The APIC Audit Programme

Independent GMP Audits
Cost Reduction
Certified Auditors

Third Party Audits of API Manufacturers,
Distributors
and Contract Laboratories

Coordinated by:

API Compliance Institute
A Division of CONCEPT HEIDELBERG

www.api-compliance.org

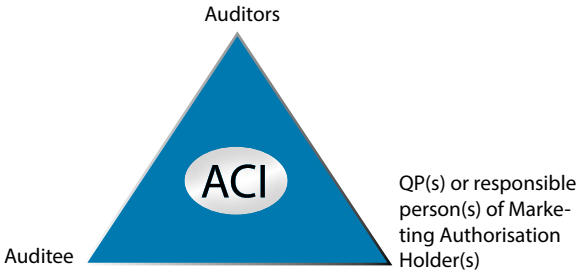
The APIC Audit Programme developed by APIC/CEFIC

The "***APIC Audit Programme***" is an independent third party audit programme for auditing API manufacturers, distributors and API contract manufacturers and/or contract laboratories.

This programme was developed by APIC/CEFIC in line with the European Authorities guidances. The APIC „the Active Pharmaceutical Ingredients Committee" is a sector group within CEFIC (the European Chemical Industry Council).

Every manufacturer of medicinal products needs to verify the GMP compliance status of all the APIs used in manufacturing. In Europe, this is the role of the Qualified Person (QP) to verify the GMP compliance of the APIs used before releasing a batch.

The Compliance Triangle Principle as illustrated below is followed at all steps of the audit process.



API audits will be conducted worldwide. The API Compliance Institute (ACI) will coordinate the audit process.

The participation in the "APIC Audit Programme" is on voluntary basis and not limited to members of APIC.

Acceptance by the Authorities

EU and FDA Regulators emphasized that Third Party Audits are accepted. The approach of Third Party Audits is already included in the EU Directive 2001/83.

The 3 Options

Option 1:

Third Party Audit: A single customer (manufacturer of medicinal products) wants to audit the manufacturing site of his API supplier.

2 day Audit performed by one auditor.
Fee 1,600 Euro per day*

Option 2:

Shared Audit: Several customers (manufacturers of medicinal products) want to audit the manufacturing site of their API supplier.

2 day Audit performed by two auditors.
Fee 1,600 Euro per day and auditor*
The costs for the audit will be shared.

Option 3:

Mock Inspection: An API manufacturer wants to know if its company meets the ICH Q7 requirements.

2 day Audit performed by one auditor.
Fee 1,600 Euro per day*

In all cases the API Compliance Institute (ACI) will coordinate the audit process.

Reduce Audit Burden and Costs

As described above in Option 2, Third Party Audits can be performed as a shared audit. The costs will be shared between the customers.

Certified Auditors

The audits will be conducted by auditors registered as APIC Certified Auditors. APIC Certified Auditors will undergo extensive training programmes. Learn more about the qualification and certification scheme here - https://www.ichq7-week.org/

Validity

The basic audit report is valid for three years.

Follow-Up Audits

The customers will decide on need for follow-up audit and timing of next periodic audit.

*The costs for travel and accommodation as well as for the audit report will be charged additionally.

The APIC Audit Programme – More Details

You will find more information about the APIC Audit Programme here - https://www.apic.cefic.org/publications.html

Contact

If you are interested in joining the APIC Audit Programme, please contact us for further information:

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APIC Active Pharmaceutical Ingredients Committee

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