

# The APIC Audit Programme

## *Annex 2*

### Agreement on Audit Execution

between

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**(Qualified Person (QP) of the Manufacturing Authorisation Holder or responsible person of the API manufacturer, hereinafter referred to as "Customer".)**

In case of more than one customer('shared audit') all 'customers' have to be listed here or separate agreements are signed for reasons of confidentiality.

and

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**(Material Manufacturer to be audited, hereinafter referred to as "Auditee")**

When the Material manufacturer initiated an audit himself for the purpose of 'self-inspection', the Material manufacturer becomes 'customer' and 'auditee' at the same time.

and

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**Lead Auditor**

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**Co-Auditor**

**and**

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**API Compliance Institute  
Rischerstraße 8  
D- 69123 Heidelberg  
(hereinafter referred to as "ACI" )**

## **§ 1. Subject of the Agreement**

An audit will be conducted on behalf of the Customer by APIC Certified Auditor(s) in order to verify the degree of compliance of the auditee with the relevant cGMP guidance. The observations of the auditors will be compiled in an audit report, which will be sent to the auditee no later than 3 weeks after completion of the audit. Any cGMP deficiencies found during the audit will be classified by the Auditors and reported in the closing meeting of the audit.

If the customer wishes that specific cGMP topics relevant to their products are assessed during the audit, these specific points should be amended at the end of this contract. The amendment is issued to the auditors only and a report on these specific points has to be documented separately by the auditors and reported only to the specific customer.

## **§ 2. Selection of Auditors**

The customer and the auditee reserve the right to refuse an auditor selected by the ACI. An auditor cannot be recruited, if his employer is in competition to the customer and/or the auditee and/or the Auditor has performed consulting activities for the customer and/or the auditee for at least five years before the planned audit.

## **§ 3. Date of the Audit**

The audit date(s) will be arranged between the auditee and the Auditors after signing of the agreement on audit execution and after agreement to the nominated auditors by the auditee and the customer.

## **§ 4. Audit Report**

The audit report prepared by the auditors will give objective evidence of any cGMP Deficiencies found during the audit and each deficiency will be classified. The auditee will respond to the deficiencies within 7 weeks after the audit and provide the CAPAs incl. Target date, the auditors will ensure that a response has been received for each deficiency and will then sign the final report and return to the ACI. The ACI will then send copies of the signed audit report to the customer(s) and auditee 9 weeks after the audit. The original audit report will be archived by the API Compliance Institute for 10 years. If the CAPAs for the deficiencies have not been received within this time frame the audit report will be signed by the auditors and sent without the CAPA list to the customers. The CAPA list will then be forwarded by the ACI to the customers once the CAPA list has been prepared by the auditee. Independent from the time line the auditors will ensure that a response has been received for each deficiency.

## **§ 5. Audit Follow Up**

The customer is responsible to review the proposed actions included in the audit report by the manufacturer to ensure that the audit deficiencies have been adequately addressed in relation to the cGMP Status of the material(s)

The manufacturer is responsible to provide to each customer periodic updates of progress with the corrective actions based on the timelines proposed in the audit report.

The customer is responsible for follow up to check that corrective actions have been appropriately addressed in a timely manner.

The customer is responsible for follow up and closure of CAPA's resulting from the audit and will also decide if a specific follow up audit related to the deficiencies is necessary. Within 3 years after the audit took place the API Manufacturer is obliged to inform the ACI about any major changes to the scope covered by the audit report (examples are: changes in the manufacturing process/location and specifications)

## **§ 6. Costs**

XXX Euro including travel costs per Day and Auditor for one customer audit. Depending on the scope/time of the audit and number of auditors a justified cost proposal will be made by ACI".

In case of intercontinental traveling (outside Europe and the African countries adjacent to the Mediterranean) an extra charge of XXX Euro will be invoiced.

## **§ 7. Mode of payment**

The mode of payment is agreed as follows:  
100% on placement of order without deductions. The payment must be received before the audit is conducted.

## **§ 8. Confidentiality**

Part of this agreement is the secrecy agreement which will be signed by the customer, the auditee and the auditors (see a proposed agreement in Annex 3). The ACI undertakes not to disclose any specific information related to the customer and/or the auditee especially such as audit reports, to any other party unless all parties agree to sharing of the audit report.

## **§ 9. Liability**

1. The ACI shall be held liable in causes to the customer and/or the auditee during the implementation of the Agreement only to the extent that they are the result of gross negligence. In case that the ACI shall be held liable the extent is limited to the costs mentioned in section 6.
2. The ACI shall not be held liable for claims by the Company regarding insufficient performance by the Auditors.
3. The ACI shall not be held liable for unsuccessful inspections by authorities after having been audited under this agreement.
4. The ACI shall not be held liable in the case of users of the audit report are taking measures leading to any kind of financial impact on the Company.

**§ 10. Copyright**

Following the Compliance Triangle Principle, the copyright of the audit report will be shared by the API Compliance Institute, the customer(s) and auditee. Herewith the undersigning parties agree that the audit report may be issued to subsequent customers of the auditee. Any requests to pass on the audit report to subsequent Third Parties should be made to the API Compliance Institute. The ACI will archive the original audit report for a period of 10 years. Copies of the audit report may be shown on request to Inspectors during inspection.

**§ 11. Written form**

All modifications and amendments to this offer are only effective if they are agreed upon by the parties involved in writing.

**§ 12. Legal venue and applicable law**

Legal venue for any disputes shall be Heidelberg. The laws of the Federal Republic of Germany are applicable.

**§ 13. Salvatory clause**

Should any of the above provisions in this Agreement be invalid this shall not impair the validity of this Agreement. It is to be substituted by the provisions coming closest to the intention of both parties which has to be laid down in writing.

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Place, date and signature of the Customer

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Place, date and signature of the Auditee

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Place, date and signature of Lead Auditor

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Place, date and signature of Co-Auditor

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Place, date and signature of ACI

## **Amendment to Audit Agreement**

The customer should describe in the section below any cGMP Topics specific to their use of the product(s) that should be reviewed by the Auditors during the audit. The Auditors will provide a separate report on these points only to the relevant customer.

Specific cGMP Topics to be covered:

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Place, date and signature of the Customer