

## <API Supplier's Logo & Address>

<Date>

Dear Customer:

According to the current European Union Law (Directive 2001/83/EC and Directive 2001/82/EC) manufacturers of medicinal and veterinary products for sale in the EU are required to use only APIs that have been produced in compliance with Good Manufacturing Practices (ICHQ7, EU GMP Guide Part II).

An audit of the Active Pharmaceutical Ingredient (API) supplier is an integral part of the Manufacturing Authorisation Holder's 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.

<API supplier>, as a global supplier of APIs is aware of these requirements, and is committed to assisting our customers in meeting their GMP commitments. Traditionally, we have done this by hosting at our manufacturing sites direct **Customer** or "**Second Party**" audits of our GMP systems and facilities.

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.

<API supplier> has reviewed the concept of the Shared Third Party Audit process for the <location> manufacturing site. It is believed that the Shared Third Party audit process will be of benefit to our Customers. This would allow for several Manufacturing Authorisation Holders to "conduct" an audit of the <location> manufacturing site for the API starting material purchased in a cost and resource efficient manner, with timeliness far greater than we can accommodate individual audits.

The API Compliance Institute (ACI), located in Heidelberg, Germany has developed a Third Party Audit Programme in partnership with the CEFIC Active Pharmaceutical Ingredients Committee. Details of this audit program are available from [www.api-compliance.org/](http://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 needs. The ACI will be pleased to provide you with more details of these controls.**

EMA has endorsed the concept of the Third Party Audit, and the ACI has training, processes and procedures in place to assure that their audits meet the guidance put forth by EMA regarding the scope of the audit and potential conflicts of interest. On customer request the audit standard that is used to audit against can be extended to other HA guidelines and requirements.

<API supplier> is currently canvassing our –World wide Customers to determine the level of interest for participating in a Shared Third Party Audit. The typical approach based on individual company audits is time-consuming and expensive for both the API supplier and Manufacturing Authorisation Holder. The coordination of a Shared Third Party Audit of the <API supplier> manufacturing site is viewed to be an effective and efficient means for Manufacturing Authorisation Holders Accountable Persons (QPs for EU) to certify that APIs purchased from <API supplier> are compliant with the ICH Q7 guidelines on Good Manufacturing Practices for starting materials.

We are inviting your company to participate in a **Shared Third Party Audit of the <API supplier> manufacturing site** tentatively scheduled for <date>. The ACI has agreed to coordinate potential participating companies and products to create the most efficient **Shared Third Party Audit** possible. As the **Shared Third Party Audit** needs to cover both general GMP systems and Product Specific issues, you are encouraged to contact the ACI before <date> to assure that the products your firm purchases are included in the audit scope and that your QP (mandatory in EU) or accountable Quality Responsible Person of each mManufacturing Authorisation holder will be able to agree to use this resulting report to fulfill your GMP obligations. To assist you in the process, we have provided a form (attached) that can be sent by FAX to the ACI to declare your interest in participating in this audit.

The costs of the Third Party Audit would be shared by the number of Manufacturing Authorisation Holders who will sponsor the audit of the <API supplier> Manufacturing site. The ACI will calculate the shared costs of the audit, based on the number of participants and products and forward this to you for your final acceptance not later than <date>.

If you have any questions, please feel free to contact myself, your <API supplier> commercial contact or Dr. Gerhard Becker, of the ACI.

If you wish to participate in the Shared Third Party Audit please contact Gerhard Becker of the API Compliance institute using the form attached.

Sincerely,

<API supplier's contact person>