

Annual Report
2023 – look back
2024 – 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 2023, in a world that is continually evolving, APIC introduced a new organisational structure, to provide better support to our members. An Advisory Committee composed of former APIC presidents was created to maintain know-how and advise newcomers.



In 2024, the Board will propose to the General Assembly that we appoint an Advisor – someone from the industry with good technical skills, who will assist in the review of Guidelines and consolidation of comments, contribute to newsletters and presentations, and generally provide extra support where needed.



In 2023, APIC's Operating Rules were reviewed, giving the members of the General Assembly the power to set and control the priorities and activities of the organisation. As in the past, the General Assembly will approve the budget and elect Board members proposed by the President.

APIC's President (Luisa Paulo)



Also in 2023, a new strategy was consolidated, which will be presented to the General Assembly for approval in November this year. The APIC Board, a team I am proud to lead, is confident that the new strategy will bring a breath of fresh air and better service to the API industry.



As an organisation, APIC counts on the support and active participation of all members in the working groups and task forces.



In October 2024, we will hold the 27th APIC global API conference in Vienna. 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 we will 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 recognized experts, who advance and influence the global GMP and Regulatory environment.



Thank you all for your confidence in choosing me!

*Annual Report
2023 – look back*



APIC

Internal changes

Members

- <https://apic.cefic.org/about-us/members/>
- Increased from **67** to **70** (3 new members)
- **We welcomed Biospring, CordenPharma, K+S Minerals**

New organisation structure

- <https://apic.cefic.org/about-us/committees/>
- Clearer structure and roles
- Increased "leadership" capacity

Updated operating rules

- Simplified
- More democratic
- More power to APIC's General Assembly



Adobe Acrobat
Document

Digital tools

- Internal Sharepoint sites are being reshaped
- Extranet forum has been reactivated and usage (number of posts) is increasing → <https://www.apicmembers.org/>

Achievements

(Re)new(ed) APIC initiatives

- New Task Force Synthetic Peptides
- New Task Force Digitalisation
- Reactivation Task Force Cleaning validation
- Reactivation Task Force Good Distribution Practices

New/updated APIC guides

- ICH Q7 HTD
- Data Integrity
- Supplier Management
- Quality Agreement

Authorities

- Continued collaboration with EDQM, EMA, [ICH.org](https://ich.org), Japan, South-Korea, Brazil
- Initial contact with Chinese and Indian Authorities

APIC annual conference

- Authorities (US, EU, JP, BR,...) and industry speakers
- 122 participants last year (81 on-site + 41 remote)
- <https://apic.cefic.org/event/apic-26th-annual-conference/>

External challenges

PFAS

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

Nitrosamines

- Task Force Nitrosamines
- Continued to gather the differences in regional expectations and negotiating for harmonisation

Industry Associations

- Initial queries on how APIC can improve collaboration with other industry Associations

*Annual Report
2024 – look forward*



APIC



Internal changes

Strategy

- Finalise APIC's renewed strategy (linked to the renewed Mission and Vision)
- Continue with the implementation

Roles

- Further elaboration on roles & responsibilities of APIC's Leadership team

Communication

- Optimisation of internal and external communication and meetings

Digital tools

- Further optimization of internal Sharepoint site
- LinkedIn for APIC (re)activated
- <https://www.linkedin.com/company/apic-cefic/>

Internal challenges

Leadership

- Some senior and seasoned APIC leaders will leave, with opportunity for new members to step into leadership roles

Face-to-Face

- Limitations on travel (budget) of APIC members and thus limitation on face-to-face meetings

External challenges

PFAS

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

Nitrosamines

- Task Force Nitrosamines
- Continue 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 relationship with EMA
- Further expanding the relationship with Authorities, e.g. South-Korea, China, India

Industry Associations

- Further develop relationship with other industry Associations
- Promoting meetings to align on a common ground, for the most critical topics that are affecting API industry

Annual Report
The End



APIC