonization for Continuous Manufacturing

Nuno Matos, Hovione

- Main scientific concepts for Continuous Manufacturing
- Differences to Batch Manufacturing
- Regulatory considerations for Continuous Manufacturing
- Next steps

3 Session B 4

Latest Developments in Nitrosamine Impurities – Impact to the API Industry

Sabina Jurca, Sandoz and
Anthony Storey, Pfizer

- API Industry challenges with nitrosamine risk assessments
- EMA Nitrosamine phase 2 activities – best practices and challenges
- Importance of API and MAH collaboration for this requirement
- Have we a global approach to nitrosamine requirements

Remote Audits - A Concept for the Future?

Jens Brillault, CU Chemie Uetikon GmbH

- Industry experience
- Authorities' approach
- Challenges and solutions

5 Session C 6

China Drug Product Regulatory Process

Chunmei (Cathy) Yang, Sandoz

- Overview of China Regulatory Policy and Requirement
- Import Products Registration Procedure and Timeline
- Proposal on API DMF strategy

Data Integrity: What's next?

Charles Gibbons, Abbvie and
Rob De Proost, Janssen Pharmaceutica

- Sustaining Data governance
- Risk based approach to audit trail review
- Efficiencies and opportunities

Update from ANVISA

Renan Araujo Gois, ANVISA

- The regulatory system in Brazil
- DIFA and CADIFA, facts and figures
- Frequently asked questions

Update on EDQM activities

Hélène Bruguera, EDQM

- Latest developments of the Ph. Eur.
- EDQM's view on the CEP of the future
- EDQM's activities with regard to API inspections, including remote inspections

Thursday | 28 October

The API world is changing rapidly. In this third day focus will be on the impact of these changes on API companies.

The Importance of Workplace Wellbeing in the Post Pandemic World

Sophie Moran, Ibec

- What does workplace wellbeing really mean – how can it be broken down into meaningful component parts
- An example of business leading the way – the Ibec Keepwell Initiative- case study
- A new working paradigm or business as usual?

Digitalization opportunities in API & GX product development

Uros Klancar, Sandoz

- Digital technologies in product's development to overcome business and society challenges
- Sandoz Product Development pathway to digital transformation
- Digital playground and opportunities for API sourcing and development

PMDA: update on inspections

Speaker to be announced

Complexity of Global API Supply Chain

Marieke van Dalen, Aspen Oss B.V.

- How to deal with different expectations
- International collaboration
- Differences between the registered processes

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 Live Online Conference:

Hilde Vanneste, *Janssen Pharmaceutica*
Nessa Fennelly, *IBEC*
Luisa Paulo, *Hovione*
Rainer Fendt, *BASF*
Matt Moran, *BioPharmaChem*
Anthony Storey, *Pfizer*
Marieke van Dalen, *Aspen Oss*
Vicky Waddington, *Alcaliber*
Jens Brillault, *CU Chemie Uetikon GmbH*
Danny De Scheemaecker, *Janssen Pharmaceutica*
Stefaan Van De Velde, *Ajinomoto Bio-Pharma Services*
Pieter van der Hoeven, *Cefic*
Sabina Jurca, *Sandoz*
Graça Mata, *Hovione FarmaCiencia SA*
Stéphanie Girard, *SEQENS*
Beate Miller, *DSM Nutritional Products*
Anne Günster, *CONCEPT Heidelberg*
Oliver Schmidt, *CONCEPT Heidelberg*

Speakers

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

Jens Brillault
CU Chemie Uetikon GmbH, Germany

Hélène Bruguera
EDQM, France

Lyle Canida
US FDA, USA

Marieke van Dalen
Aspen Oss B.V., The Netherlands

Charles Gibbons
Abbvie, Ireland

Renan Araujo Gois
ANVISA, Brazil

Sabina Jurca
Sandoz, Slovenia

Uros Klancar
Sandoz, Switzerland

Nuno Matos
Hovione, USA

Sophie Moran
Ibec, Ireland

Rob De Proost
Janssen Pharmaceutica, Belgium

Rita Purcell
HPRA, Ireland

Andrzej Rys
European Commission, Belgium

Maggie Saykali
Cefic, Belgium

Jennifer Sloan
Pfizer, USA

Anthony Storey
Pfizer, United Kingdom

Hilde Vanneste
Janssen Pharmaceutica, Belgium

Chunmei (Cathy) Yang
Sandoz, China

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, updated in February 2021
- How to do – Interpretation of ICH Q7 document & « Review form », version 14, January 2021
- APIC Guidance on Nitrosamines Risk Assessment (February 2020), including Template for Report on Nitrosamines Risk Assessment, updated in April 2021
- Q&A document - APIC 3rd party audit sub team for RSM suppliers, December 2019
- Data Integrity Best Practices Guide for APIs, version 1, March 2019

Learn about the implementation of these Guidelines at the 24th Global GMP & Regulatory API Conference.
All APIC guidance documents are available for free download on the APIC/CEFIC website: www.apic.cefic.org/publications.html

Live Online Conference Dates
Tuesday, 26 October 2021, 09.00 - 17.30 h
Wednesday, 27 October 2021, 09.00 - 17.00 h
Thursday, 28 October 2021, 09.00 - 14.00 h
All times mentioned are CET.

Technical Requirements
For our Live Online Conferences, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)
Book all three conference days for the special price of € 1,990.-.

Or book Part 1 plus Parallel Sessions (26-27 October) or Part 2 plus Parallel Sessions (27-28 October) separately for the price of € 1,680.- each. The registration fee is payable in advance after receipt of invoice.

Discounts
APIC Members 10%,
ECA Members 5%,
Inspectorates 25%.
Please note that discounts cannot be combined!

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
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24th Global GMP & Regulatory API Conference
Live Online Conference, 26-28 October 2021

I want to take part in
☐ **All three conference days** (26-28 October 2021)
☐ **Part 1 plus Parallel Sessions** (26-27 October 2021: Tuesday, 26 October 2021, 09.00 - 17.30 h; Wednesday, 27 October 2021, 09.00 - 13.00 h)
☐ **Part 2 plus Parallel Sessions** (27-28 October 2021: Wednesday, 27 October 2021, 09.00 - 17.00 h; Thursday, 28 October 2021, 09.00 - 14.00 h)

Please choose 3 out of 6 parallel sessions (one choice in Session A, B and one in Session C):

Parallel Session A
☐ Session 1: Regulatory hurdles and opportunities
☐ Session 2: ICH Q13 – Achieving regulatory harmonization for Continuous Manufacturing
Parallel Session B
☐ Session 3: Latest developments in nitrosamine impurities – impact to the API industry
☐ Session 4: Remote Audits - A concept for the future?
Parallel Session C
☐ Session 5: China Drug Product regulatory process
☐ Session 6: Data Integrity: What's next?

☐ 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)

RI/0402021

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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week 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 January 2012).

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.