Standard Operating Procedure

Title: Vendor Selection and Evaluation

Definition

Vendor	Any Manufacturer / Vendor / Supplier which has been identified (Via Phase 1) as a potential source of supply for a specific material. A vendor is a company from whom we directly obtain the material. The vendor may also be the manufacturer and may be local or overseas based. The non-manufacturing vendor can only purchase material from the approved manufacturer as directed by the Buyer.
Manufacturer	A manufacturer is the company that synthesises or produces the material. The manufacturer is normally responsible for all aspects of manufacture and quality control of the material. Technical support is often provided with respect to product knowledge, stability data, impurity profile of the material and technical expertise relating to the material. In the case of active manufacturers the manufacturer is responsible for the provision and maintenance of a Master Files. (See SOP **QMS-115**)
Approved Vendor	A Vendor or Vendor/ Manufacturer combination which has been assessed and approved (Via Phase 3) for a specific material and listed on approved vendor list
Approved Vendor List	List of approved vendor / manufacturer material combination maintained by Quality Assurance and by Technical Service Departments.
Vendor	The process of assuring the vendor's ability to fulfil given requirements before the Vendor is approved. Vendor assessment must address the issue of quality
Vendor Review	The ongoing assessment of an approved vendor based on experiences with the Vendor. For this purpose data on quality, capacity, price and service must systematically be collected and evaluated. This data must be used to reconsider the approval of the vendor whenever possible
Audit Team	The Audit team can be comprised of different specialists to cover quality, commercial and technical aspects. The Team leader must be a Qualified Lead Auditor. (See SOP **QMS-080**)
General Vendor Audits	The Quality Assurance function of the vendor assessment (Phase 2)
Certification	Is the act of approving the analytical (QC) results provided by the vendor; thereby eliminating the need to undertake some or all of the analysis on receipt by the buyer.
De-certification	Is the act of reverting back to full or partly increased analysis on receipt
Critical Packaging Component	A component in contact with the final product, or provides a level of protection for stability proposes and/or microbiological integrity
Non critical Packaging Component	No product contact, or affect on the stability of the product or microbiological impact
Critical Vendor	A service supplier who has a direct impact on Quality, on Machinery and supply to Production

Related Documents

Form-385	Vendor Audit Questionnaire
Form-390	New Supplier Assessment Form
QMS-030	Preparation, Maintenance and Change Control of Master Documents
QMS-080	Audits
QMS-110	Management and Control of Contract Work
QMS-115	Criteria for Sourcing of RM, Critical Packaging Components and Imported Finished Goods

QA/ Procurement	The results of material testing and the vendor questionnaire are to be assessed and a decision made as to whether the vendor has the capability to produce the material in question and whether to proceed with the assessment process. If the results are unacceptable then the selection process starts again.
	The frequency of General Vendor Audits depends on the needs in the individual case and is to be determined by the auditor at the completion of the audit process and documented on the audit report. Audits shall be planned scheduled and conducted in lines with SOP **QMS-080**
	Phase 3
Procurement/ QA	Phase three involves a negotiation with the vendor to handle any matters specific to the material as a result of material testing, questionnaire results or general vendor audit results.
Technical	Specifications are to be finalised and approved.
QA/ Procurement	Vendor Approved/Certification. This is valid for one item or group of items and for one site only. If the vendor manufactures several items of interest, each item or group of items must be dealt with separately.
Procurement	Initiate Purchasing Item Master Update as per **SOP PUR-005.**
Supply Chain	Approved Vendor listing to be update in accordance with **SOP PUR-005.**
	Phase 4
Procurement /QA	The quality of subsequent deliveries is continually monitored by compliance of the material to the agreed specifications and comparison with previous deliveries via trend analysis. Vendors/manufacturers are evaluated based upon the following criteria: • Ability to consistently comply with the agreed material specification requirements. • Quality of materials monitored as part of the post-production stability surveillance of finished products. • Data reviewed from compilation of number of deliveries, degree of rejects, number and extent of problems encountered in production, stability data showing untoward trends attributed to material deficiencies or changes.
QA	Approved vendors are to be re-audited at regular intervals as determined by Business needs.
	De-certification of Approved Vendor
QA/ Procurement Manager	If an approved vendor, for reasons such as failure in quality and / or commercial issues is no longer considered appropriate for use, the vendor is to be withdrawn from the approved vendor list. See **SOP PUR-005.**

2. Specific Requirements for each Phase - Actives

Active materials can only be obtained from approved manufacturers and in accordance with the registered details with the local regulatory authorities.

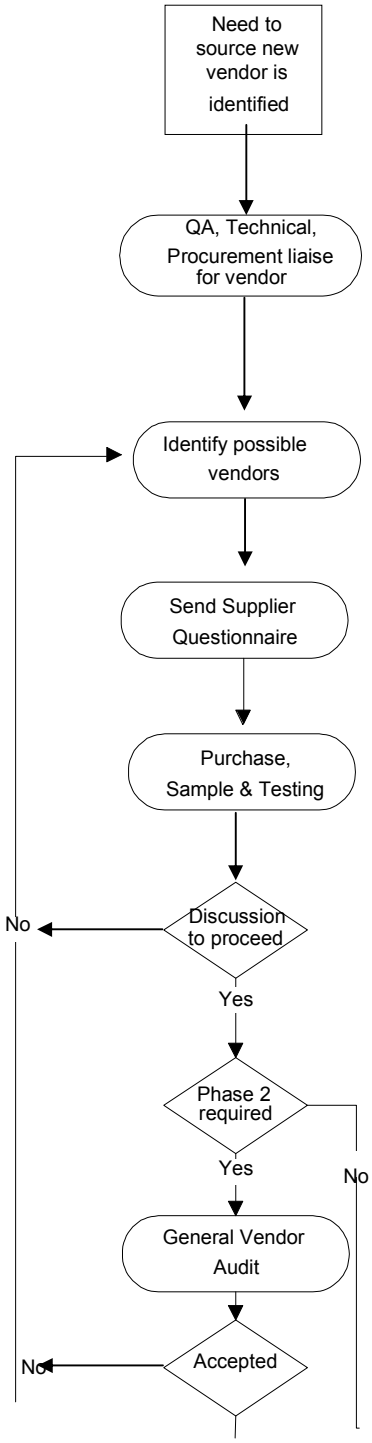
Phase 1, 2 & 3 are to be carried out in accordance with SOP **QMS-115**.

Phase 4

The evaluation is performed annually using information provided from laboratory trend cards reporting test results, stability analyses from post production stability monitoring, production records, special project minutes of meetings, and reject material/component forms.

If an adverse trend is detected by routine testing of the materials then the Laboratory Manager, in conjunction with the Procurement staff, will review, discuss and take appropriate action.

9. Appendix 1 – Flowchart- Vendor Selection and Evaluation



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