

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







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.

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.

Session C

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

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

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

EU Pharmaceutical Package – an Update

Hilde Vanneste, Janssen Pharmaceutica

- 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

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.



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, Janssen Pharmaceutica

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 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



Graca Mata Hovione FarmaCiencia SA, Portugal



Judit Chaves Sandoz Industrial Products, S.A, Spain



Nicola O'Connell Pfizer



Teresa Dannert Alsasua AEMPS, Spain



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



Ilaria Duo *Siegfried AG, Switzerland*



Rob De Proost *J&J Innovative Medicine, Belgium*



Joris Gilberts *Aspen Oss B.V., The Netherlands*



Manuela Schweiger Sandoz GmbH, Austria



Gerold Haake Siegfried PharmaChemikalien Minden GmbH, Germany



Bruno Spieldenner EDQM, France



Andrea Ilumbart Sandoz Industrial Products S.A, Spain



Anthony Storey
Pfizer Ltd., UK



Guillaume Jean *BE-FAMHP, Belgium*



Dieter Vanderlinden Ajinomoto Bio-Pharma Services, Belgium



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



Hilde Vanneste Janssen Pharmaceutica NV, Belgium



Ivica Malnar Halmed, Croatia



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

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

If the bill-to-address deviates from the

specification to the right, please fill out here:

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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For question regarding content:

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For questions regarding organisation etc.:

Ms Sarah Schmidt (Organisation Manager) at + 49 (0) 6221/84 44 16, or at s.schmidt@concept-heidelberg.de

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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		

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Cancellation until 2 weeks prior to the conference 50 %,

Cancellation within 2 weeks prior to the conference 50 %.

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First name, surname

Important: Please indicate your company's VAT ID Number

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Department

Street / P.O. Box

City

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 informe 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).

Zip Code

German law shall apply. Court of jurisdiction is Heidelberg

o APIC Member o ECA Member o Inspectorate

P.O. Number if applicable

Country

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