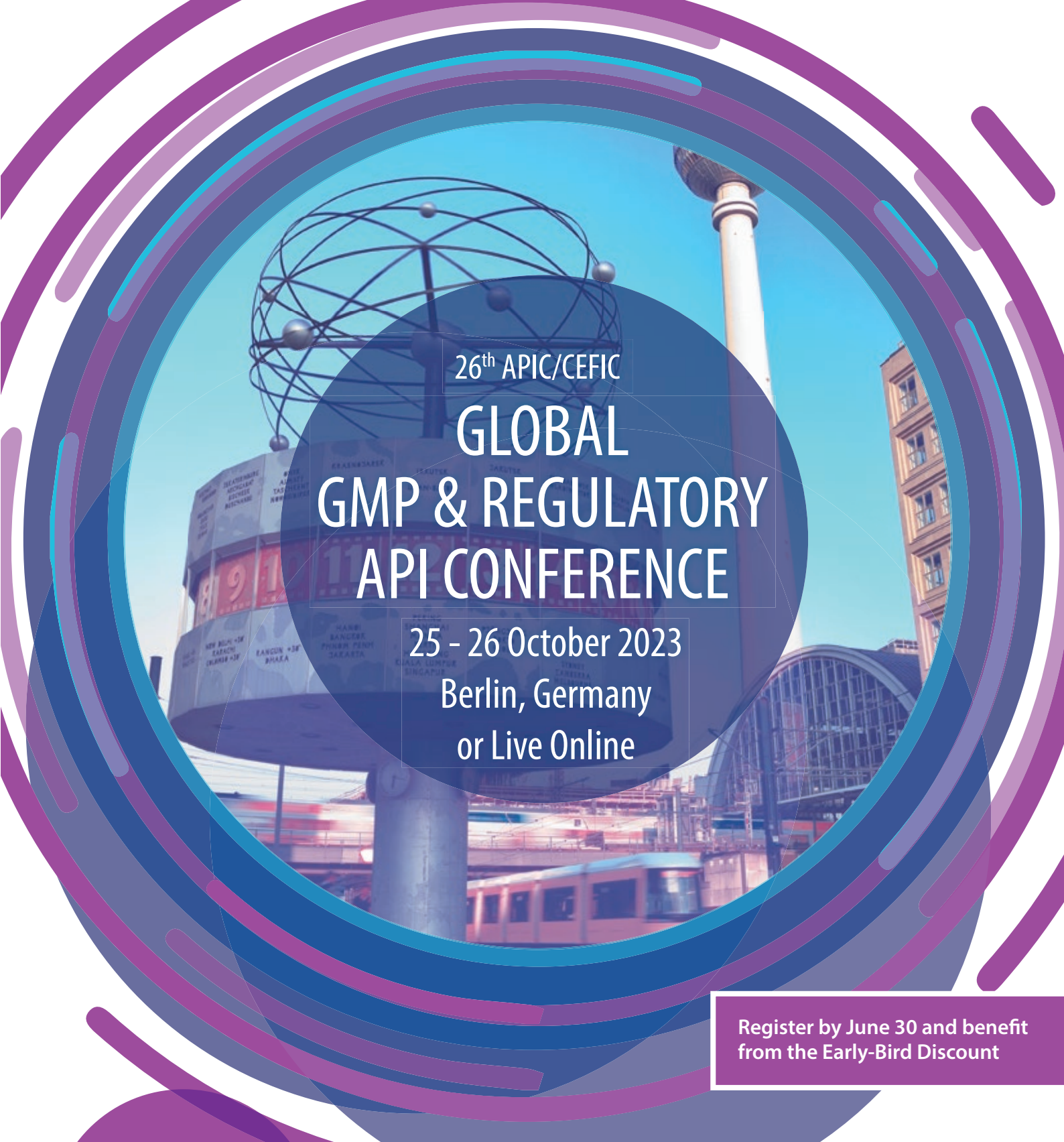

26th APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

25 - 26 October 2023
Berlin, Germany
or Live Online

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

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- FDA's view on ICH Q9(R1)
- Update from ANVISA, PMDA and EDQM
- 10 interactive Parallel Sessions with hot topics of the API Industry

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 each year joining this Conference. Speakers from ANVISA, EDQM, PMDA, 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 Conference. 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 participate.

During the Conference updates from recent European and global authorities' initiatives, activities and interpretations like the role of EDQM in protecting public health, FDA's view on on ICH Q9(R1), the regulator's perspective on the revision of the ICH M4Q guideline and updates of ANVISA and PMDA are provided. 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 | 25 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, on APIC Guidance documents and on the development of second generation APIs.

Development of second generation APIs

Dirkjan van Zoelen, Aspen Oss B.V.

- Necessity to develop second generation APIs
- Addressing the EC green deal requirements
- Challenges

New APIC Guide on best practices for managing suppliers to API manufacturers

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

- Explanation of the different chapters
- Real life experiences
- Questions & Answers section of the new APIC Guide

Update from PMDA

To be announced

1	**Session A**	2

API stability studies

Susan Swiggers, Aspen Oss B.V.

- Global guidelines
- Country-specific requirements
- Practical implications

Navigating the complexities of sterile injectable submissions

Sílvia Jiménez Carbonell, Sandoz Spain &
Veronika Schwarz, Sandoz Austria

- Insights on the regulation of Sterile APIs
- Handling information sharing with MA holder focusing on aseptic processing
- Transfer of sterile API production to a new manufacturer

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.

3 | **Session B** | 4

How are health authorities inspections evolving in the world of APIs?

Stéphanie Girard, SEQENS

- Analysis of the trends in the number of inspections over the last few years
- MRA programs and examples of MRA application
- Use of remote inspections
- Analysis of the top deficiencies in key regions over time
- What's next ?

ICH M7 – Risk Assessment from API perspective

Graca Mata, Hovione

- Concepts
- Steps of risk assessment
- Case study

The role of the EDQM in protecting public health – current initiatives

Hélène Bruguera, EDQM France

- What's new in the Ph. Eur.?
- Implementation of the new CEP design
- EDQM priorities for the upcoming years

Thursday | 26 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. Quality Agreements, ANVISA API requirements and emerging markets novelties, Quality Metrics and how did COVID affect our API industry.

5 | **Session C** | 6

How did COVID affect our API industry?

Marieke van Dalen, Aspen Oss B.V.

- The pharmaceutical Industry level
- The API business level
- The API company level

Quality Agreements: APIC Guidance and Templates

Samuel Perret, SEQENS

Ricardo Martins, Vistin Pharma

- Revision of the Guidance: Quality Agreements between the API manufacturer and its customers
- New: Quality Agreements between the API manufacturer and its material suppliers or service providers

7 | **Session D** | 8

Revision of the ICH M4Q guideline: A Regulator's perspective

A.J. (Ton) van der Stappen, Medicines Evaluation Board

- What is ICH M4Q designed to do?
- What are the issues to be resolved?
- What are the objectives of the revision?
- What is the Regulator's perspective?

The case for Quality Metrics

Nuno Matos, Hovione

- Importance of Quality Metrics
- Leading and Lagging metrics
- Metrics vs. KPIs
- Deploying Quality Metrics

Digitalization in API

Tlaloc Amaro

- Update on APIC's task force on digitalization in API manufacture
- Examples of (business) case studies

Recent breakthroughs in ANVISA API requirements and Emerging Markets novelties

Augusto Carmezini, Lek Pharmaceuticls d.d., a Sandoz company

- APIC Emerging Countries Task Force presentation
- Regulatory novelties and hurdles observed in Emerging Markets
- ANVISA (Brazil) – Recent breakthroughs in API regulatory requirements and procedures

Update from the Anvisa inspectorate

Thaila Coradassi de Almeida, ANVISA

- Most common encountered GMP deficiencies
- Differences between the regions where ANVISA goes for inspections
- Specifics to consider when you receive an ANVISA inspection
- ANVISA's experience with remote inspections during the pandemic

Nitrosamine impurities – Regulatory aspects and current standing

Ajda Podgorsek Berke, Lek Pharmaceuticals d.d., a Sandoz company

- Guideline Updates on Nitrosamine Impurities
- How to meet expectations – challenges
- Understanding the Quality & Safety assessment of Nitrosamines
- Control of Nitrosamines & mitigation measures
- Outstanding gaps & way forward

ICH Q9(R1): What is New?

Alex Viehmann, US FDA

- FDA's expectations regarding QRM
- Subjectivity in risk-based decision making
- Risk management tools: how to make the best of them?

Social Event | 25 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 Berlin and invite all participants and speakers to an entertaining evening outside the hotel followed by a dinner.

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:

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*
Matt Moran, *IBEC*
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 year's Global GMP & Regulatory API Conference:

Tlaloc Amaro

Hélène Bruguera
EDQM, France

Augusto Carmezini
Lek Pharmaceuticls d.d., a Sandoz company, Slovenia

Thaila Coradassi de Almeida
ANVISA, Brazil

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

Stéphanie Girard
SEQENS, France

Gerold Haake
Siegfried PharmaChemikalien Minden GmbH, Germany

Sílvia Jiménez Carbonell
Sandoz, Spain

Ricardo Martins
Vistin Pharma, Norway

Graca Mata
Hovione, Portugal

Nuno Matos
Hovione, Portugal

Samuel Perret
SEQENS, France

Ajda Podgorsek Berke
Lek Pharmaceuticals d.d., a Sandoz company, Slovenia

Veronika Schwarz
Sandoz, Austria

A.J. (Ton) van der Stappen
Medicines Evaluation Board, The Netherlands

Susan Swiggers
Aspen Oss B.V., The Netherlands

Dieter Vanderlinden
Ajinomoto Bio-Pharma Services, Belgium

Alex Viehmann
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 26th Global GMP & Regulatory API Conference.
All APIC guidance documents are available for free download on the APIC/CEFIC website: https://apic.cefic.org/publications/

Conference Dates
Wednesday, 25 October 2023, 09.00 - 17.30 h
Thursday, 26 October 2023, 09.00 - 17.00 h
All times mentioned are CEST.

Registration – for taking part onsite in Berlin only
Tuesday, 24 October 2023, 19.00 - 20.00 h or
Wednesday, 25 October 2023, 08.00 - 09.00 h

Venue – for taking part onsite in Berlin only
DoubleTree by Hilton Berlin Ku'Damm
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone: +49 (0) 30/21 27 0
info@doubletreeberlinkudamm.com

Technical Requirements
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.-.

For the APIC Pre-Conference Session "GMP approaches for your day to day API work" 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%.

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

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. 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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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:

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CONCEPT HEIDELBERG
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69007 Heidelberg
Germany

26th Global GMP & Regulatory API Conference, 25-26 October 2023 in Berlin or live online

I will
☐ **participate on-site in Berlin.**
☐ **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: API stability studies
☐ Session 2: Navigating the complexities of sterile injectable submissions
Parallel Session B
☐ Session 3: How are health authorities inspections evolving in the world of APIs?
☐ Session 4: ICH M7 – Risk Assessment from API perspective
Parallel Session C
☐ Session 5: How did COVID affect our API industry?
☐ Session 6: Quality Agreements: APIC Guidance and Templates
Parallel Session D
☐ Session 7: Revision of the ICH M4Q guideline: A Regulator's perspective
☐ Session 8: The case for Quality Metrics
Parallel Session E
☐ Session 9: Digitalization in API
☐ Session 10: Recent breakthroughs in ANVISA API requirements and Emerging Markets novelties

☐ **I also register for the Pre-Conference Session "GMP approaches for your day to day API work" at the special rate of 890 € 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

City Zip Code Country

Phone / Fax

E-mail (please fill in)

RI/13022023

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
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks 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 July 2022).

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.