The APIC Audit Programme

<Company>

<Date>

Third Party Audit / Shared Third Party Audit at <API supplier>

Dear Sir, dear Madam,

Thank you for your request to coordinate a Third Party Audit at the API production site of <API supplier>.

The API Compliance Institute (ACI), located in Heidelberg, Germany has developed the Third Party Audit Programme in partnership with the CEFIC Active Pharmaceutical Ingredients Committee. Please find details of this audit program in the attachment and on the ACI website **www.api-compliance.org/.**

An audit of the Active Pharmaceutical Ingredient (API) supplier is an integral part of the supplier qualification procedure. This audit is either conducted by the Qualified Person, by the Company Auditors or by an Independent Third Party as a means to follow the Guidance of the European Authorities (EMA) on assessing the GMP status of an API supplier.

There exists another option which other firms have found to be acceptable to the European Authorities for meeting the GMP Assessment requirement for Manufacturing Authorisation Holders, that being:

- **Shared Third Party Audits,** which are acceptable to the European Authorities as long as:
  1) No conflict if interest is guaranteed
  2) the Qualified Person (mandatory in EU) or accountable Quality Responsible Person of each Manufacturing Authorisation Holder ensures that the scope of the audit is applicable to each Medicinal Product that uses the API as a Starting Material.

A Shared Third Party Audit in which more of <API supplier's> customers could participate would be of benefit for you as it will reduce the audit fees. The more sharing partners participate in the Shared Third Party Audit the lower the costs for the audit will be. Please find attached example calculations for a standard Third Party Audit (2 auditors 2 days) shared by 2, 3 and 5 sharing partners. It will also be beneficial to <API supplier> in terms of reducing the number of audits they require to host from their customers.

Therefore we would like to ask whether you agree to the participation of other Manufacturing Authorisation Holders which are supplied by <API supplier> within a Shared Third Party Audit at the <API supplier's> site.

The Audit Program includes Strict Controls over Confidentiality – both in terms of the API Process Confidentiality and Customer Confidentiality. The controls include Signed Confidentiality Agreements with the independent auditors who will have no conflict of interest with the API Supplier or their customers and who will sign to assure that process confidentiality will be maintained. The customer(s) receives insight in the auditor(s) expertise and can react upon. There will be separate Audit Agreements with each customer. The program intends to be flexible in relation to the customers needs. The ACI will be pleased to provide you with more details of these controls.

Please note that the APIC Third Party Audit program is only fully accepted by the European Authorities if the Manufacturing Authorisation Holder initiates the Third Party Audit / Shared Third Party Audit process. So please confirm that you are the Manufacturing Authorisation Holder in Europe – or specify the market country (s) if audit against other HA standards is required - for the final dosage forms which are manufactured using the APIs from <API supplier>.

We have attached an example of the Audit Agreement that can be signed separately for each customer to protect confidentiality and there is a section for each customer to define specific points that should be covered by the auditors.
If you are interested in entering into a Shared Third Party Audit process please let us know. The ACI will then coordinate the participation of other sharing partners within a time window to be determined.

We are looking forward to hearing from you.

Best regards,

i.V. Dr. Gerhard Becker
Project Manager

API Compliance Institute