24th APIC/CEFIC

# GLOBAL GMP & REGULATORY API CONFERENCE

26 – 28 October 2021
Berlin, Germany
or broadcasted live
to your desk!

**Register by June 30 and benefit from 5% Early-bird Discount**

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

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 an on-site and online event. The lectures will be held live in Berlin 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 will take part in the 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. They are practically oriented and supposed to be highly interactive.**

# 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

### 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

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

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

### Conference App

Use the conference app for the best conference experience! Get information about lectures, speakers and exhibitors and create your personal conference schedule. You can find the app via the QR code or in the Apple iTunes/Google Play Store (search for PharmaEvents).


**Important Information**
Presentations, CVs of the speakers, plans of the Conference rooms and schedules of the Conference Days are available in the App!
Note: there will be no print-outs available during the Conference.

# Wednesday | 27 October

The second day of the 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

### ANVISA Update

*Speaker to be announced*

### 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

### PMDA: update on inspections

*Speaker to be announced*

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

## Improving Acceptance of organisational changes

*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

## 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

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:

**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*

**Sabina Jurca**
*Sandoz, Slovenia*

**Uros Klancar**
*Sandoz, Switzerland*

**Nuno Matos**
*Hovione, USA*

**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.

- How to do – Interpretation of ICH Q7 document & « Review form », version 14, November 2020
- APIC Guidance on Nitrosamines Risk Assessment including Template for Report on Nitrosamines Risk Assessment, February 2020
- 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

**Conference Dates**
Tuesday, 26 October 2021, 09.00 h – 17.30 h
Wednesday, 27 October 2021, 09.00 h – 18.00 h
Thursday, 28 October 2021, 09.00 h – 14.00 h

**Registration for Part 1 – for taking part onsite in Berlin only**
Monday, 25 October 2021, 19.00 h – 20.00 h or
Tuesday, 26 October 2021, 08.00 h – 09.00 h

**Registration for Part 2 – for taking part onsite in Berlin only**
Wednesday, 27 October 2021, 08.30 h – 09.00 h

**Technical Requirements – for taking part online only**
For our webinars, 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.

**Venue – for taking part onsite in Berlin only**
Pullman Berlin Schweizerhof
Budapester Straße 25 | 10787 Berlin
Germany
Phone +49 30 26 96 0 | h5347@accor.com

**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!**

**Accommodation – for taking part onsite in Berlin 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.

**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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69007 Heidelberg
Germany

**24th Global GMP & Regulatory API Conference**
26 - 28 October 2021, Berlin, Germany or live online
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 h – 17.30 h; Wednesday, 27 October 2021, 09.00 h – 13.00 h)
☐ **Part 2 plus Parallel Sessions** (27-28 October 2021: Wednesday, 27 October 2021, 09.00 h – 18.00 h; Thursday, 28 October 2021, 09.00 h – 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?

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

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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.