



The APIC Audit Programme

Annex 1

Contract between Auditor and the API Compliance Institute

AGREEMENT

between

(hereinafter referred to as the "Auditor")

and

**API Compliance Institute
Rischerstr. 8
69123 Heidelberg**

(hereinafter referred to as the "ACI")

§ 1 Nature of the Agreement

The parties agree on a co-operation defined within the framework of this agreement for conducting audits by the Auditor on behalf of the ACI. This agreement defines the tasks and obligations of the Auditor. It does not define any obligation for the ACI to assign the Auditor on a regular basis.

Both parties intend to continue this co-operation for further audits unless one of the options described in §10 apply.

§ 2 Obligation of the Auditor

The Auditor must have a valid certificate for auditing, issued by CEFIC/APIC.

The Auditor will act independently of the ACI during the audits; he is not bound to any instructions and takes all assessments based on his/her own judgment.

The Auditor cannot be recruited for an audit if his/her employer is in competition to the Auditee. By signing this Contract, the Auditor undertakes to confirm that he/she has not performed consulting activities for the customer and/or Auditee for at least five years before agreeing to take part in an APIC Third Party Audit.

§ 3 The Audit

The ACI will assign audits to the Auditor based on the demand and availability of the Auditor. The ACI will determine if the Auditor acts as lead Auditor or Co-Auditor for a certain audit.

Before assignment the ACI will check the availability of the Auditor.

§ 4 Tasks of the Auditor

The Auditor shall perform audits for the number of days specified by the customer and the Auditee as confirmed by the ACI.

The ACI will send the completed pre-audit questionnaire together with the accompanying documents from the Auditee to the Auditors for the purpose of preparation. It is expected that the Auditors will familiarise themselves with the information provided by the Auditee prior to the audit. The Auditors may require additional information from the Auditee. Therefore, the Auditors may get in direct contact with the audit responsible person of the Auditee. After the completion of the Audit, the Auditors shall return the questionnaire and the accompanying documents to the ACI.

The Auditor will be informed of his / her partner by the ACI in due time.

The Auditor(s) provide(s) an agenda to the Auditee and Customer and seek(s) for agreement before the audit.

Details of the audit, including shifting of days, may be arranged by the Auditor(s) and the Auditee / customer themselves together with a notification to the ACI.

It is the responsibility of the Auditor(s) to provide an Audit Report no longer than 3 weeks after the audit was conducted. The deficiencies noted during the audit must be classified and reported verbally at the audit closure meeting.

The Auditor(s) are responsible to ensure responses are given by the Auditee to any GMP deficiencies included in the audit report.

§ 5 Charging

The Auditor will be paid EUR 600,-- per day for each day of the audit. In addition he will receive a single payment of EUR 600,-- for preparation of the audit and preparing the Audit Report.

In cases of intercontinental traveling (outside Europe and the African countries adjacent to the Mediterranean) the Auditor will receive an additional payment of one day. The amount of payment will be negotiated on an individual basis.

The charging will be done after the final Audit Report is provided.

In cases the preparation of the Audit Report will be delayed (i.e. more than 3 weeks) the Auditor(s) payment will be reduced by half of his daily charge for each week of delay.

§ 6 Reimbursement of Travel Costs

The customer will administer travel arrangements and the hotel accommodation for the Auditors. This will ensure that the costs are in line with the travel policy of the customer and that costs are minimised. Costs not directly paid by the customer will be reimbursed by ACI. Costs will only be reimbursed on the basis of receipts.

§ 7 Confidentiality

The parties undertake to maintain reciprocally strictest confidentiality about the business matters and trade secrets of all involved parties, the auditors, the customer(s) and the auditee.

Confidentiality in the course of the co-operation remains even beyond termination of the co-operation, unless purpose and object of the agreed co-operation demand otherwise and thereafter only after an appropriate understanding has been reached.

Any departure from this paragraph requires prior written consent of the contractual partners.

The ACI shall not be liable for compensation for this confidentiality obligation.

The Auditors are obliged to sign a secrecy agreement with the customer and/or Auditee for each audit. A proposed secrecy agreement is available in Annex 3 of the APIC Audit Programme.

§ 8 Liability for withdrawal and non-performance

Should any of the parties to this Agreement withdraw from the Agreement or not perform its contractual duties it shall be liable to indemnify the other party for any damage arising from it.

§ 9 Issuing of statements

Neither the Auditor for the ACI nor the ACI for the Auditor are authorised or empowered to represent the respective other party in legal transactions or to issue statements of knowledge and/or consent and/or perform other actions in the name of the respective other party.

In order to avoid misunderstandings, this factor will be emphasized appropriately at all times vis-a-vis third parties.

§ 10 Cancellation

The agreement becomes invalid with immediate effect if the Auditor does not renew his certification by participating regularly (at least every three years) in a recognized GMP Conference/Course and reporting the number of audits performed during this period.

The Auditors may terminate the agreement at any time by notifying the ACI in writing.

The ACI is allowed to cancel the agreement in cases of serious concerns about the Auditors ability of auditing, knowledge about the subject and/or behaviour towards the Auditee or the customer. In case of disagreement by the Auditor, CEFIC/APIC will take a definite decision.

§ 11 Place of Jurisdiction

The venue for any legal action shall be Heidelberg, Germany. This Agreement shall be governed by German law.

Date, Location, Signature of the Auditor

Date, Location, Signature of ACI