APIC

active pharmaceutical ingredients committee

25 years of promoting patient safety

specialty chemicals

CEFIC SECTOR GROUPS

Who is APIC?

The Cefic* Sector Group APIC (the Active Pharmaceutical Ingredients Committee) was founded in 1992 as a direct consequence of the rapidly increasing European regulations affecting the manufacture of Active Pharmaceutical Ingredients (APIs).

APIC represents producers of APIs and API intermediates in Europe. Its membership consists of more than 60 companies, located all over Europe, and of several national industry associations.

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.

Mission statement

- To promote the use of compliant APIs in medicinal products to ensure patient safety.
- To represent the interests of its members by being recognised experts who advance and influence the global GMP and Regulatory environment.

Strategic objectives

- Networking/Advocacy: To continually improve contacts and to increase the profile of APIC.
- Level Playing Field: To strongly advocate compliance in all global markets and its enforcement through inspection.
- Post approval change authorisation: To put the responsibility to manage change into the hands of industry.
- Harmonisation: To support global harmonisation in the fields of quality and regulatory affairs.

- Cefic (the European Chemical Industry Council): The Brussels-based organisation that represents the European Chemical Industry

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Strengths

- Continuous awareness of and communication on new regulations affecting APIs.
- Large network of contacts with health authorities worldwide as well as with other industry stakeholders.
- Very active and pro-active role in defending the interests of APIC manufacturers from a perspective in which the safety of patients is taking the central position.
- High integrity.
- Expertise and technical knowledge of its members.

Major achievements

As an industry leader APIC is responsible for the following achievements amongst many others:

- Contributed to the adoption of ICH Q7 – developed 'How to do' industry guide to Q7.
- Developed and launched the Third Party 'APIC Audit Programme'.
- Issued a "Quality Agreement Guideline and Template" – extensively used by API companies and their customers.
- Supports and inputs into ongoing improvement of Certificate of Suitability (CEP) system and procedures.

APIC structure

Reporting to APIC's Executive Committee are its two main working groups as well as other ad-hoc Task Forces:

- Working Group on Regulatory Affairs
- Working Group on Quality / GMP

learn more on apic.cefic.org

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