



The APIC Audit Programme

Annex 2

Agreement on Audit Execution

between

(Qualified Person (QP) of the Manufacturing Authorisation Holder, hereinafter referred to as "Customer".)

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

and

(API manufacturer to be audited, hereinafter referred to as "Auditee")

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

and

Lead Auditor

Co-Auditor

and

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

§ 1. Subject of the Agreement

A two-day GMP audit will be conducted on behalf of the Customer by two APIC Certified Auditors in order to verify the degree of compliance of the auditee with the ICH Q7A Guide "GMP for APIs". The observations of the auditors will be compiled in an audit report, which will be sent to the customer and the auditee no later than 3 weeks after completion of the audit. Any GMP 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 GMP topics relevant to their Medicinal Products Manufacturer 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 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 GMP Deficiencies found during the audit and each deficiency will be classified. The auditee will respond to the deficiencies within one month, 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. The original audit report will be archived by the API Compliance Institute for 7 years.

§ 5. Audit Follow Up

The customer's Qualified Person(s) is responsible to review the proposed actions included in the audit report by the API manufacturer to ensure that the audit deficiencies have been adequately addressed in relation to the GMP Status of the Active Pharmaceutical Ingredients used in the Manufacture of the relevant Medicinal Products.

The API 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 will also decide if a specific follow up audit related to the deficiencies is necessary.

§ 6. Costs

The costs of the audit are € 8.400,-- plus value added tax for a one customer audit.

The costs for a shared audit depend on the number of QP(s) involved. The costs of the audit will be divided through the number of QP(s) involved. A handling fee of €200 will be added per customer.

Example:

Shared audit with 4 QP(s) (customers):

€8,400 : 4 = € 2,100 + €200 (handling fee) = €2,300 per customer.

In case of intercontinental traveling (outside Europe and the African countries adjacent to the Mediterranean) an extra charge of 1.200 € will be invoiced.

Additional costs in form of expenses (e.g. hotel and traveling) will be invoiced separately.

§ 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.

Any requests to pass on the audit report to subsequent Third Parties should be made to the API Compliance Institute.

Written agreement will be required from the customer(s) and auditee before the audit report may be issued to a subsequent Third Party.

The ACI will archive the original audit report for a period of 7 years.

Copies of the audit report may be shown on request to European Member State Inspectors during inspection of the Medicinal Product Manufacturers.

§ 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.

Place, date and signature of the Customer

Place, date and signature of the Auditee

Place, date and signature of Lead Auditor

Place, date and signature of Co-Auditor

Place, date and signature of ACI

Amendment to Audit Agreement

The customer should describe in the section below any GMP Topics specific to their use of the Active Pharmaceutical Ingredients 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 GMP Topics to be covered:

Place, date and signature of the Customer