



REVIEW ON VENDOR DEVELOPMENT IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Selection of an appropriate vendor and periodic evaluation of the vendor is therefore a critical stage. There are so many vendors/suppliers which are supplying raw material / packing materials to the pharmaceutical industries. Handling of vendor development process is one of vital step in pharmaceuticals. This Article introduces the procedure for Vendor Development in Pharmaceutical Industry with its flow, documentation, rejection and approval.

Vendor development is an essential process for sourcing material in the right quality, of right quantity, at the right price from the right source, at the right time and place. Thus, source selection begins after the user department forwards material requisition form to purchase department. On asking, selected vendor generally supply "initial sample" and "mandatory documents" If approved, this would then be followed by "initial supply". The evaluation of "initial supply" shows satisfactory results, then vendor development team visits at the vendor's site consisting of QA/QC, Procurement etc. The vendor development team should make a detailed study of processes, organization and other allied matters necessary for vendor evaluation.

KEYWORDS: Vendor, Qualification, Development, Pharmaceutical.

INTRODUCTION

In pharmaceutical industries, there are various raw materials used to require for the formulation of the products. Manufactures do require various APIs, Excipients, Packing Materials to launch their product in market.

Pharmaceutical companies focusing on quality and to meet your customers expectations by producing quality pharmaceutical products, pharma company need to look carefully at all aspects of quality, including robust vendor management.

The important step now is to select the material from this group of vendors such that they meet the company's desired specification.

Pharmaceutical vendor development is the process by which your pharmaceutical organization works with vendors. This helps enhance the quality of your products, mitigate risks, and control costs.

Effective vendor management is not only essential for maintaining your company's brand value but is also a core responsibility for pharmaceutical manufacturers. National and international regulatory standards expect pharmaceutical companies to have protocols/procedures

in place for selecting, retaining, and collaborating with approved vendors.

Need of vendor development

- Selection of right suppliers
- Selection of quality materials
- Continuous improvement of supplier performance
- Enhance product quality
- More efficient supplier practices
- Less waste and more lean processes
- To reduce the cost of the product.
- To maintain the supply of the product for consumer in time.

Responsibilities

1. Procurement/Purchase Department: Vendor identification, sample and documents arrangement, audit coordination.
2. CQA/QA: Vendor document verification, vendor audit, vendor approval.
3. R&D: Sample testing, R&D trails

Pharmaceutical Vendor Management Requirements

- As per ISO 9001:2015 Section 8.4 (control of externally provided processes, products, and services), your pharmaceutical company must ensure

that vendors of products, services, or processes are in conformance with your requirements. In addition, you will determine the type of controls to be implemented for these products, services, or processes.

- The ICH Q10 III G (Management of Outsourced Activities and Purchased Materials) standards describe pharmaceutical companies' quality systems and the responsibilities of the management concerning control and review of all outsourced activities and quality of purchased materials.
- The EU-GMP Guideline Chapter 7, Section 4 (Outsourced Activities) standards highlight that the contract giver (namely the pharmaceutical manufacturer) has overall responsibility for all processes and protocols for control of outsourced activities.
- Pharmaceutical Inspection Co-Operation Scheme (PIC/S) – Guide to GMP For Medicinal Products Part I Chapter 7 (Outsourced Activities) mentions that all outsourced activities must first be defined, agreed upon, and controlled. This will prevent future misunderstandings.
- Likewise, the Pharmaceutical Inspection Co-Operation Scheme (PIC/S) – Guide To GMP For Medicinal Products Part II Chapter 17 (Agents, Brokers, Traders, Distributors, Repackers, and Relabellers) deals with third-party vendors who repack, relabel, manipulate, distribute, or store an API or an intermediate.
- All these regulations, standards, and guidance documents refer to the requirements that you, as the manufacturer of pharmaceutical products, must enforce to manage suppliers(s) and/or purchasing controls.

Overall, these regulatory requirements state the following:

- i. You must have a written contract between your pharmaceutical company and the vendor. This will cover all outsourced activities.
- ii. You should assess the legality and suitability of the vendor for your requirements before signing the contract.
- iii. You will provide the vendor with all the necessary information for them to give you the product as per current regulations.
- iv. You will audit the vendor and review their performance. You will identify and implement, wherever required, needed improvements.
- v. You are responsible for reviewing and assessing all the documents and records, and for the records of all outsourced activities.

Requirements for vendor qualification process

- Questionnaire for vendor assessment
- Analysis of sample & machine trials
- Physical audit/Quality agreement

Steps for Pharmaceutical Vendor Management

1. Define User Requirements
2. Perform Initial Supplier Selection Process
3. Conduct a Quality Appraisal
4. Generate Quality Agreements
5. Perform Ongoing Monitoring and Control of Key Suppliers

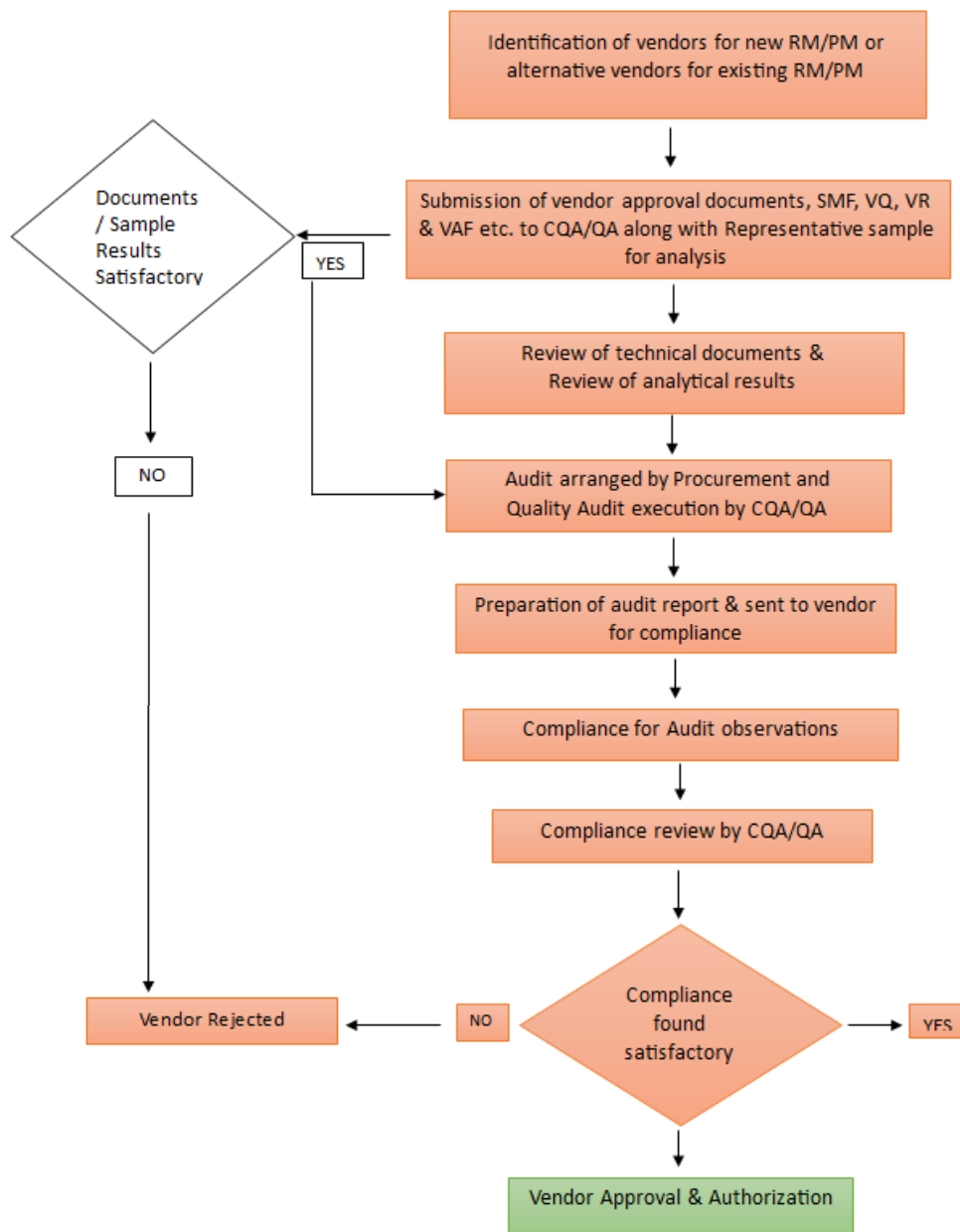
Procedure

Vendor Development

1. Procurement/purchase department shall find vendors depending on reputation and financial stability of the vendors.
2. Procurement/purchase department shall send specifications, vendor registration form and vendor questionnaire to the identified vendor. Obtain three representative samples of the latest batches along with the COA and required documents.
3. R&D shall review sample label, and vendor COA with respect to shelf life, pharmacopeial grade & tests etc with specification. R&D trails shall be performed.
4. After satisfactory sample analytical results, Procurement/purchase shall provide vendor approval form with set of complete documents in vendor approval form to CQA/QA.
5. Procurement department shall develop at least 3 vendors for any raw/packing material.
6. On the basis of satisfactory review of submitted documents, testing results and R&D trail report, CQA/QA shall take decision about conducting the site audit of the vendor.
7. Vendor shall possess minimum GMP requirement as mentioned for raw material vendors and packing material vendors.
8. In case, there is delay in getting some of the prerequisite documents or audit date from vendor due to any of reason, provisional approval may be given for such vendor on mutual discussion with Quality and Procurement/purchase department.
9. Complete file of vendor approval shall be submitted to Head of Quality. Head of Quality shall take the decision to approve / reject the vendor based on the review of submitted documents. CEO shall be responsible for authorization of RM/PM vendors.
10. After authorization, procurement department shall initiate change control process.
11. After approval of change control process, CQA/QA department shall provide email communication to all stakeholder about vendor approval.
12. CQA/QA shall maintain the complete records related to vendor approval.

Vendor audits policy:

- i. All API vendors, primary and secondary packaging material vendors shall be audited.
- ii. Vendor shall be audited by representatives from CQA/QA and Procurement/purchase.

Process Flow:**CONCLUSION**

Vendor development process is an essential part of pharmaceutical industries. Moreover, national and international regulatory mandated the vendor qualification for all over the pharmaceutical sector. It helps in selecting a limited number of vendors by conducting detailed analysis. After analysing the vendors by using suitable procedures, the best vendor is selected among them. Vendor development meets the need of pharmaceutical manufacturers to run smooth business with quality and customer satisfaction.

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