Audit Report

Audit Report in the framework of the APIC Audit Programme	
Company	
Location	
Address	
Country	

Subject of Audit	

Audit Date(s)	
Auditor (lead)	
Co-Auditor(s)	
primary audit hosts/escorts	

Signature of Auditor(s)	
Lead Auditor	**Co-Auditor**

Attachments	

Audit Report

1. Management Summary

Purpose/scope of audit	
Executive summary	Number of observations (critical, major, other) Overview of main Strengths Overview of main high risks area's

2. General information

2.1 Give an overview of the company and site such as whether it is part of another group, its ownership, how the company was formed, previous site names, age of the site, what is the nature of the sites business and how many APIs, intermediates, starting materials and raw materials are manufactured, site size and the number of staff employed in total and for the specific products being audited and other specific product related information e.g. if the site performs the full manufacture or only part of the manufacture.
2.2 Give an overview of the company compliance status based on available audit history.

2.3 Give an overview of their inspection record and which health authorities have inspected the auditee.

2.4 Record the activities which were not covered during the audit related to the original agreed audit plan.

2.5 Give an overview of the staffing levels for the site and departments plus working patterns.

2.6 Give an overview of the CAPA status of earlier performed audits if requested by the customer.

3. Audit details

Report all the topics covered during the audit.

The Aide Memoire can assist in compiling the audit report details as per applicable ICH Q7 chapters.

For convenience the relevant ICH Q7 chapters and subsections are listed below.

For sections 3.1 to 3.18 ensure adequate detail is given on observations that will be listed in section 4 to allow reviewers of the report enough information to assist in their assessment of the observations to their operations/compliance requirements.

For each (sub)-chapter, list the areas visited and relevant documents reviewed.

Audit Report

The items highlighted in Yellow, are topics considerd not relevant for Raw Materials and starting materials. Based on the companies risk assessment this proposal can be used to compile a fit for use audit agenda for raw materials and starting materials

3.1. Quality Management

3.1.1 Principles

3.1.2 Quality Risk Management (EU part II)

3.1.3 Responsibilities of the Quality Unit(s)

3.1.4 Responsibility for Production Activities

3.1.5 Internal Audits (Self Inspection)

3.1.6 (Annual) Product Quality Review

3.2 Personnel

3.2.1 Personnel Qualifications

3.2.2 Personnel Hygiene

3.2.3 Consultants

3.3 Buildings and Facilities

3.3.1 Design and Construction

3.3.2 Utilities

3.3.3 Water

3.3.4 Containment

3.3.5 Lighting

3.10.3 Validation of Analytical Methods

3.10.4 Certificates of Analysis

3.10.5 Stability Monitoring of APIs

3.10.6 Expiry and Retest Dating

3.10.7 Reserve Samples

3.11 Validation

3.11.1 Validation Policy

3.11.2 Validation Documentation

3.11.3 Qualification

3.11.4 Approaches to Process Validation

3.11.5 Process Validation Program

3.11.6 Periodic Review of Validated Systems

3.11.7 Cleaning Validation

3.12 Change Control

3.12.1 A formal and effective change control system must be in place

3.13 Rejection and Re-Use of Material

3.13.1 Rejection

3.13.2 Reprocessing

3.13.3 Reworking

3.13.4 Recovery of Materials and Solvents

3.13.5 Returns

3.14 Complaints,Recalls

3.14.1 A formal and effective change complaint and recall system must be in place

3.15 Contract manufacturers including laboratories

3.15.1 If cGMP activities are outsourced a formal and effective control system must be in place.

3.15.2 Quality agreement

3.15.3 Defined Roles & Responsibilities

3.16 Agents, Brokers, Traders, Distributors, Repackers, and Relabellers

3.17 Specific Guidance for APIs Manufactured by Cell Culture/Fermentation

3.18 APIs for Use in Clinical Trials

4. Observations

Include a summary assessment of the status of previous audit corrective and preventive actions if requested to be reviewed as part of the audit plan.

Observation definitions:

Key for Classification of observations

Level	Classification rating
Critical	A deficiency which has produced, or leads to a significant risk of producing an Active Pharmaceutical Ingredient that could be harmful to the human or veterinary patient. The condition violates essential cGMP-rules and/or essential quality assurance practices.
Major	A non-critical deficiency which has produced or may produce a product, which does not comply with its marketing authorization or which indicates a "major" deviation from cGMP, or a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such
Other	A deficiency, which cannot be classified as either critical or major, but which indicates a departure from cGMP.(A deficiency may be "other" either because it is judged as "minor", or because there is insufficient information to classify it as a major or critical).

Audit Report

Contact,detail:

Audit Report

No.	Auditors' Observations	Classification Reference	Response of Auditee	Target Date Responsibility
	Classification ●●			