

Supplier and Contractor Audit

An Audit conducted in order to assess the cGMP and/or Technical/Quality Contract compliance of an existing supplier (different material or service).

7.1.3 Re-approval Audit (Time Cycle)

A re-approval Audit is an inspection of a previously approved supplier or contract manufacturer, already providing services and/or product. A time cycled Audit is conducted in order to assess the supplier's facility and services continued cGMP and/or Technical/Quality Contract compliance. Re-approval will be conducted pending the intended use and the frequency of use.

7.1.4 For Cause Audit

An Audit initiated as a result of a recognized problem in the services or product provided by a supplier or contract manufacturer.

7.2 Audit cycle time

In order to keep a supplier in an approved status, they must be audited on a defined time cycle. Cycle times are based on the type of work performed by the contract firm.

<i>Please use this listing as a reference only</i>	
Category (A) suppliers must be audited on an annual basis	<ul style="list-style-type: none"> API supplier Sterile contract manufacturer
Category (B) suppliers must be audited every two years	<ul style="list-style-type: none"> Non –Sterile Drug product suppliers Key raw material and intermediates suppliers Contract testing laboratories
Category (C) suppliers must be Audited every three years	<ul style="list-style-type: none"> Raw material suppliers Other suppliers

7.3 Pre Audit (preparation) activities

7.3.1 Planning of a new supplier Audit

It is the task of the Lead Auditor to manage all Audit activities.

During the preparation phase he/she ensures that:

- An Audit specific questionnaire concerning the product/supplier is created and agreed by the team and will be send to the new supplier.
- All additional agreements must be made with the vendor (e.g. agreeing of Audit date, Audit plan).

7.3.2 Supplier's Response to the Audit Questionnaire

The Lead Auditor ensures that the supplier will answer and set an appropriate time frame before the Audit is performed. Base



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