The EU Pharmaceutical Legislation Reform: Impact on the API Industry

An ECA course prior to the 28th APIC/CEFIC Global GMP & Regulatory API Conference

21 October 2025
Barcelona, Spain

Send us your questions and real-life scenarios/challenges for the break-out sessions!

Highlights

Practical assistance and experiences how to introduce a new intermediate manufacturer and how to deal with a new impurity in your API! Get the information from our speakers about the quality and regulatory perspective of:

- Important changes for the API industry caused by the EU Pharmaceutical Legislation Reform
- Handling revisions of CEPs at EDQM
- API Changes: Validation and Implementation

ECA Academy
Your GMP/GDP Information Source

Objectives

This ECA course provides an overview of the EU Pharmaceutical Legislation Reform and its impact on the API industry – from a regulatory and GMP point of view. During interactive sessions you will get to know:

- Which GMP and regulatory aspects have to be considered to successfully submit a change
- How to introduce a new intermediate manufacturer
- How to deal with a new impurity in your API and what actions have to be taken
- How to define critical quality attributes, critical process parameters, critical material attributes and an accurate control strategy

Furthermore, you will have the opportunity to reach clarification on ambiguous issues by bringing your questions up for discussion during the so-called break-out sessions.

This ECA course ideally complements the following 28th APIC/CEFIC Global GMP & Regulatory API Conference.

Background

The API world is changing rapidly. Nowadays, changes are a daily business in the API industry. Companies are struggling with the challenge of how to implement the new regulations and requirements caused by e.g. reforms of the guidelines. To ensure the quality of their products throughout their life cycles, API changes need to be validated, submitted and implemented successfully. On the one hand, the theoretical obligations need to be considered and well known, while on the other hand the practical implementation needs to be beneficial and manageable in day-to-day API work.

Hot topics are presented in three lectures and two case studies. Additionally, you will have the chance to discuss your own topics with the speakers during the break-out sessions. Besides explaining the requirements of the guidelines of e.g. the revised variations guideline, for the respective themes, the speakers will share their approaches, experiences and best practices on these API related quality and regulatory topics.

Target Audience

This ECA course is designed for all persons involved in the manufacture of APIs, especially for persons from production, quality control, quality assurance, technical and regulatory affairs departments. We are also addressing interested parties from the pharmaceutical industry as well as GMP inspectorates.

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/

Important Information
The presentations will be made available to you prior to the ECA course as PDF files. After the event, you will automatically receive your certificate of participation.

Programme

An Overview of the EU Pharmaceutical Legislation Reform

- Background of the revision
- Key elements of the proposal
- Important Changes for the API industry
  - the revision of the variations guideline
  - the introduction of the API certificate

Handling Revisions of CEPs at EDQM

- Impact of the EU guideline on classification of variations on the EDQM guideline for revisions of CEPs
- Key aspects to submit successfully a change

API Changes: Validation and Implementation

- Defining critical quality attributes, critical process parameters, critical material attributes and accurate control strategy
- Eudralex Vol 4 Annex 15 on process validation
- Implementation steps and performance monitoring
- Use PV and scientific knowledge to implement Lean GMP systems

Break-out Sessions
Take advantage of the **experiences** of our speakers and send us your questions and real-life scenarios/challenges prior to the ECA course. Your questions and examples are appreciated and will be answered as comprehensively as possible by the experts during the break-out sessions and Q&A sessions.

Case Study 1

Introduction of a new Intermediate Manufacturer

- What to do in house: how to validate this change?
- What regulatory actions to take?

Case Study 2

Finding a new Impurity in your API

- What to do in house: how to qualify this impurity?
- What regulatory actions to take?

Speakers

Hélène Bruguera
EDQM, France
Ms Hélène Bruguera worked for the pharmaceutical industry for 10 years in analytical development and in the preparation of the quality part for marketing applications. She joined the EDQM in year 2000, and she is currently the Head of the Certification Department. Ms Bruguera deals with the management of CEP applications as well as the EDQM inspection programme for active substances manufacturers. She is also involved in international platforms related to the quality of medicines and active pharmaceutical ingredients, in particular as member of the ICH QDG and the IPRP Quality Working Group.

Marieke van Dalen
MARA Consultancy, The Netherlands
Ms Marieke van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. Marieke has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.

Francois Vandeweyer
VDWcGMP Consultancy, Belgium
Mr Francois Vandeweyer joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit. Starting from 1995 he joined the QA department. Several Senior Manager responsibilities. 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019 he has been a freelance consultant.

Date ECA course

Tuesday, 21 October 2025, 09.30 - 17.15 h
(Registration and coffee 09.00 - 09.30 h)

All times mentioned are CEST.

Venue

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

Fee

1,290.- EUR per delegate plus VAT.

A special fee of 1,190.- EUR is granted to participants who also register for the 28th APIC/CEFIC Global GMP & Regulatory API Conference.

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

Accommodation

CONCEPT HEIDELBERG 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 you register 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions 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
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

☐ **The EU Pharmaceutical Legislation Reform: Impact on the API Industry,** 21 October 2025 in Barcelona, Spain

☐ **I also register for the 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

☐ 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)

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 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.

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