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 production site of < supplier>.

The API Compliance Institute (ACI), located in Heidelberg, Germany has developed the 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/.**

An audit of a 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 a supplier.

There exists another option which other firms have found to be acceptable to the European Authorities for meeting the cGMP Assessment requirement for Manufacturing Authorisation Holders (MAH) and API manufacturers, 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 MAH and/or API manufacturers ensures that the scope of the audit is applicable to each API as a Starting Material. and each material used in API manufacturing respectively.

A Shared Third Party Audit in which more customers could participate would be of benefit for you as it will reduce the audit fees. The more customers participating in a Shared Third Party Audit will lower the costs for the audit. Please find attached example calculations for a standard Third Party Audit (2 auditors 2 days) shared by 2, 3 and 5 customers. It will also be beneficial to 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 Customers which are supplied with the same material within a Shared Third Party Audit at the < supplier's> site.

The APIC Audit Programme

The Audit Program includes Strict Controls over Confidentiality – both in terms of the Material, Process Confidentiality and Customer Confidentiality. The controls include Signed Confidentiality Agreements with the independent auditors who will have no conflict of interest with the Supplier or their customers and who will sign to assure that confidentiality will be maintained. The customer(s) receives insight from the auditor(s) expertise which they 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 MAH and/or API manufacturer initiates the Third Party Audit / Shared Third Party Audit process. So please confirm that you are the MAH and/or API manufacturer–

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.

API Compliance Institute
Rischerstr. 8
69123 Heidelberg

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.A. Anne Günster
Project Manager

API Compliance Institute

The APIC Audit Programme

<Supplier>

<Date>

Third Party Audit / Shared Third Party Audit at your 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 products in scope of the audit requested by <company> are 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 (APIC). 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 Materials, Process Confidentiality and Customer Confidentiality. The controls include Signed Confidentiality Agreements with the independent auditors who will have no conflict of interest with the Supplier or their customers and who will sign to assure that confidentiality will be maintained. The customer receives insight from the auditor(s) expertise which they 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 a 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 a supplier.

There exists another option which other firms have found to be acceptable to the European Authorities for meeting the cGMP Assessment requirement for Manufacturing Authorisation Holders (MAH) and API manufacturers, 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 MAH and/or API manufacturers ensures that the scope of the audit is applicable to each API as a Starting Material. and each material used in API manufacturing respectively.

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.

The APIC Audit Programme

If you are interested in entering into a Shared Third Party Audit process please let us know.

API Compliance Institute
Rischerstr. 8
69123 Heidelberg

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,

i.A. Anne Günster
Project Manager
API Compliance Institute

<Supplier's
Logo & Address>

<Date>

Dear Customer:

According to the current European Union Law (Directive 2001/83/EC, the FMD amendement 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 supplier is an integral part of the Manufacturing Authorisation Holder's (MAH) and/or API manufacturer's supplier qualification program. This audit is either conducted by the Qualified Person, by the Company Auditors or by an Independent Third Party) on assessing the cGMP status of a supplier.

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

There exists another option which other firms have found to be acceptable that being:

- **Shared Third Party Audits,** which are acceptable as long as:
  1) No conflict of interest is guaranteed
  2) the Qualified Person (mandatory in EU) or accountable Quality Responsible Person of each MAH and/or API manufacturers ensures that the scope of the audit is applicable to each API as a Starting Material. and each material used in API manufacturing respectively.

< 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 customers to "conduct" an audit of the <location> manufacturing site for the material(s) purchased in a cost and resource efficient manner, with timeliness far greater that 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(APIC). Details of this audit program are available from **www.api-compliance.org/.**

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

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.

<I supplier> is currently contacting 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 supplier and the customers. The coordination of a Shared Third Party Audit of the < supplier> manufacturing site is viewed to be an effective and efficient means to certify that Materials purchased from <I supplier> are compliant with the applicable items of ICH Q7 guideline on Good Manufacturing Practices

We are inviting your company to participate in a **Shared Third Party Audit of the < 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 cGMP systems and Product Specific issues, you are encouraged to contact the ACI (**API Compliance Institute Rischerstr. 8 69123 Heidelberg)** before **<date>** to assure that the products your firm purchases are included in the audit scope
The costs of the Third Party Audit would be shared by the number of customers who will sponsor the audit of the <supplier> Manufacturing site. The ACI will calculate the shared costs of the audit, based on the number of participants and forward this to you for your final acceptance no later than <date>.

If you have any questions, please feel free to contact myself, your < supplier> commercial contact or Anne Günster, of the ACI.

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

Sincerely,

<supplier's contact person>