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Vendor Qualification and Evaluation in Pharmaceutical Industry

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ABSTRACT

To deliver a high quality and safe medicines, it is a must to certify the vendor according to the GMP requirement. This qualification is done to prevent the adverse events, prevent the recalls or serious illness or death due to the low standard quality of manufactured medicines. Vendor qualification is the process by which a vendor is assessed to determine, if it can provide the required goods or services to the standards that the purchasing company requires. This article explains about the detailed procedure for qualifying raw material vendors, packaging vendors and service providers. This also explains the vendor assessment and the reassessment. Vendor re-assessment must be carried out at least once a year for each packaging material and the raw material. The manufactured part number is used for tracking. Supply Chain Management team (SCM) should request the QA department to generate Manufacturing Part Number. Explained about the vendor rating. The vendor must be disqualified if the batch will not adhere to specification of critical tests. For further evaluation and investigation, vendor must be once again qualified. Vendor must be informed regarding the removal and the reasons must be explained clearly. Vendor Relationship Management (SRM), is systematic planning and managing of all interactions with suppliers to maximize its value.



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a vendor is assessed to determine if it can provide the required goods or services to the standards that the purchasing company requires.

Swathi and Nambiar (2015) A drug product consists of an API, starting materials, excipients and materials used for packaging. These play a major role in assuring the efficacy and quality of the product. Every vendor must be assessed and must be certified from the product development stage, until the batch is finished (**Chotai, 2010**).

Selection of vendors

1. Ensure whether the manufacturer is new to the company or not.
2. Decide whether the API is new or second source.
3. Vendor's reputation assessment should be done.

INTRODUCTION

Chotai (2010) The qualification process is defined by the American Society for Quality Control (ASQC) as "the process of demonstrating whether an organization is capable of fulfilling the specified requirement." Vendor qualification is the process by which

- (a) Check the FDA inspection profiles
- (b) Find out the relationships with other companies.
- (c) Past history of failure or recall.
- 4. Check their qualification of manufacturing process reports
- 5. Capacity of vendors: This can be checked by specifying them the required quantity and required time to supply the product and one must supply within that time.
- 6. The location of the vendor is also essential.
- 7. API selling price should be known, for the sake of profit evaluation.
- 8. Technical evaluation must be done.
- 9. Production samples which are received must be checked for its quality.
- 10. The qualification data of finished batch must be checked and reviewed before decision making.
- 11. Final report is made using the following data,
 - (a) Vendor history
 - (b) Audit reports
 - (c) Laboratory findings
- 12. If any change in the management is done, then vendor must be requalified.

General flow chart for vendor qualification

Vendor qualification process includes 3 steps,

1. Questionnaire for vendor assessment
2. Analysis of sample & machine trials
3. Physical audit/Quality agreement

Questionnaire for vendor assessment

Figure 1 shows,

Analysis of samples and machine trials

Figure 2 shows,

Physical Audit & Quality Agreement

Figure 3 shows,

Vendor approval procedure for raw materials and primary packaging materials

1. (SOP For Vendor Qualification, 2019), Supplier Chain Management department should start the selection of vendor for the supply of the raw materials or primary packaging materials.
2. The specifications for the raw materials and packaging materials will be sent to the vendors.

3. To know about the process, VAQ (Vendor Assessment Questionnaire) will be sent to the vendors by SCM team.
4. Those filled questionnaires from vendors will be received by SCM team.
5. They will send it to QA for review.
6. All the documents sent by vendor shall be reviewed.
7. Vendor must provide the samples and those samples will be tested for its quality.
8. If vendors cannot supply the required number of samples in specified time, then they are rejected.
9. The samples provided will be analysed by QC and reported to QA.
10. If the results comply with standards, then QA will plan for a vendor audit.
11. Vendor audit will be planned and scheduled and then conduct an audit.
12. If the results are in compliance, then approval will be given.
13. For qualifying a vendor, mandatory requirement is Vendor Questionnaire, assessment sample analysis and physical audit.
14. For final approval MPN must be generated

(a) In case of raw materials, first batch which is manufactured will be monitored.

(b) In case of primary packaging material, evaluation like extractability, stability required and leachability studies must be required.

Vendor approval procedure for secondary packaging materials

1. (Pathway, 2017), Supplier chain management department should start the selection of vendor for the supply of the secondary packaging materials.
2. The specifications for the secondary packaging materials will be sent to the vendors.
3. To know about the process, VAQ (Vendor Assessment Questionnaire) will be sent to the vendors by SCM team.
4. Those filled questionnaires from vendors will be received by SCM team.
5. They will send it to QA for review.

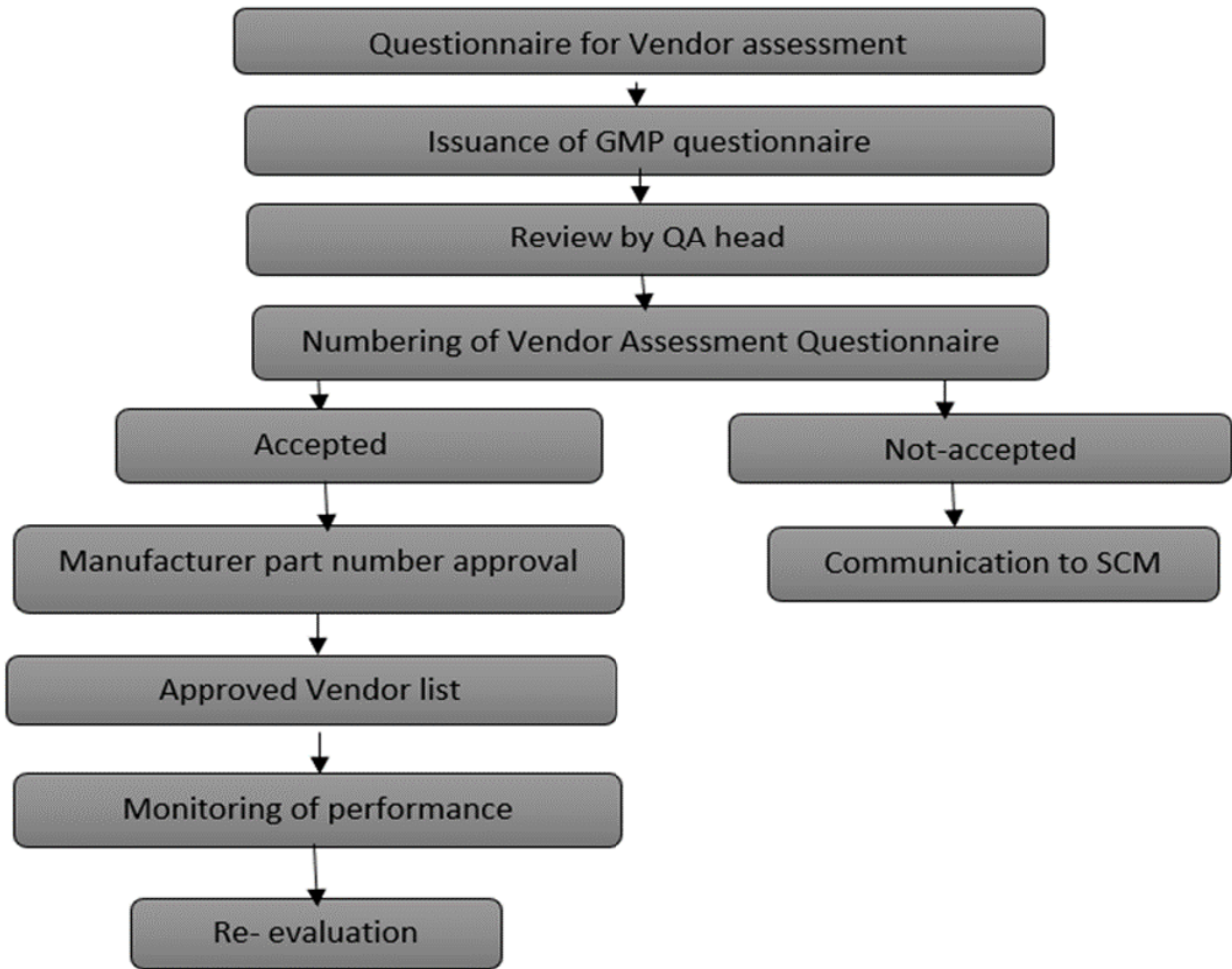


Figure 1: Questionnaire for vendor assessment

6. All the documents sent by vendor shall be reviewed.
7. Vendor must provide the samples and those samples will be tested for its quality.
8. If vendors cannot supply the required number of samples in specified time, then they get rejected.
9. The samples provided will be analysed by QC and reported to QA.
10. If the results comply with standards, then QA will plan for a vendor audit.
11. Vendor audit will be planned and scheduled and then conduct an audit.
12. If the results are in compliance, then approval will be given.
13. For qualifying a vendor, mandatory requirement is vendor questionnaire, assessment sample analysis and physical audit.
14. If in case, any secondary packaging material is obtained from approved vendor, then, that must be approved for new materials based on sample analysis and machine trials.

Manufacturer Part Number (MPN)

PartNumber System

Manufacturing Part Number is used within the company as a procedure/system for the departments and the individuals to track and find out the parts. Categorize the parts in standardized way and create efficiency in most of the manufacturing processes (Part Number System, 2019).

Factors influenced while selecting a part number system

1. The plant must use and manage the part numbers while choosing the part number system.
2. It is very difficult to switch from one-part number to another; if team is well known with the previous part number, the new part number must have improved the efficiency.

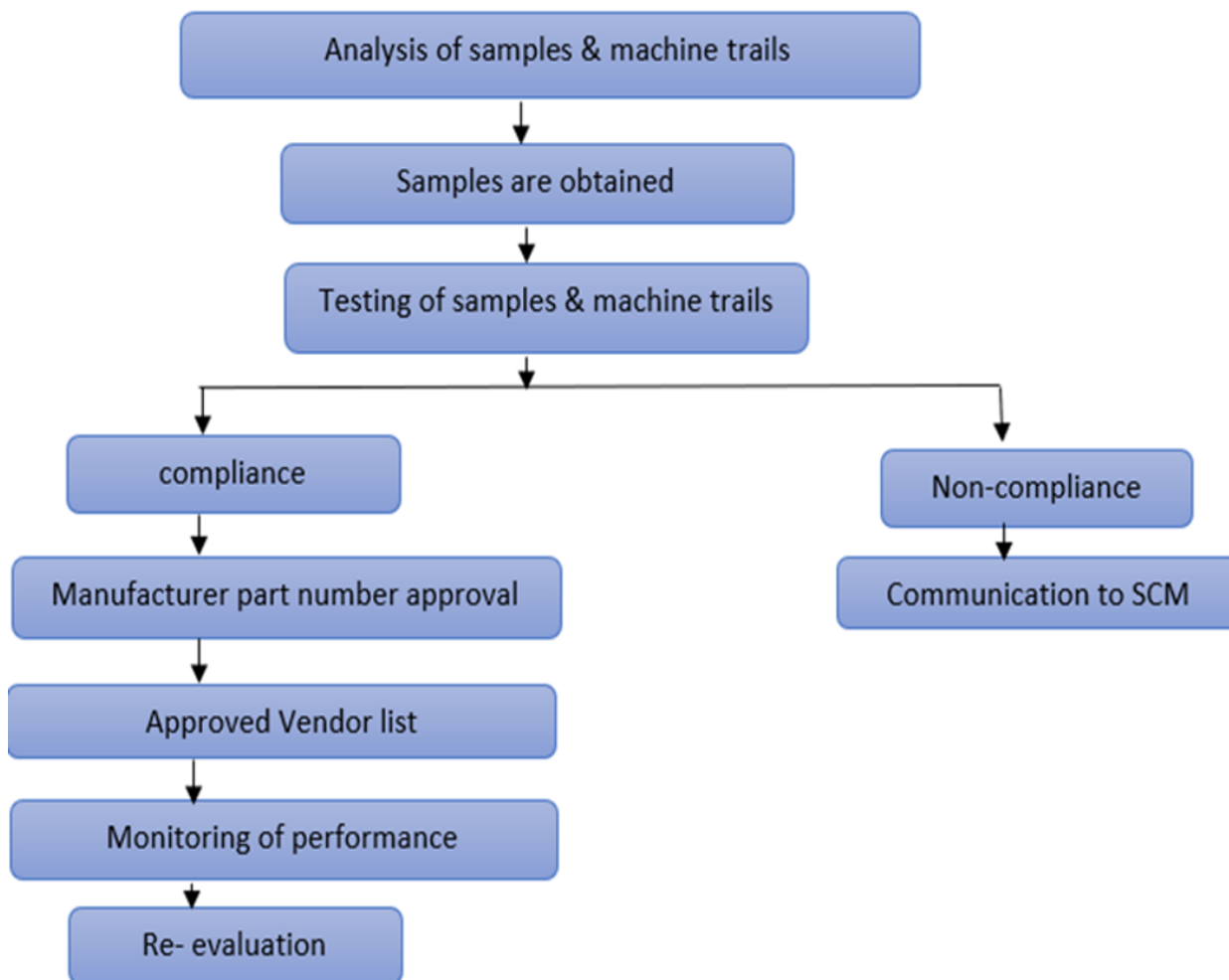


Figure 2: Analysis of samples and machine trials

3. If you are starting the number system, then you have to consider the following,
4. Why is part number used in your company?
5. You must get feedback from the team members on how to structure a system.
6. Is the part number given to the vendors/ suppliers?
7. You must know which part number to be used.
8. You have to manage the part numbers.

MPN Generation

1. Supply chain management team (SCM) should request the QA department to generate Manufacturing Part Number.
2. To create MPN, SCM must provide all the details such as vendor code, manufacturer code, item code, to QA department for generating MPN number.

Vendor qualification for service providers:

1. (Boardley, 2015), Ensure that the firm’s regulatory history, documentation, process and Quality Control system.
2. Explain the quality agreements which distribute the regulatory responsibilities
3. Qualify the product attributes which are manufactured, by inspection and independent verification.
4. Practically visiting every vendor is not possible. Before planning an audit,
5. A thorough review of the firm’s regulatory history, followed by a desk-based audit of process documents for cGMP compliance, may yield vital information about the overall quality of manufacturing operations.
6. Identification and mitigation of risk factors is essential in deciding what level of scrutiny to apply to a firm.

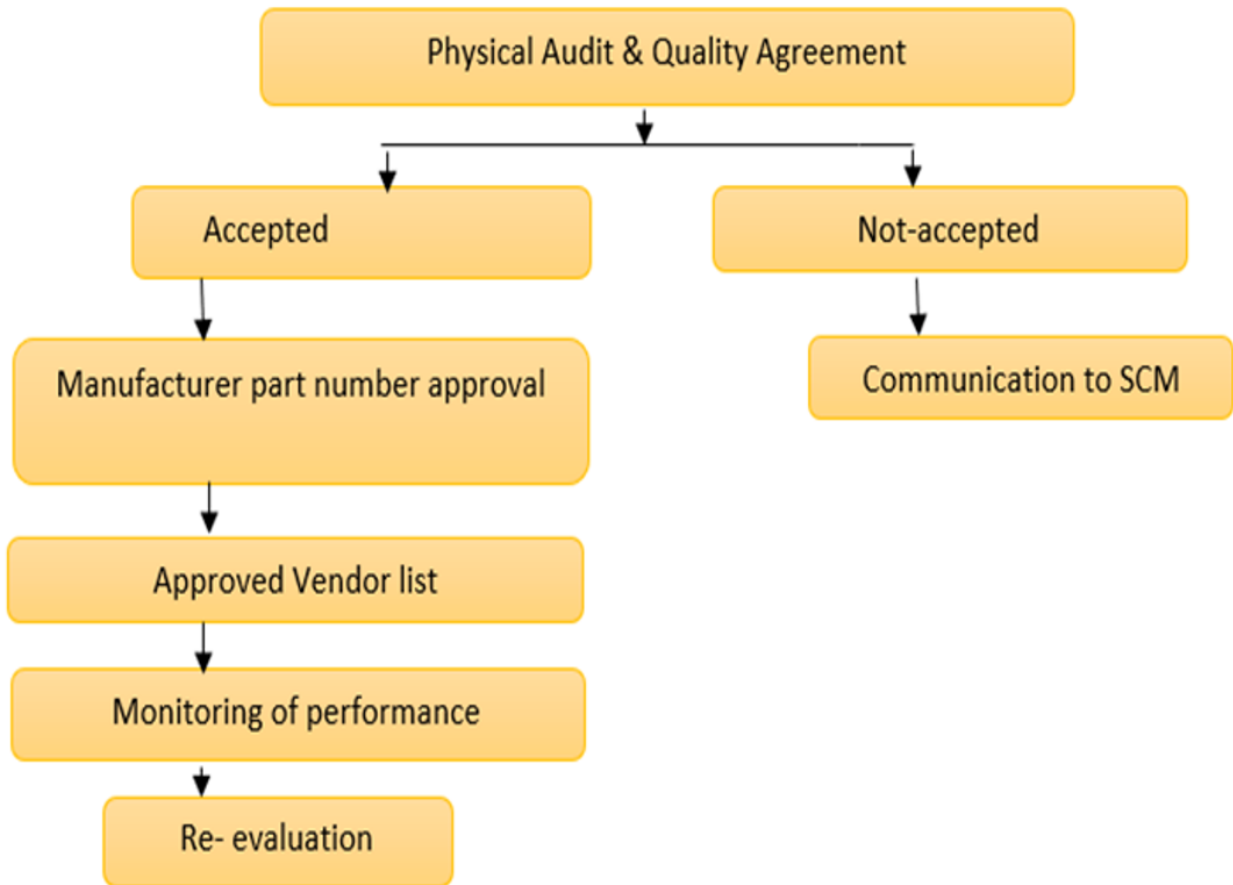


Figure 3: Physical Audit & Quality Agreement

VENDOR AUDIT	Calibration
	Quality records
	Inspect and test
	Process control
	Quality system
	Handling packaging storage delivery
	Purchase
	Design control
	Contract review
	Document control
	Nonconforming product control
	Vendor quality control
	Product identification and lot traceability

Figure 4: Vendor Audit

RATING	RULES
Grade 1	Vendors fall into this category, if there are no quality issues. i.e., Zero defects.
Grade 2	Vendors fall into this category, if complaints are received but they are not related to quality issues.
Grade 3	Vendors fall into this category, if complaints are regarding quality issues but, there is no major impact on product quality.
Grade 4	Vendors fall into this category, if their low standard products.

Figure 5: Vendor Rating

Procedure for removal of vendor from the approved list

1. (Choudhary, 2019), The vendor must be removed from the list for the following reasons,
2. The vendor must be disqualified if the batch does not adhere to specifications of critical tests. For further evaluation and investigation, vendor must be once again qualified.
3. When three continuous batches are observed, and those batches are not adhering to the specifications of minor test, then vendor must be disqualified.
4. When reviewed, if 3 batches among 10 batches fail to meet out the specifications, then, the vendor must disqualify.
5. For 40% of the supplies, if the delivery schedule is not followed, vendor is disqualified.
6. If vendors are disqualified, then, there is difference in prices among the purchase order and the invoice.

Corrective Action and Preventive Action

If vendor is removed from the approved list, then inclusion of vendor can be done by following CAPA,

1. Vendor must be informed regarding the removal and the reasons must be explained clearly.
2. To ensure the existence of quality system in the organization, facility audit must be conducted by head of purchase department, quality assurance head and quality control department.

3. Low quality issues such as the schedule of delivery and speed of delivery must be disqualified.
4. After adequate adherence to all the points above, vendor inclusion can be done in the vendor list which is temporary.

Vendor Audit

(Vendor Audit, 2019), To audit a vendor following must be considered,

Figure 4 shows,

Vendor Evaluation

(Vendor Evaluation and Audit, 2019) Evaluation of vendors are of 3 types

1. Use of records in the informal use
2. After the fact evaluation
3. Before designing the fact

Use of records in an informal manner

In the case of vendor assessment, the information may be collected from different sources like diaries, log books, financial records or journals. Information may also be collected from the past history. This information may allow the evaluation of an event in a better way and can help making wiser decisions.

After the fact evaluation

After completion of an event, by answering the questions asked by the auditor, helps in collecting data for future plans and decisions.

Before designing the fact

In this case, the auditors gather the data regarding the history of the project.

There are many tools and tips through which the industries successively rate their vendor's and suppliers, track performance and continuously increase overall productivity of the industry.

Establish performance indicators

At the beginning, the managers have to think and determine, all the characteristics that a vendor should have, to create specific performance criteria for assessing and tracking the vendors and suppliers regularly on quarterly, monthly or annual basis.

The things which are to be assessed are the size of the company, QMS number of certifications, complaint history etc.

Classify Multiple Vendors and Suppliers

If the company has a large number of vendor's, suppliers and managers, they will design a survey to assess them. It will be different to apply a survey to each and every vendor. Hence, vendor should be assessed by classifying them into different levels based on the effect they have on your product or service.

Plan an evaluation method

common methods used to evaluate a vendor or supplier are survey evaluation forms software application and system metrics.

They have to conduct audits regularly

Vendor quality evaluation

The quality of the vendors can be evaluated by considering the following points,

1. Delivery
2. Customer service
3. Quality
4. Pricing

Delivery

1. Materials should be delivered on time.
2. Proper items should be delivered in proper quantities.
3. There should be proper documentation for delivering materials.

Customer servicing

1. Adhere to policies of the industry.
2. Proper technical emergency support should be provided etc.

Quality

1. Warranty policy should be given.
2. Reliability and durability of the product meet these specifications.
3. The Instructions should be provided.

Pricing

1. Stability of the price.

If there are any changes in the price it should be informed in advance.

Vendor Rating

Figure 5 shows,

Maintain good relationship

1. ([Vendor Management, 2016](#)), It is important to maintain a good relationship with the vendors and suppliers, managers of the company should speak to them frequently.
2. Be honest with the payment issues payment should be done on time.
3. Vendors should understand the expectations and need of the company.

Vendor Re-assessment

1. ([Compliance Policy Guide \(CPG\), 2019](#)), Vendor re-assessment must be carried out at least once a year for each packaging material and the raw materials.
2. The rate of rejection must be assessed for 30 batches of a specific materials from a same vendor.
3. For data compilation, data must be collected from all other units.
4. If the rate of approval is more than 90%, then the vendor can be approved and re-assessment may not be required further.
5. If the rate of rejection is more than 10% then QA Department must conduct vendor audit to assess the reasons for lack of consistency in supplies.
6. The vendor must be rejected in case of a non-transferable cause.
7. If needed, this assessment is also created before the compilation of batches data based on supplies received.
8. QA Department of the plant must update the approved vendor list consequently and communicate to purchase and warehouse departments.

CONCLUSIONS

The process of vendor qualification essentially deals with the selection of vendors, which is a technique for evaluating the suitable vendors for the industries. 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. If there is any change in the management, then requalification is done.

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