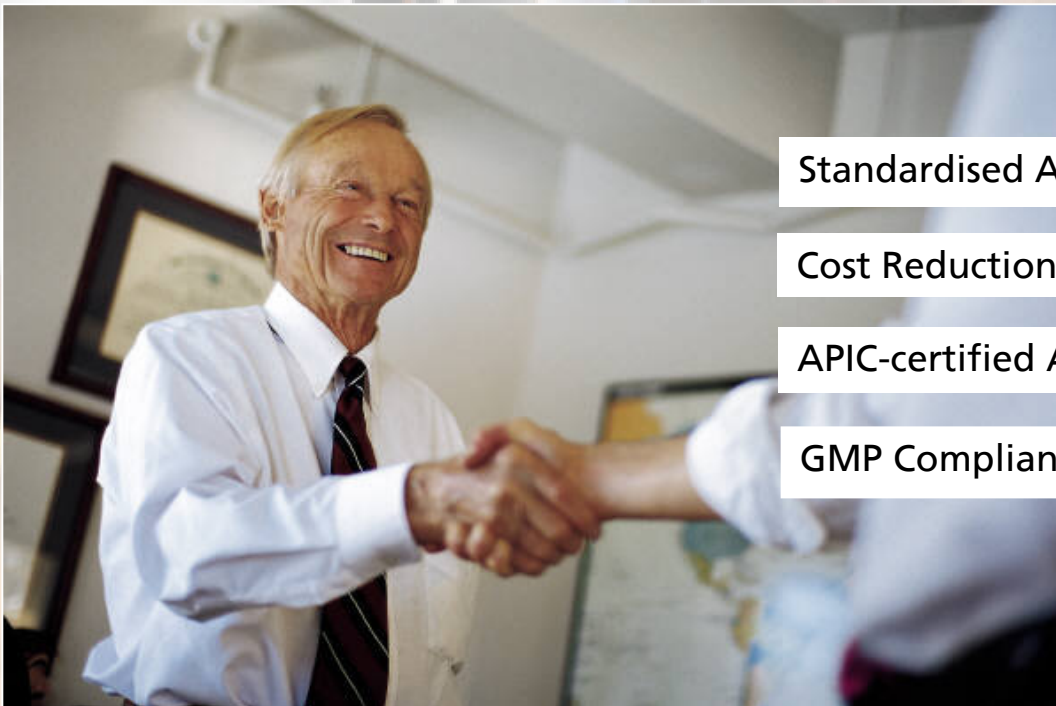


# *The APIC Audit Programme*



Standardised Audits

Cost Reduction

APIC-certified Auditors

GMP Compliance Evaluation

A Third Party Audit Programme for  
API Manufacturers

An Initiative of APIC in co-operation with  
CONCEPT HEIDELBERG

**APIC** Active Pharmaceutical  
Ingredients Committee  
A sector group of



## What is the "APIC Audit Programme"?

The "APIC Audit Programme" is a third party audit programme for auditing API manufacturers.



This programme was developed by APIC/CEFIC in co-operation with CONCEPT HEIDELBERG. It is the aim of the APIC Audit Programme to provide independent audit reports that the API manufacturer can pass on to pharmaceutical companies for their supplier qualification. The participation in the "APIC Audit Programme" is on voluntary basis and not limited to members of APIC.

## How can GMP audits be standardised?

There are three basic principles of the "APIC Audit Programme" for standardizing audits:

- ✓ experienced and trained auditors that are registered as APIC certified auditors
- ✓ standardised process for preparing audits
- ✓ release of audit report by experienced API specialists of CONCEPT Heidelberg

The audits are conducted by APIC certified auditors

- who have the professional experience,
- who have completed an ICH Q7a compliance education course and a special APIC Auditor Training
- who have participated in regular auditor refresher seminars.

The audits are conducted on the basis of the **ICH Q7a (Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients)** with regard to the APIC Auditing Guide.

## Save money and optimise the GMP Audit

The aims of The "APIC Audit Programme" are:

- ✓ standardised GMP audits of API manufacturers
- ✓ minimised costs by
  - decreasing the frequency of audits when making the audit report available to pharmaceutical companies
  - standardized costs for audits



## What do others think about this programme?



Similar programmes have already been established in other areas:

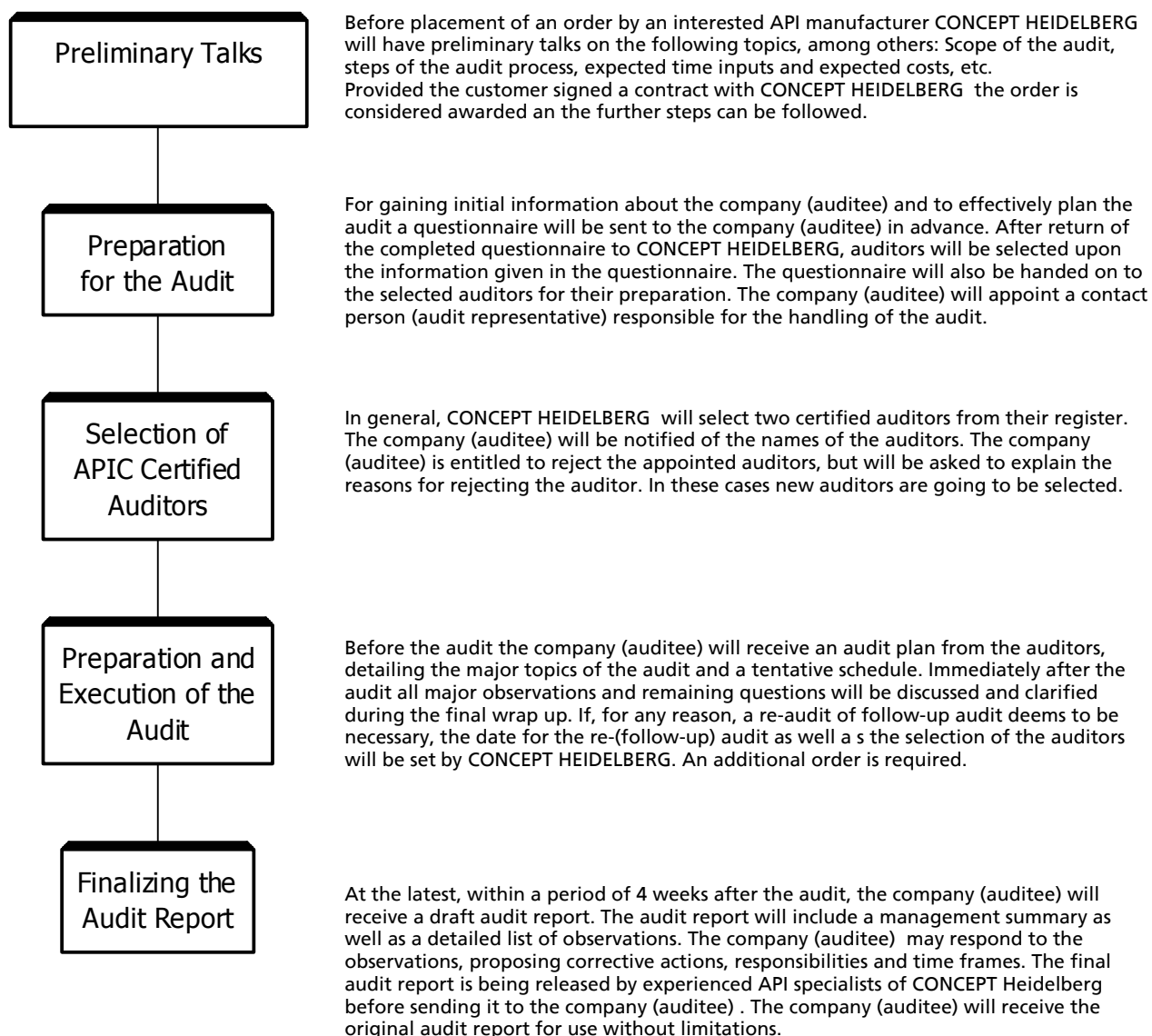
ARC (Audit Repository Center), a PDA-associated company, offers auditing programmes for the audit of software suppliers, the IPEC (International Pharmaceutical Excipients Council) provides Third Party Auditing Programmes for excipient suppliers. With regard to the acceptance of Third Party Audits IPEC member *Irwin Silverstein* said "lawyer with both industry and FDA experience have been involved in developing the program and (that) nobody has raised a concern that the third party audit would present more of a problem than having your own people do the same audit". (Gold Sheet, Vol 34, No. 1, January 2000)

## The "APIC Audit Programme" - Step by step -

A GMP audit can be initiated by but is not limited to:

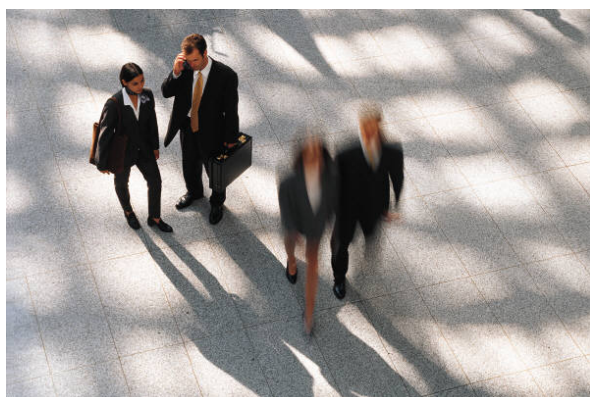
- Manufacturer of active pharmaceutical ingredients
- Agents, brokers, distributors, repackers and relabellers of APIs
- Contract manufacturers of API manufacturers
- Contract laboratories of API manufacturers

The following flow chart describes the steps from the initial contact with the company (auditee) throughout the finalisation of the audit report:



## The Auditors

In general, the audits will be conducted by two auditors who are registered as APIC certified auditors.



**APIC certified auditors** will undergo extensive training programmes as described on page 2 of this brochure and have to verify their professional experience.

APIC will authorise a register of certified auditors who are allowed to conduct the audits within the framework of the "APIC Audit Programme".

## Validity

The basic audit report is **valid for three years**. Prior to the expiration, a new audit for the renewal of the validity can be carried out at the company's (auditee's) site.

## Costs

The average costs for a GMP Audit conducted by two qualified APIC auditors will be EURO 8.400,-- plus VAT plus travel expenses.



## Contact

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

**CONCEPT  
HEIDELBERG**

OR

**APIC** Active Pharmaceutical  
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