23rd APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

In Amsterdam, The Netherlands
or broadcasted live to your desk!
28 – 30 October 2020

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- FDA: Innovation and continuous manufacturing
- Latest developments in nitrosamine impurities
- Update from EDQM

APIC active pharmaceutical ingredients committee (25 years of promoting patient safety)

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 is a special year and will be remembered for a long time. The Covid-19 pandemic is shaping our professional environment as well as our private lives. But life goes on and we need and want to educate ourselves.

Therefore the APIC Steering Committee has decided to offer this year's APIC/CEFIC Global GMP & Regulatory API Conference also as a Live Online Conference. As a participant, you may attend either directly on site in Amsterdam or live online at your screen.

You can register for the conference now and decide later how you participate.

The GMP part of the Conference, of which the final module is a Joint GMP & RA session, provides updates from recent authorities' initiatives, activities and interpretations related to GMP compliance of API manufacturing. Hear from industry speakers about their approaches and best practices on compliance related to the various existing and emerging aspects of API GMP.

The Parallel Sessions are no workshops. They are practically oriented and supposed to be highly interactive.

GMP part | 28 October

Development and application of Mutual Recognition Agreements

Speaker to be named by EMA

Proactive application of operational excellence in the external supply chain

Cathal O'Duinn, Janssen Pharmaceuticals

- Framework for deploying operational excellence
- Data driven approach to risk identification
- Proactive deployment and sustainability

Life Cycle approach to process validation

Stefaan van de Velde, Ajinomoto Bio-Pharma Services

- How science and risk based logic can help continuously improving processes
- Practical approach

ANVISA's view on inspections

Rosimeire Pereira Alves da Cruz, ANVISA

- Status and Review of current inspection activities
- Top 10 Findings from ANVISA's inspections
- Outlook on future inspection program

Risk based approach to supplier management

Dieter Vanderlinden, Ajinomoto Bio-Pharma Services

- Regulatory requirements and expectations
- Industry best practices - how to manage suppliers?
- Elements to consider to support risk based approach

Fraud in generic pharmaceutical manufacture: A worldwide life-threatening danger

Katherine Eban

- The various forms of fraud
- How inspectors are being fooled
- How do APIs fit in?
- Are we solving the problems?

APIC Industry Best Practice documents

APIC developed a number of guidances on GMP and Regulatory Affairs, e.g.

- 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 23rd Global GMP & Regulatory API Conference or at the Pre-Conference.

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

Parallel Sessions | 29 October

GMP | Session A | RA

Quality culture
Speaker to be announced
- What is quality culture?
- Why is the quality culture of an organisation important to APIs and patients?
- How is the quality culture of an organisation developed?
- How can you assess an organisation quality culture?

Specifics for Sterile APIs
Cristina Jimenez Sala, Sandoz Industrial Products S.A
- Sterile API production – Annex 1 GMP
- Regulatory consequences
- The relationship with the customers

GMP | Session B | RA

ICH Q13 – Continuous Manufacturing of Drug Substances and Drug Products
Nuno Matos, Hovione
- ICH Q13 purpose
- Continuous Manufacturing process benefits for Industry
- Guideline status and next steps

API registration in Brazil: an overview
George Hartong van Lokven, Aspen Oss B.V.
- Brazil specifics
- Registration procedures: past, present and future

GMP | Session C | RA

Cleaning in multipurpose facilities
Florent Trouillet, Siegfried (Evionnaz)
- Health authorities' requirements and cleaning challenges for multipurpose facilities
- Criteria for risk analyses to develop cleaning methods and cleaning validation strategy in a multipurpose facility
- Risk-based approach for limit setting on intermediates and early development products
- Practical examples

APIC´s Experience with API Registrations in China
Beate Miller, DSM Nutritional Products
- The Regulatory Framework in China
- Chinese DMF Requirements
- Experience of APIC Members & Case Studies

Joint GMP And Regulatory Affairs part | 29 October

Update from EDQM
Hélène Bruguera, EDQM
- Latest news on the certification scheme
- The EDQM inspection programme

Latest developments and lessons learnt in nitrosamine impurities – an EMA view
Dr. Robert Bream, EMA
- History of the incident
- Overview of root causes identified so far
- Outcome of the different referrals
- Implementation plan and regulatory expectations from call for review
- Possibly a summary of the lessons learnt exercise document

Latest developments in nitrosamine impurities – impact to the API industry
Sabina Jurca, Sandoz & Anthony Storey, Pfizer
- Why are nitrosamines a concern?
- What is expected from the API Industry from a GMP and regulatory perspective?
- Interactions between API Industry and marketing authorisation holders

Impact of API globalisation on drug shortages
Speaker to be announced

Innovation and continuous manufacturing

Dr Sau (Larry) Lee, FDA

- FDA's efforts to modernize drug manufacturing
- Guidance for Industry: Quality Considerations for Continuous Manufacturing
- Batch vs. continuous manufacturing
- FDA's Emerging Technology Program

Regulatory Affairs part | 30 October

After several regulatory topics will have been presented during the second conference day, the RA part of the conference will highlight key aspects of registration procedures in Saudi Arabia and Korea as well as, aspects of future ASMF assessment and CEP modernisation.

ICH Q12 - Now the hard work starts in implementation

Frank Montgomery, AstraZeneca

- How to define ECs and where in the CMC should they be listed
- PACMP – advantages and how to use
- PLCMP – advantages and how to use

API Filing in South Korea: What do Korean Authorities expect?

Jeong-Ja Oh, Synex Consulting

- Overview on South Korean DMF System
- Experiences with DMF Procedure and Watch-outs

Saudi Arabia, Gulf States: Registration procedures for APIs

Ibrahim H. Mujammami, SFDA

- The Regulatory Framework
- Registration procedures for APIs
- International collaboration

CEP modernisation : an APIC perspective

Marieke van Dalen, Aspen Oss

- Improvements to the current system
- Outlook to the 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, Belgium*
Nessa Fennelly, *IBEC, Ireland*
Luisa Paulo, *Hovione, Portugal*
Rainer Fendt, *BASF, Germany*
Matt Moran, *BioPharmaChem, Ireland*
Anthony Storey, *Pfizer, United Kingdom*
Marieke van Dalen, *Aspen Oss, The Netherlands*
Vicky Waddington, *Mallinckrodt Pharmaceuticals, Ireland*
Jens Brillault, *SEQENS*
Danny De Scheemaecker, *Janssen Pharmaceutica*
Stefaan Van De Velde, *Ajinomoto Bio-Pharma Services*
Pieter van der Hoeven, *Cefic*
José Caparros, *Centrient*
Sabina Jurca, *Sandoz,Slovenia*
Graça Mata, *Hovione FarmaCiencia SA*
Beate Miller, *DSM Nutritional Products*
Anne Günster, *CONCEPT Heidelberg, Germany*
Oliver Schmidt, *CONCEPT Heidelberg, Germany*

Important Information

You will receive a USB stick when you register in Amsterdam. Note: there will be no print-outs available during the conference. Additionally, the presentations will be available for download.

Speakers

The following speakers will be present at this years Global GMP & Regulatory API Conference:

Dr Robert Bream
EMA, The Netherlands

Hélène Bruguera
EDQM France

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

Katherine Eban

Dr Sau (Larry) Lee
US FDA, USA

George Hartong van Lokven
Aspen Oss B.V., The Netherlands

Cristina Jimenez Sala
Sandoz Industrial Products S.A, Spain

Sabina Jurca
Sandoz, Slovenia

Nuno Matos
Hovione, USA

Beate Miller
DSM Nutritional Products, Switzerland

Frank Montgomery
AstraZeneca

Ibrahim H. Mujammami
SFDA, Saudi Arabia

Jeong-Ja Oh
Synex Consulting, South Korea

Cathal O'Duinn
Janssen Pharmaceuticals, Ireland

Rosimeire Pereira Alves da Cruz
ANVISA, Brazil

Anthony Storey
Pfizer, United Kingdom

Florent Trouillet
Siegfried, Switzerland

Dieter Vanderlinden
Ajinomoto Bio-Pharma Services, Belgium

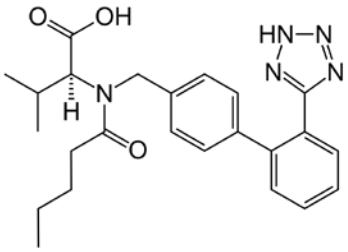
Stefaan van de Velde
Ajinomoto Bio-Pharma Services, Belgium

Nitrosamine Impurities – GMP and Regulatory requirements

a pre-Conference Session on 27 October 2020

This pre-Conference Session ideally complements the subsequent 23rd APIC/CEFIC Global GMP & Regulatory API Conference.

If you register both for the pre-Conference Session „Nitrosamine Impurities – GMP and Regulatory requirements " and the 23rd Global GMP & Regulatory API Conference, you will benefit from a special rate of ***890 €*** *(instead of 990 €) for the pre-Conference Session!*



Registration
Tuesday, 27 October 2020, 19.00 – 20.00 h or
Wednesday, 28 October 2020, 09.00 h - 10.00 h
Regulatory Affairs Part:
Thursday, 29 October 2020, 8.00 - 8.30 h

Conference Date
Wednesday, 28 October 2020, 10.00 h – 17.20 h
Thursday, 29 October 2020, 08.30 h – 17.50 h
Friday, 30 October 2020, 09.00 h – 13.00 h

Venue
Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11 | 1019 BR Amsterdam
Netherlands
Phone: +31 205191200
Fax: +31 205191230
Email: hotel.amsterdam@movenpick.com

Fees (per delegate plus VAT)
Book all three conference days for the special price of € 1,990.-.
Or book the GMP Part (28-29 October) or the Regulatory Affairs Part (29-30 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
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation link 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 you register online at www.api-conference.org

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
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For question regarding content:
Ms Anne Günster (Operations Director)
at + 49 (0) 6221/84 44 50, or at
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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager)
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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

23rd Global GMP & Regulatory API Conference
28 - 30 October 2020, Amsterdam, The Netherlands or live online
I want to take part in
☐ **All three conference days** (28-30 October 2020)
☐ **GMP part** (28-29 October 2020)
☐ **Regulatory Affairs part** (29-30 October 2020)

Please choose 3 out of 6 lectures (one out of each parallel session):

Parallel Session A
☐ Lecture 1: Quality culture
☐ Lecture 2: Specifics for Sterile APIs

Parallel Session B
☐ Lecture 3: ICH Q13 – Continuous Manufacturing of Drug Substances and Drug Products
☐ Lecture 4: API registration in Brazil: an overview

Parallel Session C
☐ Lecture 5: Cleaning in multipurpose facilities
☐ Lecture 6: APIC´s Experience with API Registrations in China

☐ **I'm also registering for the pre-Conference Session "Nitrosamine Impurities – GMP and Regulatory requirements " at the special rate of 890 € plus VAT.**

I will
☐ **participate on-site in Amsterdam**
☐ **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

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

vers2/07052020

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.