28th APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

22 - 23 October 2025

in Barcelona, Spain

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

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- Sustainable API companies
- Update from PMDA, AEMPS, Halmed, BE-FAMHP 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 EDQM, AEMP's, Halmed, PMDA, BE-FAMHP, from Industry and Industry Associations will discuss the latest developments in the field of GMP and Regulatory Compliance.

During the Conference updates from recent European and global authorities' initiatives, activities and interpretations like EDQM's international co-operation with other authorities, AEMPS' experience with the EU ASMF worksharing procedure, the new amendments to the Japanese Pharmaceuticals and Medical Devices Act and the regulator's perspective of the Revision of the ICH M4Q Guideline are provided. Hear from industry speakers sharing their approaches and best practices on all API related topics.

Wednesday | 22 October

The first day of the Conference provides, besides the first set of Parallel Sessions with various GMP and RA topics, updates about AEMPS', EDQM's and PMDA's activities, the revision of the ICH M4Q Guideline and recent developments in mutagenic impurities.

The Experience of AEMPS with the ASMF Procedure

Teresa Dannert Alsasua, AEMPS

- AEMPS contribution in National and European procedures
- ASMF procedure:
  - An analysis of its use in National and European procedures
  - Frequently asked questions
  - AEMPS' experience with the EU ASMF worksharing procedure

Revision of the ICH M4Q Guideline from a Regulator's Perspective

Ivica Malnar, Halmed

- M4Q(R2) revision update – current EWG thinking
- New organisation in presenting quality information
- ICH M4Q(R2) implementation challenges
- A Regulator's perspective

Recent Developments in Mutagenic Impurities, with Focus on Nitrosamines

Ajda Podgorsek Berke, Lek Pharmaceuticals, a Sandoz company
Filip De Bock, Lek Pharmaceuticals, a Sandoz company

- Overview of the regulatory guidelines – recent updates
- Recent developments in mutagenic impurities, with focus on nitrosamines
- Challenges & Impact on industry
- Way forward

1 | **Session A** | 2

Annex 1 – Challenges for the API Industry

Andrea Ilumbart, Sandoz Industrial Products
Judit Chaves, Sandoz Industrial Products

- Brief Introduction to Annex 1
- Implementation and the most relevant Challenges
- Sterile Substances registration in the EU: Related Guidelines aligned with Annex 1

From Data Integrity to Data Governance

Rob De Proost, J&J Innovative Medicine

- Data Governance imbedded in QMS
- Reflection on DOM supported by Risk Management
- Closed loop continuous improvement process

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

APIC Regulatory Group Activities

Ilaria Duo, Siegfried
Graca Mata, Hovione FarmaCiencia

- Recent updates on regulatory requirements
- Regulatory changes & practical examples
- Control strategy

The Hitchhiker's Guide to Supplier Management

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

- Short overview of the APIC Supplier Management guide
- Templates
- Observed questions and challenges

The new Amendments to the Japanese Pharmaceuticals and Medical Devices Act

tba. PMDA Speaker

- The recent situation related to pharmaceutical regulations in Japan
- Details of the amendments

Update on EDQM Activities

Bruno Spieldenner, EDQM

- The European Pharmacopoeia (Ph. Eur.)
- EDQM's activities with regard to the CEP procedure
- EDQM's international co-operation with other authorities

Thursday | 23 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. regulatory starting materials, API manufacturer inspections and the risk-based approach for like-to-like changes.

5 **Session C** 6

Risk-based Approach for like-to-like Changes

Nicola O'Connell, Pfizer

- Why the regulatory landscape is impacting such changes
- Can a like for like change impact processing /quality
- Risk based principles for such changes

Title tba.

7 **Session D** 8

From Small Generic Molecules to Biosimilars: Understanding Regulatory Differences and Commonalities

Manuela Schweiger, Sandoz

- Small molecule generics and biosimilars: differences in regulatory pathways and requirements
- Two categories from a regulatory standpoint: well-established regulatory standards vs. more nuanced regulatory approaches
- Key distinctions and shared features

Title tba.

Regulatory Starting Materials – Do we all understand the Definition equally?

Nevenka Kragelj Lapanja, Lek Pharmaceuticals., a Sandoz company

- Overview of regulatory requirements
- Experience and challenges of the pharmaceutical industry
- Lessons learned

EU Inspector's view on API Manufacturer Inspections

Guillaume Jean, BE-FAMHP

- Conduct of inspections of API manufacturers
- Current and future focus areas during inspections
- Main deficiencies observed during recent inspections
- Main differences between inspections inside and outside of the EU

Quality Oversight Requirements for Contract Manufacture

Anthony Storey, Pfizer

- The importance of contract manufacturing to the industry
- The need for oversight/governance for such activities
- What makes a good partnership model for both parties

EU Pharmaceutical Package – an Update

Hilde Vanneste, J&J Innovative Medicine

- Understanding the EU Pharmaceutical Package
- Positive impacts and challenges of the EU Pharmaceutical Package
- Overview of the update of the classification guideline
- Impact on industry practises

Use of Recovered Solvents in API Production: Reducing the Environmental Footprint

Joris Gilberts, Aspen Oss

- Reducing the environmental footprint of APIs: use of recovered solvents
- Position of APIC's TF on current challenges
- Roadmap of APIC's TF to come with practical guidance

Social Event | 22 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 Barcelona 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 Leadership Team for developing the Conference:

Ilaria Duo, *Siegfried*
Stéphanie Girard, *SEQENS*
Pieter van der Hoeven, *Cefic*
Sabina Jurca, *Sandoz*
Graça Mata, *Hovione FarmaCiencia*
Luisa Paulo, *Hovione*
Danny De Scheemaecker, *Pharmaron*
Anthony Storey, *Pfizer*
Hilde Vanneste, *J&J Innovative Medicine*
Stefaan van de Velde, *Ajinomoto Bio-Pharma Services*
Vicky Waddington, *Sterling Pharma Solutions*
Karolien Verheyden, *Ajinomoto Bio-Pharma Services*

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:

Filip De Bock
Lek Pharmaceuticals d.d., a Sandoz company, Slovenia

Judit Chaves
Sandoz Industrial Products, S.A, Spain

Teresa Dannert Alsasua
AEMPS, Spain

Ilaria Duo
Siegfried AG, Switzerland

Joris Gilberts
Aspen Oss B.V., The Netherlands

Gerold Haake
Siegfried PharmaChemikalien Minden GmbH, Germany

Andrea Ilumbart
Sandoz Industrial Products S.A, Spain

Guillaume Jean
BE-FAMHP, Belgium

Nevenka Kragelj Lapanja
Lek Pharmaceuticals d.d., a Sandoz company, Slovenia

Ivica Malnar
Halmed, Croatia

Graca Mata
Hovione FarmaCiencia SA, Portugal

Nicola O'Connell
Pfizer

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

Rob De Proost
J&J Innovative Medicine, Belgium

Manuela Schweiger
Sandoz GmbH, Austria

Bruno Spieldenner
EDQM, France

Anthony Storey
Pfizer Ltd., UK

Dieter Vanderlinden
Ajinomoto Bio-Pharma Services, Belgium

Hilde Vanneste
J&J Innovative Medicine, Belgium

APIC Industry Best Practice documents

APIC developed a number of guidances on GMP and Regulatory Affairs, e.g. "Nitrosamine Risk Management: Guidance for API Manufacturers" or "How to do – Interpretation of ICH Q7 document & « Review form »".

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

Conference Dates
Wednesday, 22 October 2025, 09.00 h - 17.30 h
Thursday, 23 October 2025, 09.00 h - 16.00 h
All times mentioned are CEST.

Registration
Wednesday, 22 October 2025, 08.00 - 09.00 h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona
Spain
Phone: +34 (93) 503 53 00
sants@barcelo.com

Accommodation
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.

Conference language
The official conference language will be English.

Fees (per delegate plus VAT)
Book both conference days for the price of 1,680.- EUR

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

The registration fee is payable in advance after receipt of invoice.

For the ECA course "The EU Pharmaceutical Legislation Reform: Impact on the API Industry" a special fee of 1,190.- EUR (regular fee: 1,290.- 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!

Registration

Via the attached reservation form, by e-mail , by fax message, or online via QR-Code at www.api-conference.org

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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69007 Heidelberg
Germany

28th Global GMP & Regulatory API Conference, 22-23 October 2025 in Barcelona, Spain

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: Annex 1 – Challenges for the API Industry
☐ Session 2: From Data Integrity to Data Governance
Parallel Session B
☐ Session 3: APIC Regulatory Group Activities
☐ Session 4: The Hitchhiker's Guide to Supplier Management
Parallel Session C
☐ Session 5: Risk-based Approach for like-to-like Changes
☐ Session 6: Title tba.
Parallel Session D
☐ Session 7: From Small Generic Molecules to Biosimilars: Understanding Regulatory Differences and Commonalities
☐ Session 8: Title tba.
Parallel Session E
☐ Session 9: Regulatory Starting Materials – Do we all understand the Definition equally?
☐ Session 10: EU Inspector's View on API Manufacturer Inspections

☐ **I also register for the ECA course "The EU Pharmaceutical Legislation Reform: Impact on the API Industry" at the special rate of 1190 € 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)

LW/05052025

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.