The APIC Audit Programme

<API Supplier>

<Date>

Third Party Audit / Shared Third Party Audit at your API production site

Dear Sir, dear Madam,

Recently we received a request for a Third Party Audit by <company> who is one of your customers. The scope of the audit <company> wants to have covered is the following:

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The API Compliance Institute (ACI), located in Heidelberg, Germany has developed a Third Party Audit Program 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/.**

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 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(s) needs. The ACI will be pleased to provide you with more details of these controls.

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 of 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 your customers could participate would be of benefit for you as it will reduce the numbers of audits at your site. Therefore we would like to ask whether you

- agree in general to a Shared Third Party Audit
- can identify more of your customers as potential sharing partners for the Third Party Audit at your site.

We have attached an example of a standardized letter which you may use to approach those of your customers who you identified as potential sharing partners.

If you are interested in entering into a Shared Third Party Audit process please let us know. The ACI will then coordinate the Audit at your production site together with those of your customers interested in sharing the Third Party Audit.

We are looking forward to hearing from you.

Best regards,

The APIC Audit Programme

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