

Standard Operating Procedure

Title: Vendor Selection and Evaluation

Department	Quality Management	Document no	QMS-045	
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Document Owner

Procurement / Quality Assurance Manager

Affected Parties

All colleagues working in a team for vendor selection and evaluation process from the Procurement, QA, Technical Services and Laboratory Departments.

Purpose

To define the process by which Vendors are assessed and evaluated in accordance with the GMP requirements and Corporate Policies to create conditions for adequate material availability and adherence to specification.

Scope

Note: It is recommended to use this procedure in conjunction with SOP **QMS-115**.

This SOP describes the process for the selection of vendors for raw materials (Active Ingredients & Excipients), Packaging Components, Laboratory Supplies, Engineering Supplies, Bulk Product & Imported Finished Goods.

This SOP does not describe the process of selection of a Contract Manufacture, (see SOP **QMS-110**)

The process of vendor assessment and evaluation is divided into four phases.

Vendor Assessment

- Phase 1. Technical discussions
- Phase 2. General Vendor Audit
- Phase 3. Item specific evaluation

Vendor Evaluation

- Phase 4. Ongoing vendor evaluation

This phased approach is to be applied to the following purchasing activities. Specific details pertaining to each group are outlined in the procedure.

The progress of each Vendor, through this phased process, may be changed by management by means of documented discussion to be held on Vendor's file.

A Vendor may be designated as approved without undergoing the following procedure under the following conditions:

- Via the legislation of local regulatory authority.
- Following submission of data as part of a product registration process.

It is the responsibility of Quality Assurance to ensure that all relevant requirements are communicated and adhered to.