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Review Article

Pharmaceutical Quality Assurance

A Short Review on Vendor Evaluation, Approach, Criteria and Questionnaire

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ABSTRACT: Vendor evaluation, a part of the cGMP which is used to ensure the procured products from the vendors,are meeting their quality standards. To avoid the procurement of substandard products from vendors, it is necessary to qualify the vendor / supplier which can avoid the adverse effect on the quality standards, regulatory requirements, and safety of the patients. The main objective of this review paper is to provide an overall outline of the vendor evaluation and to avoid quality failure and promote patient safety. This review paper covers the methods and criteria for evaluating of vendors in the pharmaceutical industry. This paper focuses on vendor evaluation by questionnaire to meet current Good Manufacturing Practice (cGMP). This text reviews the practical challenges faced and strategic plans of the pharmaceutical industry to achieve compliance management and the quality standards of products. An overview of the methods and approaches followed by the pharmaceutical industry to meet the regulatory requirements which were proposed by the leading regulatory bodies like the US Food and Drug Administration (USFDA) and European Medicines Agency (EMA) is briefly described. Most of the studies focus on criteria and methods, but rarely on approaches and questionnaires. Study includes the approaches, methods, criteria and questionnaire to achieve the quality and regulatory compliance and also emphasizes the vendor to stay confident on quality and the compliance of their products produced. The key points on the vendor questionnaire were effectively discussed, which remains the most common and effective method of vendor evaluation. This review paper also helps the professionals to arrive at an overall outline about the vendor evaluation aspects and questionnaire. The outcome of the study shows the importance of vendor evaluation, which helps in supply chain management.

KEYWORDS: Vendor Evaluation, Questionnaire, Vendor Qualification, Supplier Selection.

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1. INTRODUCTION

The pharmaceutical industry is the second largest sector among the global industries which has a vast market value. The pharmaceutical industry should meet the regulatory requirements which are proposed by leading regulatory bodies like the US Food and Drug Administration (USFDA) and European Medicines Agency (EMA). All industries should focus on regulatory compliance management. It's the responsibility of the pharmaceutical industry to maintain its own quality standards and meet current Good Manufacturing Practice (cGMP)[1]. To in-line with the standards and regulatory requirements, every pharmaceutical industry has their own strategic plan over the vendor evaluation and its performance verification[2].The practical challenge of every pharmaceutical industry is to assure the continuous supply of quality products that are sampled, tested and then approved for the intended use by the means of effective compliance system. i.e. (Vendor Evaluation System)[3]. The quality unit of pharmaceutical industries is responsible for qualifying and approving the vendors and to monitor the quality of the product continuously in line with the specified requirements[4]. Vendor evaluation is a part of the cGMP which is used to ensure the procured products are being produced consistently and reproducibly according to their quality standards. To avoid the procurement of substandard products from vendors, it is required to certify vendors / supplier based on the cGMP guidelines. This can avoid adverse effects on the quality standards, regulatory requirements, and safety of the patients. A written agreement should be made between both vendor and consumer which includes all the responsibilities related to the queries raised by the vendor / consumer[5]. The effective evaluation of the supplier / vendor is done by using the vendor evaluation questionnaire. The main objective of this review is to manufacture good and quality products which were delivered to the customers and to confirmwith the regulatory and statutory requirements[6]. This review on Vendor Evaluation comes up while searching the article about vendor evaluation. Most of the review paper lacks approaches and questionnaires for vendor evaluation to evaluate their vendors. This review paper has been prepared to cover those lacking topics (approaches, criteria and vendor questionnaire) which will help the professionals to acquire a basic knowledge over the vendor evaluation. This review is intended to deliver the key points of various methods in vendor evaluation.The effective evaluation of the supplier / vendor is done by using the vendor evaluation questionnaire, which constantly includes the dimensions like Quality, Regulatory and Statutory Compliance and the Technical Evaluation. Vendor Evaluation can be applied to monitor the performance of the vendor / supplier which makes the way for the continuous improvement. The Vendor Evaluation is the way to check the effectiveness of the vendor and their supplies. This can promote good quality of the outcomes and increases the profit of the firm. The qualification of the vendor is not only based on the initial assessment, but it also continues after the evaluation and the approval of the vendor. The vendor can be excluded after the approvalalso. This scenario is briefly described in the review. To gain moral support from the customer, the firm should ensure the vendor qualification if properly done and in an effective manner.

VENDOR EVALUATION

An evaluation and approval process of the vendors / suppliers by the means of quantitative and qualitative assessments is known as Vendor Evaluation. This evaluation is used to determine the vendors / suppliers, if they are meeting the organizational standards and obligations. Vendor evaluation is more important between the two bodies to maintain a safe and good portfolio. Vendor Evaluation can be applied to monitor the performance of the vendor / supplier over the quality and the compliance which makes the way for the continuous improvement[7,8].

2. APPROACHES AND METHODS

There are different methods and approaches to carryout a supplier / vendor assessment to assess their Quality Management Systems and the policies. The following methods can be used for evaluating the supplier / vendor.

- Commercial
- Technical
- Records
- Before the fact
- After the fact

2.1 Commercial

While evaluating the supplier / vendor, one should consider their commercial side of the business like prompt delivery, reputation, clients, and awards.

2.2 Technical

A supplier / vendor should be technically sound.

2.3 Records

Firm should collect data from public sources and award notices.

2.4 Before the fact

Firm should collect data about the supplier / vendor from relevant sources before the history of the contract / project.

2.5 After the fact

The Firm should collect the data like operational success and failures after the first delivery / shipment to analyze the supplier / vendor performance[9].

3. *VENDOR EVALUATION CRITERIA*

The best supplier/vendors to help the firm to satisfy their customers consistently. This can be achieved by effective evaluation of the supplier / vendor. Therefore, criteria for evaluating the supplier / vendor are mandatory. The important dimensions to be considered during evaluatingsupplier / vendor are as follows:

- Assurance of supply
- Quality and regulatory compliance
- Cost / Procurement supply
- Technical / Innovation
- Communication capabilities and Responsiveness

The effective evaluation of the supplier / vendor is done by using the vendor evaluation questionnaire which constantly includes above dimensions. The first step towards the customer focus is to meet the regulatory and the statutory requirements along with the customer requirements. One of the main benefits of the ISO Quality System is to implement the regulatory and the statutory requirements for improving the effectiveness of processes and services[10,11].

4. STEPS INVOLVED IN VENDOR EVALUATION

The firm's utmost responsibility is to evaluate the vendor. This could be possible only if the vendor has an effective and efficient vendor evaluation programme. The purpose of the vendor evaluation is to set definite criteria to evaluate and certify the vendor. The steps followed during the vendor evaluation are mentioned as follows:

- Supplier Selection
- Due Diligence
- Quality Assessment
- Change and Production Assessment
- Supply Chain Security
- Ongoing Assurance and Evaluation

4.1 Supplier Selection

The stepsofthe supplier selection process start with the minimum information which contains product name, user specifications and required quantity. While qualifying the vendor, firms may request the details which include the specifications, manufacturing, packaging & labeling systems, material safety data sheets, and analytical methods. The compromised cross-functional team shall access the below mentioned parameter while qualifying the vendor.

- Quality Compliance
- Regulatory Compliance
- Procurement Cost
- Technical Knowledge
- Communication

4.2 Due Diligence

Before making a contract with the vendors, the firm should conduct the appropriate due diligence to build confidence over the vendor. The documented evidence shall be collected for establishing the proper long-term business relationships by the means of different approaches such as Quality Risk Management, according to International Conference on Harmonisation (ICH)-Q9. Due Diligence is applicable only for the critical raw materials such as Active Pharmaceutical Ingredients (API) and it is not applicable for the Non-Critical Raw materials.Due diligence shall be performed based on the Quality Risk Management as per ICH-Q9 to assess the vendor's ability and the compliance to the system. The firm shall make the different approaches to evaluate the commercial potential of the vendor by selecting the cross-functional team and the expertise team collects the information and concludes their decision. The overall report shall be prepared to identify the recommendation based on evaluating the vendor.

To arrive conclusion, the following areas need to be checked:

- General Material Information
- Quality Systems
- Plant Visit
- Documentation
- Manufacturing Process
- Analytical methods & Stability
- Regulatory
- Intellectual Property
- Environment, Health and Safety

4.3 Quality Assessment:

The Quality Assessment will be conducted by the firm based on the category of the raw materials and outcome of the quality assessment shall be used for evaluating vendor. The report shall be prepared by collecting all the data related to quality assessment.

The data related to quality assessment are as follows:

- QC testing
- Tanker cleaning certification
- Transmissible Spongiform Encephalopathy**(**TSE) certification
- Historical performance
- Response to questionnaire
- Manufacturer questionnaire
- Audit data and completion
- Compliance history
- Reputation
- Third party certification
- Authority inspections

Most of the data discussed in Quality Assessment shall be covered by due diligence. However, that data remains a part of the Quality Assessment. Based on the satisfactory outcome of the Quality Assessment, the decision will be made about the contract with the vendor. The decision shall be authorized by the Quality Unit only.

4.4 Change Control and Production Assessment:

A systematic approach to managing all the changes that are made to the system / process is known as change management. The change is classified into two types: i) Permanent Change Control ii) Temporary Change Control
The changes are categorized into three ways:

- Minor
- Major
- Moderate

The five main steps involved in Change Control and Production Assessment are as follows

- Initiation of change
- Execution of change
- Evaluation of change
- Closure of the temporary change control package
- Effectiveness check

4.5 Supply Chain Security

The activities of supplier qualification and management are the direct communication between the vendor and the firm. In the modern scenario, substandard products and fraudulent activities have increased phenomenally. Due to this, the Supply Chain Security is more important. The regulatory bodies like US FDA and EU developed various methods to evaluate the vendor and make them a proper and safe portfolio and promote long-term relationships between the firm and Vendor.

4.6 Ongoing Monitoring and Evaluation

A periodic evaluation should be performed after approval of a new vendor. The cross-functional team with all departmentexpertisewill evaluate all types of aspects related to the vendor and the Quality Unitwill review on the outcome of the evaluation and re-approve the vendor12,13.

5. INCLUSION AND EXCLUSION OF VENDOR

5.1 *Inclusion of Vendor*

In general, the vendor shall be qualified by the purchase department and quality unit of the firm. Based on the firm's requirement, the purchase department shall opt for the relevant vendors.

5.2 *Source of vendors*

- New material procurement from existing vendors.
- New material procurement from a new vendor.
- Existing material procurement from a new vendor.

After selection of appropriate vendors, three consecutive batch samples will be collected and tested. Quality unit will provide the analytical report along with a conclusion summary to the purchase department. By considering analytical result outcomes and satisfactory completion of site audit, the purchase department includes the vendor as a provisional vendor.

5.3 Exclusion of Vendor

The vendor shall be excluded from the list of approved vendors for the following reasons:

- Failure on the critical test.
- The three consecutive failures in minor tests.
- Poor delivery plan.
- Mismatch of the amount in delivery challan and the invoice.
- Three failures out of 10 consignments.

Once the vendor is excluded from the approved vendor list, the Purchase department raises the query and is in need of proper justification for their error in the supply of goods14,15.

6. VENDOR/SUPPLIER EVALUATION QUESTIONNAIRE:

6.1 *Product Information*

Product Name
IUPAC / Chemical Name
Molecular Formula
Therapeutic category
Structural Formula

6.2 Manufacturing Site Information

Site Name
Address
Registered Office
Contact Person
Designation
Telephone
Fax Number
E-mail
Is the company a division of another corporation?

6.3 General Information

- Has the firm adopted a quality assurance system?
- How many persons are engaged in this Quality Assurance system?
- Is the firm certified as per regulatory bodies like ISO, WHO, US FDA, and /or any others?
- Is the firm audited by an independent body (national authority or private organization)?
- Does the firm have a valid factory license under Factories Act?
- Has the firm developed a procedure to identify applicable legal and regulatory requirements with respect to Health, Safety & Environment?
- Is there any procedure to identify & control Air emission, Effluent generation, Hazardous waste generation?

6.4 Organizational and Management Responsibility

- Does the firm operate under a corporate quality policy?
- Is a Quality Policy, Quality manual; Mission and Vision of the firm is available and followed?
- Is an organization chart available?
- Does the organization have a written job description for everyone?
- Are QA, QC independent?

6.5 Product Specific Information:

- Is the firm agreed to audit from members of the Quality team & relevant customer/regulatory authority?
- Is the product manufactured at a commercial level?

Size of the batch :
Duration of batch execution :
Annual production capacity :

- Is a dedicated production block and equipment available?
- Is any hazardous material involved in the batch manufacturing?
- Do firm manufacture/handle following types of products in the facility?
    - Steroids / Hormones
    - Cytotoxics
    - Penicillins / Cephalosporins
    - Other hazardous substances
- Are product / any raw material involved in the process of product derived from animal origin?

- Is the product free from Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)?
- Is any raw material involved in the process derived from plant /Vegetable origin?
- Is process validation carried out?
- Is there any contract manufacturing organization and contract testing laboratory?
- Do firm test each batch according to agreed specifications of both our firms?
- Can firm provide a Certificate of Analysis for every batch?
- Is the firm agreed to provide support for Drug Master File filing and regulatory queries?
- Are an on-going holding time / stability testing program conducted?
- Is temperature/humidity maintained in the sample storage area?
- Is the following storage and transportation condition available?
    - Freeze (below 0°C)?
    - Between 2°C-8°C?
    - Between 8°C-30°C?
    - At ambient condition (Not more than 40°C)?
- Any other special requirement?
- Is packing style for Solid Materials available?
    - Primary packaging
    - Secondary packaging
    - Net weight per packaging
- Mention the Shelf life / Retest period.
- Are the following items of information stated on the container?
- Name and address of manufacturer :
- Name of product :
- Batch number :
- Net weight :
- Mfg. Date :
- Expiry / re-test period :
- Storage and transportation care :
- Caution : :
- Is Material Safety Data Sheet (MSDS) supplied with every consignment?
- Is there any property like Hygroscopic/light sensitive/air sensitive/fuming/highly hazardous involved in process?
- Are there any special safety regulations required during handling?[16]

6.6 Personnel

- Strength of the employee in each department?
- Is defined procedure available for training and job responsibilities of employee?
- Is regular and adequate training conducted to employees?
- Is proper maintenance of the training records available?
- Do personnel follow the safety dressing and gowning procedures?
- Is additional personnel protective equipment available?
- Is periodic medical check carried out for all employees and respective records maintained?
- Are personnel with open wounds / contagious disease identified?
- Is there a procedure available for no product contact?
- Is a proper restroom facility, change room; Lockers and canteen provided?
- Does the employee work on shift basis and if yes, please mention the timings.

6.7 Health, Safety &Environmental Management System

- Has the firm prepared and implemented Health Safety & Environment policy?
- Is the firm following all the statutory requirements related to Environmental laws, Factory Act, Petroleum Rules, etc.?
- Is the Environmental management system implemented like ISO 14001?
- Is the Health & Safety Management system implemented like Occupational Health and Safety Assessment Series (OHSAS) 18001?
- Is there Emergency Response Plan available?
- Are employees trained to mitigate all kinds of emergencies?
- Are there fire hydrants or fire extinguishers available?
- Are persons trained to operate Fire Fighting facilities?
- Are specific Personal ProtectiveEquipment (PPE)'s provided?
- Is Effluent treatment plant available for treating process & sewage effluent?
- Is there any membership available for disposal of Hazardous waste?
- Are Standard Operating Procedure (SOP)'s prepared & implemented for Accident / Incident reporting & Investigation?
- Are SOP's prepared & implemented for the Work Permit system?
- Are First Aid Boxes provided in required areas?

6.8 Facility Design and Construction

- Is the building maintained properly, fully finished, painted and without any cracks and holds?
- Is the proper internal surface of Walls, Floor and Ceiling done with relevant material and free from cracks and permit ease to cleaning?
- Is there adequate space for placement of equipment available?
- Are closed systems for outside equipment available?
- Is adequate lighting provided?
- Is the Building within the Factory Act 1948?
- Are procedures for cleaning of equipment, facilities, and buildings available?
- Are there written procedures for pest control available?

6.9 Water System

- Is water periodically monitored for chemical and microbiological quality?
- Does process water and cleaning water meet its requirements?
- Is the treatment process to achieve defined water quality available?
- Is a sampling and testing plan available for water?[17]

6.10 Warehouse

- Are procedures for receipt, handling, storageand issuance of raw materials, and packing materials available?
- Is an approved vendor list available at the warehouse?
- Are changes in source/supplier handled with Quality Management System procedures?

- Are incoming materials visually examined for damage and correct labels?
- Is a checklist available for all incoming materials to represent the details of materials?
- Is quarantine, approved and rejected materials areas segregated and properly labeled?
- Is the rejected material area having restricted access?
- Is a separate area designated for sampling and dispensing of raw materials?
- Is dedicated storage space available to prevent degradation and contamination?
- Are storage facilities available for temperature-sensitive materials?
- Are temperature and humidity monitored in facilities for the storage of materials?
- Are fiber drums and polyethylene bags stored in the pallets and dedicated storage spaces?
- Is the first in first out principle followed?
- Is a procedure like cleaning and proper labeling available in case materials stored outdoors?
- Is a tanker cleaning certificate received during the solvent tanker receipt?
- Are records of each material maintained?
- Is retest period defined for all raw materials?
- Is a procedure available to identify the materials under the retest period?
- Is a defined procedure available for cleaning of dispensing tools?
- Is cleaning status displayed on each accessory at warehouse?
- Is a defined procedure for cleaning of re-used containers available and previous labels removed or defaced?
- Is separate area storage of finished products available?
- Are separate storage areas provided for quarantined, approved, rejected, returned or recalled products and temperature-sensitive finished products in the finished products area?
- Does the firm conduct any transportation studies to ensure transport and storage conditions?
- Is firm follow the periodic calibration procedure for weighing scales at the warehouse?
- Is the sampling area available with the appropriate and relevant pressure difference?[18]

6.11 Sampling and Testing of incoming Raw Materials

- Are sampling procedures and sampling plan available?
- Is defined sampling location available to prevent contamination?
- Are containers labeled after sampling?
- Are specifications established and approved by quality unit?

6.12 In-Process Sampling and Controls

- Are procedures available to monitor & control the performance of the In-process sampling?
- Are in-process controls approved by the Quality Unit?
- Is in-process sampling carried out by production?
- Are sampling and testing methods for in-process controls available and approved?

6.13 Production

- Are roles and responsibilities defined for all personnel?
- Are production personnel trained for respective jobs?
- Are equipment status displayed about the batch and its cleanliness?
- Are logbooks maintained for usage and cleaning of production equipments?
- Is production equipment used within the operation range?
- Is calibration and preventive maintenance of equipment properly scheduled and done?
- Is proper labeling and identification procedure available for major equipment and utilities?
- Is a lubricant, heating fluids or coolants are not in contact with Intermediates/KSM and RM ensured?
- Are procedures for the cleaning of production equipment available?
- Is the equipment cleaning performed between the production of different batches and products?
- Is record maintained for batch-to-batch, periodic and product change over cleaning and acceptance criteria defined?
- Is the equipment cleaned at defined intervals if it is dedicated?
- Are primary work instructions for each product prepared by productions and approved by quality unit?
- Does a primary work instruction contain the following?
  Product Name including document reference code
  Complete list of Raw materials
  Required quantity
  Production blocks and major equipment
  Process sequences, critical process parameters, sampling instructions, in process control, time limits, expected yields.

- Are batch production records verified before issuance for exact primary version?
- Do records possess a unique batch number?
- Does the Batch record contain the following?
  Date and time
  Identification of equipment
  Identification of materials used
  Actual results
  Sampling performed
  Signature of the person sampled
  In Process laboratory test results
  Actual yield
  Description of the packaging and labels used
  Deviation/ Investigation
  Results of complete testing
- Are weighing and measuring devices of suitable accuracy available?
- Do containers contain the following information
  Name of material
  Code number
  Weight
  Retest date
- Are critical weighing, measuring operations, and critical process parameters witnessed?
- Is blending of different batches carried out?
- Are all individual batches tested before blending?
- Is the blending process documented and the blended batch tested to meet its specifications?
- Does the batch record of the blended batch allow traceability of individual batches?
- Are Out OfSpecification batches blended with other batches meeting the specification?
- Are defined procedures available in production to prevent contamination of Intermediate/KSM?

- Are there specific precautions taken to avoid contamination of the KSM/Intermediate after purification?
- Are procedures in place to ensure use of correct packing materials and labels?
- Is procedure for preventing cross-contamination available?[19]

6.14 Reprocessing / Rework

- Is procedure for reprocess and rework available?
- Is unique batch code for reprocess/rework batch available?
- Is the supply of reprocess/rework batch after approval?

6.15 Recovery of Materials including Solvents

- Are defined procedures available for the recovery of materials?
- Is specification available and approved for recovered materials?
- Are recovered materials tested and released against established specifications?
- Are recovered materials used at the same stage in which theyare used?
- Are established process validated by using recovered solvents / materials?

6.16 Complaints, Returns and Recall

- Do firm have procedure for handling of market complaints and return materials?
- Are record maintained for all complaints and returns?
- Are adequate Corrective Action Preventive Action (CAPA) provided?
- Are returned KSM/Intermediate properly quarantined?
- Are records of returned goods containing following information
  - Product Name
  - Contact person originating the complaint
  - Nature of complaint
  - Date of complaint received
  - Detail investigation report
  - Action taken (Including the person acting)
  - Response provided to the originator
  - Final decision on KSM/Intermediate
- Is returned materials evaluated for their quality before reuse?
- Is there recall procedure available?
- Does the recall procedure include
  - How was the recall initiated?
  - Who should be informed?
  - How is recalled material treated?

6.17 Batch Production Record Issuance and Retrieval:

- Is a procedure available for issuance and retrieval of batch production records?
- Are batch production records issued by the quality unit?
- Is the issuance and retrieval record maintained?
- Is the checklist for batch production records available?
- Are all stage batch production records reviewed and approved by the quality unit before the release of the KSM/Intermediate?
- Are all deviations, investigations, and out of specifications reviewed as part of the batch record review?
- Is the quality unit releasing all KSM/Intermediate that are shipped outside the control of the company?

6.18 Quality Control

Are all sampling plans and testing procedures reviewed and approved by the Quality Unit?

- Do specifications available for all raw materials used in manufacturing?
- Is defined procedure available for handling of Out of Specification (OOS)?
- Are all Out of specification results investigated and documented?
- Are procedures available for preparation of reagents and standard solutions?
- Is procedure available for calibration of all instruments available in quality control laboratory?
- Are all quality control laboratory instruments subjected to periodic maintenance?
- Are primary reference standard stored under appropriate conditions?
- Is source of the primary standard documented?
- Are procedures available to prepare, identify, test store and approve secondary reference standards?
- Is any skip/reduces testing followed for raw materials, in process, intermediate & final KSM/Intermediate?
- Is an authentic Certificate of analysis issued for each batch of KSM/Intermediate?
- Is Name of KSM/Intermediate, batch Number, manufacturing date and expiry date available on the Certificate of Analysis?
- Is the Certificate of Analysis (COA) dated and signed by authorized personnel of the Quality Unit
- Is customer specification and method of analysis ensured during the final dispatch release?
- Does the laboratory test record contain the following
  - Description of the sample including name, batch no or code, date, when sample was taken, quantity
  - Reference to test method
  - Complete record of all the raw data
  - Record of all calculations and statements of results
  - Signature and date of person who performs the test and who reviews it
- Are the following records maintained?
  - Modification to test methods
  - Calibration of laboratory instruments
  - Stability/hold time study testing performed
  - OOS Investigations
- Are reserve samples stored? What is the duration of storage of the reserved sample?
- Are reserves samples stored in the same packing and storage condition of API?
- Is a sample available to conduct at least 2 full analyses?

6.19 Quality Management System

- Is the Quality Unit independent from production?
- Is the decision on the release of a product taken by the quality unit independently?
- Is the quality unit involved in all quality-related activities?
- Are all QMS documents reviewed and approved quality unit?
- Is the quality unit responsible for the following activities?
  - Release/rejection of KSM/Intermediate (to be sold)

- Establish system to release/reject materials and labels
- Review and approval of batch production records
- Ensure critical deviations are investigated and documented
- Approval of specifications, master documents, SOPs, work instructions
- Internal audits
- Approval of suppliers/contract manufacturer/laboratories
- Handling of change controls and customer notifications
- Approval of validation documents
- Perform product quality reviews
- Handling of deviations/out of specifications
- Handling of market complaints and customer response
- Ensuring calibration/maintenance program

- Is there an authorized person for the release of KSM/Intermediate?
- Is management notified for serious GMP deficiencies and/or product defects?
- Is a procedure available for conducting self-audit?
- Is there an audit schedule?
- Are audit findings and corrective actions documented?
- Are all internal audits closed on time?
- Is there procedure to notify the audit findings to senior management?
- Are product quality reviews conducted for all products?
- Are procedures available for preparation, review, approval, and distribution of documents related to manufacturing?
- Are revision, superseding and retrieval of documents controlled and a revision history maintained?
- Are documents promptly retrievable?
- Is access to label limited to authorized personnel?
- Are procedures available for reconciling the quantities of labels issued and used?
- Are all unused labels bearing batch numbers being destroyed?
- Is the specimen label included in the batch production record?
- Is the company's overall validation policy documented?
- Is validation protocol approved by the quality unit?
- Is a process validation report prepared that includes the results obtained comprised of recommendations for changes to correct deficiencies?
- Is procedure available for qualification of suppliers of raw materials?
- Is the approved vendor list approved by the quality unit?[21]

6.20 Qualification

- Are current drawings for equipment and critical installations maintained?
- Is a procedure available for qualification of critical equipment and ancillary systems?
- Is appropriate qualification (DQ, IQ, OQ and PQ) performed for all critical equipment and ancillary systems?
- Is a qualification protocol/report approved by the quality unit?
- Is the qualification status of all critical equipment reviewed periodically?

6.21 Maintenance and Calibration:

- Is a procedure available for periodic preventive maintenance of all production equipment and utilities?
- Is a preventive maintenance schedule for all equipment available and followed?
- Is a procedure available for periodic calibration of all critical gauges/components of the equipment?

6.22 Contract Manufacturers (Including Laboratories)

- Is a procedure available for qualification of contract manufacturers and testing laboratories?
- Is there a written agreement with the contract manufacturers and testing laboratories?
- Are roles and responsibilities mentioned in written contract agreement?
- Are contract manufacturers and testing laboratories audited periodically?

6.23 Questionnaire Filled by(Supplier / Vendor):

Name :
Designation :
Date :

6.24 Questionnaire Completion:

Name :
Designation :
Date :

By using this evaluation method (questionnaire), the firm shall get the details of the vendor / supplier and it will be more helpful in qualifying the vendors[21-23].

7. BENEFITS OF VENDOR EVALUATION

The vendor assessment process can be quite a challenging one. There are plenty of benefits in evaluating the supplier / vendor and as follows:

- Reduced costs
- High Efficiency
- Long-term Relationships
- Cyber risk Assessment
- Business improvement

7.1 Reduced costs

Every firm shall look over the best quality and deliveryof the products over the reduced costs. If theyarereducing cost, they might end up with the loss of quality products and customers too. So, every supplier / vendor offers to reduce their costs by adding the volume or further discounts.

7.2 High Efficiency

By continuous / ongoing assurance of the materials, firm shall rate the efficiency of the supplier / vendor. This will provide a positive and smooth flow of business and with high efficiency.

7.3 Long-term Relationships

Proper supplier / vendor management like foster communication and loyalty, relationships may remain long term. This may result in mutually beneficial outcomes.

7.4 Cyber Risk Assessment

A modern threat to all firms is cyber theft. All firms need, their information to be protected and safe. Hence they are involved in the Cyber Risk Assessment on supplier / vendor.

7.5 Business Improvement

Proper examination of the supplier / vendor will help the firm to get good quality products with best price and also makes them serve better to their customers[24].

8. CONCLUSION

Vendor evaluation is essential and more important than auditing and remains as a risk assessment tool. It is necessary to certifythe vendor to assure the quality of the procured products. This overview highlights the importance of vendor evaluation and methods regarding questionnaires to qualify vendors. The firm should certify the vendor in accordance to the regulatory guidelines to avoid substandard products which may cause adverse effect on the patient's safety and the quality of the products. The efficient qualification of the vendors promotes the supply of good quality products and reduces the nonconformance. This helps to verify the vendor is in line with the regulatory requirements and meeting the consumer's standards and their needs. Vendor evaluation prevents from the poor purchasing decisions which can cause difficult situations leading to poor quality products and regulatory non-compliance and adverse effect on company profits. Throughout history, the firm needsvendor compliance over the regulatory requirements and quality standards to gain and maintain moral support from their consumers.

9. AUTHOR CONTRIBUTION STATEMENT

Preethi Mullaivendan Conceptualized and designed the study and prepared the original draft. Dr. Shabna Roupal Morais discussed the methods, approaches, and criteria of Vendor Evaluation and provided the necessary and valuable inputs the design of the original draft. All authors discussed the outcomes and approved the final version of the manuscript.

10. CONFLICT OF INTEREST

Conflict of interest declared none.

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