

*Annual Report*  
*2025 – look back*  
*2026 – look forward*



**APIC**

# APIC's President (Luisa Paulo)



At the end of the year, we need to review what we have accomplished and outline what we plan to do in the year ahead.

The following slides provide more information.



2025 was a successful year, fully aligned with the Strategic Objectives that guided the APIC Board and Leadership Team. The mission was updated to reflect APIC's current direction and thinking.



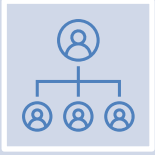
In line with the strategy to become more proactive, a Senior Advisor role was developed, the contract terms defined, and two Senior Advisors selected.



The mission was revised to incorporate sustainability, reflecting APIC's commitment to supporting greater competitiveness within the API industry:

***To promote the use of compliant APIs in medicinal products to ensure patient safety and to represent the interests of the European API industry worldwide by advancing and influencing the global GMP and Regulatory environment through our expertise. To support the sustainability of the European API industry.***

# APIC's President (Luisa Paulo)



Year after year, the active engagement of all members is vital to achieving our objectives. APIC invites all interested members to participate in its Working Groups and Task Forces.



In 2025, the 28th APIC global API Conference was held in Barcelona. For the first time since 2020, it took place as a fully in-person (non-hybrid) event, featuring high-quality presentations on key topics such as mutagenic impurities, data integrity, ICH M4, supplier management, ASMF procedure, and EDQM activities.



In October 2026, we will hold the 29th APIC Global API Conference in Copenhagen, once again as a fully in-person event. We will welcome speakers from industry and Health Authorities who will address key topics such as EU Variations, the ICH harmonization process, cleaning, continuous manufacturing, and real-time release testing, among others.



Thank you for the support and commitment provided by the Board and Leadership Team.

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# Internal changes

## Members

- <https://apic.cefic.org/about-us/members/>
- APIC member companies increased from 76 to 79.
- We welcomed Axplora (DE), Bayer (DE), Chr. Olesen Synthesis A/S (DK).
- <https://apic.cefic.org/about-us/committees/>
- [APIC-organisation-structure](#)

## Digital tools

- Internal Sharepoint sites are continuously being improved upon request by APIC members → [SHP-APIC-all](#)
- Increased use of the APIC Member Forum → <https://www.apicmembers.org/>
- Regular posts on LinkedIn → [APIC-CEFIC | LinkedIn](#)

# Achievements

## New APIC Task Forces

- Bio Specific
- Sustainability

## Re-activation of APIC Task Forces

- Synthetic Peptides
- Oligonucleotides

## APIC Guides and Position Papers

- Quality Agreement Template for Regulatory Starting Materials ("RSMs") and Critical Materials
- Position Paper on recovered solvents

## Authorities

- Continued collaboration with EDQM, EMA, [ICH.org](https://ich.org), Japan, South-Korea, Brazil

## Industry Associations

- Re-established annual meetings with EFPIA and MfE

## APIC annual conference

- Authorities (US, EU,...) and industry speakers
- APIC 28th Conference in Barcelona with 140 participants
- <https://apic.cefic.org/event/apic-28th-annual-api-conference/>

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2026 – look forward*

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# External focus/work areas

## Sustainability

- Monitor, evaluate and comment on the upcoming additional rules that govern (and thus limit) the re-use of solvents

## EU pharmaceutical legislation

- Monitor, evaluate, comment, and drive the implementation of the pharmaceutical legislation

*Annual Report*  
*The End*

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