

Annual Report
2024 – look back
2025 – look forward



APIC

APIC's President (Luisa Paulo)

As another year begins, we take a look back over the past year and look forward to what lies ahead.

This is what you can expect to see in the following slides.
However, I would like to give some additional information.



In 2024, we began implementing some of the strategic objectives defined in 2023, namely, to increase contact with other industry associations including the ones in India and China.



In 2025, we will continue to implement our strategic objectives, specifically on topics such as sustainability, in direct collaboration with CEFIC and EFCG.



In 2025, we will continue to issue new and revised guidances with the collaboration of all APIC members.

APIC's President (Luisa Paulo)



As an organisation, APIC counts on the support and active participation of all members in the Working Groups and Task Forces.



In 2024, the 27th APIC global API Conference was held in Vienna. This was a hybrid conference, with very good presentations and discussions, bringing some very important topics to the industry's attention, specifically PFAS, Perls and sustainability.



In October 2025, we will hold the 28th APIC global API Conference in Barcelona. We remind you of the importance of participation in this event. Speakers from industry and Health Authorities from all over the world will give very interesting and helpful lectures, discussing the latest developments in GMP and Regulatory Affairs.



Only with the commitment and dedication of all of us will we achieve our Mission:

To promote the use of compliant API in medicinal products, to ensure patient safety, and to represent the interests of European-based companies producing APIs globally, by being recognised experts, who advance and influence the global GMP and Regulatory environment.



Thank you all for your confidence in choosing me!

*Annual Report
2024 – look back*



APIC

Members

- <https://apic.cefic.org/about-us/members/>
- Increased from 71 to 77 !
- We welcomed Ardena Oss and Pharmaron, and Abifina, BDMA, JAPTA, KPTA as partners.
- <https://apic.cefic.org/about-us/committees/>

Digital tools

- Internal Sharepoint sites are being reshaped
- Increasing use of the APIC Member Forum
<https://www.apicmembers.org/>
- LinkedIn posts

Achievements

New APIC Task Forces

- Sustainability WG (reusable / sustainable solvents)
- Quality in Clinical Manufacturing TF

New/updated APIC guides

- [ICH Q7 HTD](#)
- [Data Integrity](#)
- [Supplier Management](#)
- [Quality Agreement](#)

Authorities

- Continued collaboration with EDQM, EMA, [ICH.org](#), Japan, South-Korea, Brazil
- New contacts with Chinese and Indian Authorities

APIC annual conference

- Authorities (US, EU,...) and industry speakers
- APIC 27th Conference in Vienna with 104 participants
- <https://apic.cefic.org/event/apic-27th-annual-api-conference/>

External challenges

PFAS

- Supporting EFCG on the assessment of impact of the upcoming limitations towards the future manufacture and availability of APIs

Nitrosamines

- Continuing to gather the differences in regional expectations and negotiating for harmonisation

Industry Associations

- Annual meetings with EFPIA and MfE have been initiated again

*Annual Report
2025 – look forward*



APIC

Internal changes

Strategy

- Finalised APIC's renewed strategy (linked to the renewed Mission and Vision) and issued a final document
- Continued with the implementation of some objectives

Roles

- Finalised the roles & responsibilities of APIC's Leadership team and issued a final document

Communication

- Optimised internal and external communication and meetings

Digital tools

- Further optimisation of internal Sharepoint site
- LinkedIn for APIC
- <https://www.linkedin.com/company/apic-cefic/>

Internal challenges

Leadership

- Leadership team, Board members and Task Force leaders elected for 2 years. Next elections will take place at the end of 2025. We will call for volunteers.

Face-to-Face

- Limitations on travel (budget) of APIC members and thus limitation on face-to-face meetings – replaced by hybrid or 100% remote.
- Therefore we organised our bi-annual WG meetings together with as many TF meetings as possible.

External challenges

PFAS

- Continuing to follow-up the evolution of potential limitations, together with EFCG
- Providing awareness within APIC membership

Nitrosamines

- Continuing to gather the difference in regional expectations and negotiating for harmonisation

External focus/work areas

Authorities

- Continuation of the good relationship and collaboration with EDQM
- Deepening the relationship with EMA and other authorities

Industry Associations

- Further develop the relationship with other industry associations (USA, Indian and Chinese)
- Promote meetings to align on common ground for the most critical topics that are affecting API industry

Annual Report
The End



APIC