Auditing Guide

Annex 1–
Pre-Audit Questionnaire

When used as part of the APIC Audit Programme, the following section applies:-

This questionnaire was brought to you by:

API Compliance Institute
Rischerstr. 8
D-69123 Heidelberg

In case of any question or comment concerning this questionnaire please contact:

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The questionnaire together with the accompanying information should be sent back to the API Compliance Institute (addressee above) after completion.

Responsible person for filling out respectively completing this questionnaire

_____

Name, Function

_____

Date, Location, Signature

Preamble

It is the purpose of this questionnaire to facilitate the preparation of the auditors for the audit at your company and to make it as efficient as possible. It is neither intended for self-assessment nor for vendor rating or qualification.

All information provided in this questionnaire will be treated strictly confidential. Nevertheless it is acceptable if your company choose not to answer some of the questions listed below.

In case your company agrees to submit some/all of the requested documents these will be returned to your company after the Audit Report is signed and issued.

A.	**General Information about the Company**	
1.	Company name	
2.	Address of Company	
3.	Name of production plant to be audited and address if different from no. 2	
4.	Telephone (Switchboard) and Fax number where the audit takes place	
5.	Name of the "audit representative" of the company for the audit (contact person)	
6.	E-mail address and telephone number of the contact person	
7.	Name of product(s) subject to the audit	
8.	Approximate size of the plant	
9.	Approximate number of employees	
10.	Is this a pure production site or are there other Headquarters functions (e.g. Research) located at the site?	
11.	Are there other companies located on the same area as the company to be audited?	
12.	If so, which companies are these and what types of products are produced?	

13.	Is the plant to be audited a pure API manufacturing site or does it also manufacture medicinal (drug) products?	
14.	Does your company have a web site that provides an overview of activities? If so, please specify:	
15.	Is there other information about your company the auditors could use for their preparation?	

B.	**Quality related Information**	
1.	Is there a Quality Policy in place?	
2.	Is there a commitment of the management to comply with GMP (ICH Q7)?	
3.	Does the company/plant maintain a Quality Management System Is the company/plant certified according to a Quality Management System standard (e.g. ISO 9001 or based on ICH Q10)?	
4.	Please provide information on the latest inspections by national or international Regulatory Authorities (authority, date, outcome)	
5.	Is your Quality Unit (QU) independent from Production (please provide organograms if possible)	
6.	Please provide the names of persons authorised to release APIs and Intermediates to be sold	
7.	Does your company conduct regular internal audits (self Inspections)?	
8.	Is there an Internal Audit schedule available?	
9.	Do you have a CEP for the product(s) to be audited? If so, would you provide us with a copy for each product?	
10.	Do you have a EDMF? If so, could you provide a copy of the Applicant's Part?	

11.	Do you have a Site Master File (SMF EU nomenclature; old DMF Type 1 US nomenclature) that you could provide ?	
12.	Has your API Starting Material been defined in agreement with your local authority or based on your internal rationale?	
13.	Are Product Quality Reviews performed? If yes, can you please provide your latest Product Quality Review for the product(s) to be audited?	
14.	Can you provide us with an example of a certificate of analysis?	
15.	Are the laboratories used on site or are contract laboratories used?	
16.	Do you use contract manufacturers for the product(s) to be audited? If so, which steps are concerned?	
17.	Name and address of any contract manufacturers	
18.	Does your company have a procedure for Supplier Qualification including contract manufacturers? If yes please provide it or summarise it	
19.	Do you have an audit plan for contract manufacturers and suppliers? If yes please provide a schedule of audits performed in last 12 months and audits planned in next 12 months or longer.	
20.	Did your company employ consultants within the past 24 months?	

C.	**Product related Information**	
1.	Is the API(s) to be audited manufactured by chemical processing, by classical fermentation or is it a biotechnological product?	

2.	Would you please provide us with a brief description of the route of manufacture?	
3.	Are any materials used of animal or human origin in API Production-if yes, please provide details and relevant certificates for example TSE/BSE status	
4.	Are the APIs stored at the facilities to be audited?	
5.	Please provide name and address if alternative storage facilities are used.	
6.	Does the production of the audited product(s) consist of dedicated or multi-purpose equipment?	
7.	Is the API to be audited regarded as highly sensitising, potent or toxic and if so can you provide a Material Safety Data Sheet?	
8.	Is a set of current drawings (P & ID) available?	
9.	Are computer systems used to control GMP operations? If yes state which ones	
10.	Are microbiological aspects / specifications relevant?	
11.	Is all GMP related documentation readily available?	

D.	**GMP related Information**	
1.	Do you have a recall procedure in place?	
2.	Do you have a procedure for handling of complaints?	
3.	Do you have a Change Control System in place?	
4.	Are critical process steps defined and validated?	
5.	Is a batch record review conducted by the QU before product release?	
6.	Are procedures in place to handle all investigations?	

7.	What is your system to monitor implementation of Corrective and Preventive actions arising from audit observations and all investigations? How does Management review the effectiveness of this system including frequency of reviews?	
8.	Do you have an OOS procedure in place?	
9.	Has the impurity profile of the API been established?	
10.	Please describe your stability programme for the products subject to audit. Please justify your re-test or expiry dates	
11.	Please describe your procedures for raw materials handling and control?	
12.	Please describe how you control the status of raw materials and allocation to production	
13.	Describe your procedures for control of packaging and labelling operations for end products	
14.	Describe your procedure for maintenance of equipment and calibration of instruments	
15.	Are the employees regularly trained and is the training documented?	
16.	Describe the type of general GMP training given to all employees and the frequency	
17.	Is the exposed API protected against contamination?	
18.	If applicable, are dedicated production areas for highly sensitising materials (penicillins and/or cephalosporins) or High Potency materials available?	
19.	Are APIs (and IM) distributed under quarantine?	

E. Comments from your Company

Please provide any additional information your company feels the auditors should be aware of before the audit:

F. Requested Documents

To facilitate proper preparation of the auditors we encourage you to provide the following documents in advance.

Documents are provided on a purely voluntary basis, but we guarantee that the submitted documents will be treated strictly confidential. All documents will be returned after the audit report is issued.

1. Information about the company
2. CEP(s) if applicable
3. Applicant's Part of EDMF(s) if applicable
4. Specimen of a Certificate of Analysis
5. Summary of last relevant Product Quality Review
6. Site Master File or at least a site map and drawings of production areas
7. Description of the manufacturing process
8. Safety Data sheet in case of sensitising or high potency or toxic product
9. Index of Quality Manual and / or Index of SOP's covering ICH Q7 Chapters relevant to your operations.
10. Impurity profile and current stability data