30 Years of APIC

25th APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

26 - 27 October 2022

Register by June 30 and benefit from the Early-Bird Discount

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- FDA's current initiatives
- Update from EMA
- 10 interactive Parallel Sessions with hot topics of the API Industry

APIC 30 YEARS
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 each year joining this Conference. Speakers from EMA, EDQM, FDA, from Industry and Industry Associations will discuss the latest developments in the field of GMP and Regulatory Compliance.

Therefore the APIC Steering Committee has decided once more to offer the APIC/CEFIC Global GMP & Regulatory API Conference as an onsite and online event. The lectures will be held live in Amsterdam 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.

The first day of the Conference provides updates from recent European authorities' initiatives, activities and interpretations like the update of EDQM about the CEP of the future, and EMA's outlook for the API industry. 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.

Wednesday | 26 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 and EMA's activities.

Update from EMA

Brendan Cuddy, EMA

- API related topics
- GMP Inspections/Inspection Database
- Mutual Recognition Agreements (MRAs)

Sustainability initiatives: Impact on API industry

Dirkjan van Zoelen, Aspen Oss B.V.

- A sustainable European API production: the various initiatives
- How to change to more sustainable production methods
- What are the challenges for changing?

1 | Session A | 2

Risk based approach during supplier qualification and management

Dieter Vanderlinden, Ajinomoto Bio-Pharma Services and Gerold Haake, Siegfried PharmaChemikalien Minden

- Preview on current work done by APIC's task force for development of the new APIC guide
- Interactive discussion on main concerns & questions of the audience

Practical experience with the Brazilian CADIFA

Susan Swiggers, Aspen Oss B.V.

- The procedure to obtain a CADIFA
- Handling changes in the CADIFA system
- Obtaining the Brazilian GMP certificate

3 | Session B | 4

How to assure successful investigations and CAPA's

Francois Vandeweyer, VDWcGMP Consultancy

- Understanding GMP requirements for deviations/investigations
- Steps in an effective investigation
- Examples of investigative tools
- The special category of Out of Specification Investigations
- Writing a good investigation report
- Verifying corrective action and preventing recurrence

Information sharing between the API manufacturer and the Drug Product manufacturer

Marieke van Dalen, Aspen Oss B.V. and Sabina Jurca, Sandoz

- Differences between Regulatory and Quality aspects
- The role of the Customer File
- Quality Agreements, Secrecy Agreements
- Good Customer Practice goes two ways

Keep up-to-date with EDQM work

Hélène Bruguera, EDQM France

- Celebrating the 11th edition of Ph. Eur
- How to facilitate the approval of CEP applications
- The CEP of the Future is for now
- Why more than ever international cooperation is needed.

Thursday | 27 October

The API world is changing rapidly. On the second day, the focus will be on FDA's initiatives and activities regarding ICH Q13 and ICH M4 (R2) and their approach for facility assessment and on the second set of Parallel Sessions about e.g. regulatory hurdles, Nitrosamine impurities and auditing Regulatory Starting Materials (RSM) manufacturers.

5	Session C	6

Regulatory hurdles and opportunities

Marieke van Dalen, Aspen Oss B.V.

- APIC interaction with Health Authorities
- Outcome of APIC's Regulatory task force meetings

Auditing manufacturers of regulatory starting materials

Cathy Wang, Ningbo Nuobai Pharmaceutical and
Danny de Scheemaecker, Janssen Pharmaceutica

- Intro of the APIC guide
- Examples and experiences in applying the guide during audits in China

7	Session D	8

Latest developments in nitrosamines – what have we learnt from the EMA's call for review?

Robert Bream, EMA

- EMA's call for review – deadline for completion in September 2022
- What have we learnt from this exercise?
- Nitrosamine impurities – are there still gaps in the scientific understanding?

Challenges with API registration in China

Stefan Fischer and Guo Ning, Cisema Limited

- Organizations and Regulations
- Introduction of the complete process with timeline and fees
- Testing at NIFDC in China
- Introduction of application documents
- Comparison EU & China
- Common deficiencies from the perspective of a EU manufacturer

9	Session E	10

ICH Q12 implementation in practice

Frank Montgomery, AstraZeneca

- Recent experience of implementation for APIs from Implementation Working Group (IWG)
- Training materials and how to apply them
- Experiences so far with implementation across ICH regions

Cloud Computing in the API industry

Michael Wegmann, F. Hoffmann-La Roche

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.

ICH Q2/Q14 – Analytical Procedures – development and validation

Mario Hellings, Janssen Pharmaceutica

- The challenges of including more methods in ICH Q2
- Scientific approaches to analytical procedure development
- Relation between Q2/Q14 and other ICH guidelines

Cloud-based Regulatory Assessment: ICH M4Q(R2) and FDA KASA Initiative

Lawrence Yu , US FDA

- Future Regulatory Assessment and Submission in the environment of Cloud Computing
- ICH's attempt in modernizing quality information submission and developing ICH M4Q(R2)
- FDA's digitalization effort including Knowledge-aided Assessment and Structured Applications (KASA) initiative

FDA – Update on current initiatives

FDA Approaches to Facility Pre-Approval/Pre-License Inspections during the COVID-19 Pandemic and Beyond

Stelios Tsinontides, US FDA

- Landscape of manufacturing & supply chains during the Covid-19 Pandemic
- FDA/CDER's Response
- Approach to Facility Assessments/Inspections
- 704(a)(4) Record Requests
- Remote Interactive Evaluations (RIEs)
- Concluding Remarks

Q13 and Continuous Manufacturing Advancement

Rapti Madurawe, US FDA

- Q13 status update and implementation plan
- Thoughts on current and future landscape of continuous manufacturing

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:

Jens Brillault, *CU Chemie Uetikon GmbH*
Marieke van Dalen, *Aspen Oss*
Rainer Fendt, *BASF*
Nessa Fennelly, *IBEC*
Stéphanie Girard, *SEQENS*
Pieter van der Hoeven, *Cefic*
Sabina Jurca, *Sandoz*
Graça Mata, *Hovione FarmaCiencia SA*
Beate Miller, *DSM Nutritional Products*
Matt Moran, *BioPharmaChem*
Luisa Paulo, *Hovione*
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*

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

Speakers

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

Hélène Bruguera
EDQM, France

Robert Bream
EMA, The Netherlands

Brendan Cuddy
EMA, The Netherlands

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

Stefan Fischer
Cisema Limited, Hong Kong

Gerold Haake
Siegfried PharmaChemikalien Minden GmbH, Germany

Mario Hellings
Janssen Pharmaceutica, Belgium

Sabina Jurca
Sandoz, Slovenia

Rapti Madurawe
US FDA, USA

Frank Montgomery
AstraZeneca, UK

Guo Ning
Cisema Limited, Hong Kong

Danny de Scheemaecker
Janssen Pharmaceutica, Belgium

Susan Swiggers
Aspen Oss B.V., The Netherlands

Stelios Tsinontides
US FDA, USA

Dieter Vanderlinden
Ajinomoto Bio-Pharma Services, Belgium

Francois Vandeweyer
VDWcGMP Consultancy, Belgium

Cathy Wang
Ningbo Nuobai Pharmaceutical Co.,Ltd., China

Michael Wegmann
F. Hoffmann-La Roche AG, Switzerland

Lawrence Yu
US FDA, USA

Dirkjan van Zoelen
Aspen Oss B.V., The Netherlands

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 »".

Learn about the implementation of these Guidelines at the 25th 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
Wednesday, 26 October 2022, 09.00 - 17.30 h
Thursday, 27 October 2022, 08.30 - 17.00 h
All times mentioned are CEST.

Registration – for taking part onsite in Amsterdam only
Tuesday, 25 October 2022, 19.00 h - 20.00 h or
Wednesday, 26 October 2022, 08.00 h - 09.00 h

Venue – for taking part onsite in Amsterdam only
Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11 | 1019 BR
Amsterdam, The Netherlands
Phone: +31 (0) 20 519 1200
hotel.amsterdam@movenpick.com

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 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 "ICH Q7 How to do - Document– Hot Topics from the revised APIC guidance" a special fee of 890,- Euro (regular fee: 990,- 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 Amsterdam 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

25th Global GMP & Regulatory API Conference, 26-27 October 2022 in Amsterdam or live online

I will
☐ **participate on-site in Amsterdam**.
☐ **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: Risk based approach during supplier qualification and management
☐ Session 2: Practical experience with the Brazilian CADIFA
Parallel Session B
☐ Session 3: How to assure successful investigations and CAPA's
☐ Session 4: Information sharing between the API manufacturer and the Drug Product manufacturer
Parallel Session C
☐ Session 5: Regulatory hurdles and opportunities
☐ Session 6: Auditing manufacturers of regulatory starting materials
Parallel Session D
☐ Session 7: Latest developments in nitrosamines – what have we learnt from the EMA's call for review?
☐ Session 8: Challenges with API registration in China
Parallel Session E
☐ Session 9: ICH Q12 implementation in practice
☐ Session 10: Cloud Computing in the API industry

☐ **I also register for the pre-Conference Session "ICH Q7 How to do - Document– Hot Topics from the revised APIC guidance" at the special rate of 890 € plus VAT.**

☐ 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/16022022

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.