

Revolutionizing Vendor Qualification: Raw Materials in Pharmaceuticals

Isha Dubey^{1*}, Pawan Patel², Gurmeet S. Chhabra³, Nimita Manocha⁴
Research Scholar^{1,2}, Professor³, Professor⁴(Principal)

^{1*}Department of Quality Assurance; ²Department of Pharmaceutics; ³Faculty of Pharmacy; ⁴ Faculty of Pharmacy and Principal,
Indore Institute of Pharmacy, Pithampur road, Opposite Indian Institute of Management, Rau, 453331,
Indore, Madhya Pradesh, India

Abstract:- Vendor qualification is a crucial step to ensure the delivery of high-quality and safe medicines, aligning with GMP requirements. The objective of this process is to avert adverse events, recalls, or potential health risks associated with substandard medication. Regulatory authorities oversee and guide vendor qualification processes. This article specifically highlights the personnel engaged in vendor qualification and the rigorous vendor selection process and QUEST approach for selecting and qualifying vendors. This article delves into the significance of vendor assessment, reassessment, and the structured approach required for qualifying vendors. The Supply Chain Management team coordinates with QA to perform vendor qualification. Vendor rating systems are explained, emphasizing disqualification if a batch doesn't meet critical test specifications. In such cases, a re-evaluation and investigation are conducted. Clear communication with the vendor regarding disqualification reasons is imperative. The review article provides an in-depth procedure for qualifying raw material vendors, emphasizing stringent quality standards.

Keywords:- ICH Guideline, ISO, QUEST Approach, Raw Material, Vendor Qualification, Vendor Rating.

I. INTRODUCTION

Vendor, often called as supplier. A seller is a person or company that sells goods/services to someone else in the economic production chain. Individuals, activities, technology, organizations, resources these are the network which involved in the creation and sale of a product, from the vendor to the manufacturer.¹The 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."^{2,3}Performing qualification is necessary to prevent the occurrence of adverse events, to prevent rejects and recalls, to prevent serious illnesses or death of customers due to low quality drug products.²

II. VENDOR QUALIFICATION

- Performing qualification is necessary to prevent the occurrence of adverse events, to prevent rejects and recalls, to prevent serious illnesses or death of customers due to low quality drug products.
- Vendor Qualification is the process of selecting, assessing and approving a vendor/supplier to determine whether it is able to provide materials of quality that meets standards and purchasing company's requirements.
- Supplier qualification indeed goes beyond and serves as a comprehensive risk assessment tool. It helps to ensure that supplier/vendor and contractors are capable of consistently providing the materials, components and services of quality that meets regulatory requirements.
- An integrated supplier qualification process should be aimed to identify and mitigate the associated potential risks adhering to the materials, components and services.
- The exact requirements for accurate and robust supplier/vendor qualification process can vary depending on the needs of industry, organisations, authorities and regulations.²

III. REGULATORY COMPLIANCE NAVIGATING VENDOR QUALIFICATION

Vendor qualification, a critical aspect of ensuring product quality and safety, is guided by both FDA regulations and Code of Federal Regulations [under 21 CFR Parts 210 and 211] and international standards like ICH (International Council for Harmonisation) and ISO (International Organization for Standardization) guidelines.

A. FDA Regulations:

The FDA emphasizes the need for pharmaceutical companies to ensure the quality of materials sourced from vendors.

Regulations such as Current Good Manufacturing Practices (cGMP) set forth standards for quality control and assurance in the manufacturing, processing, packaging, and holding of pharmaceutical products.

The FDA expects companies to have robust procedures for vendor selection, qualification, and oversight to ensure the quality and consistency of materials used in drug manufacturing.^{4,5}

B. Under 21 CFR (Code of Federal Regulations)

Particularly in sections related to pharmaceuticals like 21 CFR Parts 210 and 211, vendor qualification is a critical aspect of ensuring the quality, safety, and efficacy of drug products.

Here are some key aspects of vendor qualification under 21 CFR:

- **Quality Systems Requirements:** 21 CFR Parts 210 and 211 outline the Current Good Manufacturing Practices (cGMP) regulations that pharmaceutical companies must adhere to. These regulations emphasize establishing and following robust quality systems, including procedures for vendor selection, qualification, and oversight.
- **Vendor Selection Criteria:** Companies are expected to establish criteria for vendor selection based on factors such as quality, reliability, capability, adherence to cGMP regulations, and the ability to consistently supply materials meeting specifications.
- **Vendor Qualification Process:** A structured vendor qualification process is essential, involving evaluation, assessment, and approval of vendors before allowing them to supply materials or services critical to drug manufacturing.
- **Documentation and Record-Keeping:** Comprehensive documentation of vendor assessments, audits, and qualification criteria is mandated. Records must demonstrate that vendors meet specified quality standards and comply with regulations.
- **Ongoing Monitoring and Requalification:** Continuous monitoring of vendor performance is crucial. Periodic requalification ensures that vendors consistently meet quality and regulatory standards over time.
- **Risk Management:** Companies are expected to assess and manage risks associated with vendors, their supplied materials, and the impact on product quality. This includes establishing risk-based approaches for vendor assessment and qualification.
- **Corrective Actions and Continual Improvement:** If issues are identified during vendor qualification or through ongoing monitoring, companies must take appropriate corrective actions. There's an emphasis on continual improvement of vendor-related processes.
- Adhering to 21 CFR regulations is critical for pharmaceutical companies to maintain compliance with quality standards, ensure the integrity of their supply chain, and ultimately produce safe and effective drug products.⁶

C. ICH Guidelines:

ICH guidelines provide international standards for the pharmaceutical industry, aiming to harmonize regulations to ensure the quality, safety, efficacy, and performance of pharmaceutical products.

Specific guidelines, such as ICH Q7, focus on Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (APIs), outlining principles for quality management in the production of APIs.^{7,8,5}

D. ISO Standards:

- ISO standards, particularly ISO 9001 (Quality Management Systems) and ISO 13485 (Quality Management Systems for Medical Devices), offer frameworks for quality management and assurance systems.
- These standards provide general guidelines for establishing and maintaining quality management systems, including aspects relevant to vendor assessment and qualification.
- In the context of vendor qualification, these regulatory frameworks and guidelines typically include aspects such as:
 - **Vendor Selection Criteria:** Criteria for assessing and selecting vendors based on quality, reliability, capability, and compliance with regulations.
 - **Vendor Qualification Process:** Defined procedures for assessing vendors' capabilities, quality systems, and adherence to regulatory requirements before approval.
 - **Ongoing Monitoring and Assessment:** Continuous monitoring and periodic requalification to ensure continued compliance and adherence to quality standards.
 - **Documentation and Record-Keeping:** Maintaining comprehensive records of vendor assessments, qualifications, audits, and any corrective actions taken.

Adherence to these regulations and guidelines is essential for pharmaceutical companies to maintain a robust vendor qualification process, ensuring the integrity of the supply chain and the quality of pharmaceutical products.^{9,5}

IV. PERSONNEL INVOLVED IN VENDOR QUALIFICATION

- Head SCM for identification and selection of vendor.
- Head quality control for testing of samples.
- Head R&D to take trial of product batches.
- Head Quality Assurance/Compliance of head for evaluation and qualification of vendor.⁹

V. SELECTION OF VENDORS

- Selection of vendors shall be made after evaluating the following factors:
 - Capability of vendor to supply material of approved quality as required by purchasing company.
 - Capability of vendor to supply materials of appropriate quantity to purchasing company.
 - Vendors reputation assessment should be done by assessing –
 - Check its FDA inspection profiles.
 - Finding out the collaboration with other companies.
 - It's past history of failure or recall.

- Selling price of API /excipients or packaging materials should be known for achieving profit.
- Whether vendor is inspected and approved by regulatory authorities.
- Whether the vendor is manufacturer or distributor.
- Capability of vendor to supply the expanded needs of materials.⁹

VI. QUEST APPROACH FOR VENDOR QUALIFICATION

The supplier qualification life cycle typically applies the **QUEST Approach**:

- **Question** – define requirements and develop questions
- **Understand** – compile candidates and assess capabilities
- **Evaluate** – evaluate candidates and identify the best one
- **Site audit** – perform a comprehensive site audit

Track – re-qualify suppliers on a routine basis.^{10,11}

➤ *QUEST Approach for qualification of pharmaceutical excipient manufacturers*

The Q.U.E.S.T. methodology proposed by Cafmeyer and Lewis in 2009 involves a systematic process for selecting and qualifying vendors. Here's a breakdown of the approach for selecting and qualifying excipients vendor:

- **Q = Question Phase:**

Define the type of excipient needed for drug product manufacturing to meet product characteristics, safety, and efficacy. Develop a specified raw material specification with a scientific rationale for proposed usage.

- **U = Understanding Phase:**

Vendor engagement: request documents and samples, assess three submissions, understand particle requirements, finalize excipients based on trials, use scientific rationale.¹²

- **E = Evaluation Phase:**

Identify the best potential vendor based on the specified requirements.

- **S = Site Audit Phase:**

Conduct onsite and offsite verifications based on the criticality of the excipient.

- **T = Track Phase:**

Continuously monitor and requalify the vendor's performance. This involves reviewing any issues associated with the goods or services supplied. Establish a schedule for periodic requalification of each qualified vendor.

This Q.U.E.S.T. approach ensures a thorough and strategic process for selecting and maintaining excipient vendors, emphasizing scientific rationale, continuous monitoring, and periodic requalification to uphold quality standards.³

VII. VENDOR QUALIFICATION PROCESS

- The Vendor qualification process will be coordinated by the Head of QA, who will work in collaboration with the Manager of the Purchase Department and other relevant departments. When it comes to qualifying additional or alternative vendors for materials already in use, the Manager of the Purchase Department will take the lead.¹³
- The process kicks off with the Purchase Department conducting an evaluation based on factors such as:
 - The vendor's reputation,
 - Adherence to quality standards, and
 - Analysis of prevailing marketing trends.
- This evaluation helps in generating a preliminary list of potential new vendors for each material.
- Once this list is prepared, the Manager of the Purchase Department will facilitate the vendor qualification process in tandem with the QA team. The qualifications obtained from the QA department will then be forwarded to the respective vendors.

A. *Structured Approach for Vendor Qualification Includes Several Procedures:*

- Initiation by the Purchase Department
- Vendor Qualification Questionnaire
- Analysis of samples and trials of machines
- Physical audit and Quality Agreement²

In detail:

➤ *Initiation by the Purchase Department:*

The purchase department initiates the process of creating a new vendor list for each material. This could be based on factors like the reputation of the vendor, quality standards, and marketing trend analysis.

➤ *Vendor Qualification Questionnaire:*

- A vendor questionnaire is a series of questions used to help in evaluating or assessing overall risk.
- Questionnaires are a central part of doing work carefully and with ongoing monitoring.
- Vendor questionnaires will inform level of risk when compared to risk score.
- A vendor qualification questionnaire is used to assess potential vendors. This questionnaire is divided into three parts:
 - ✓ **Part A - Basic Information:** This section collects fundamental information about the vendor, such as site details, contact numbers, production capacity, turnover, organizational performance, and major customers.
 - ✓ **Part B - Technical Information:** Here, technical details about the vendor's manufacturing site are gathered. This might include information about the facilities, equipment, certifications, and quality control processes.
 - ✓ **Part C - Product-Specific Information:** This section focuses on the specific details of the product the vendor is supplying. This could include specifications, quality standards, and any other relevant information specific to the materials being purchased.¹³

B. Sending Qualification Questionnaires:

The purchase department employs a structured approach in sending qualification questionnaires to potential vendors based on different scenarios.

For new vendors, the complete qualification questionnaire (Parts A, B, and C) is sent to thoroughly assess their capabilities. In the case of qualifying a new material

from an existing vendor, only Part C of the questionnaire, along with the material specification, is sent, assuming that the vendor's general qualifications have been previously established. This approach ensures a comprehensive evaluation of potential vendors while streamlining the process for existing vendors, contributing to the maintenance or enhancement of material quality and reliability for the organization.

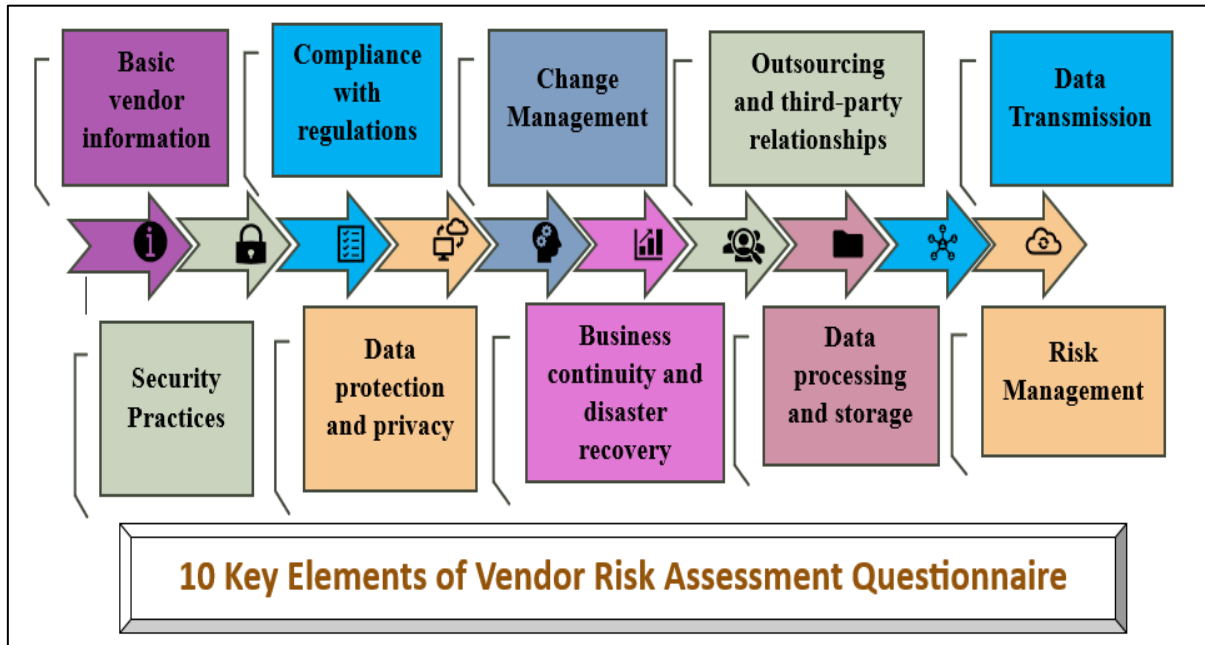


Fig. 1: Vendor risk assessment questionnaire.¹⁴

C. Analysis of samples and trials of machines:

While ensuring product quality it becomes necessary for pharmaceutical industry to analyse the samples that are purchased from the vendor so that it meets regulatory requirements and customer satisfaction.²

For performing analysis of samples, following procedure is undergone:

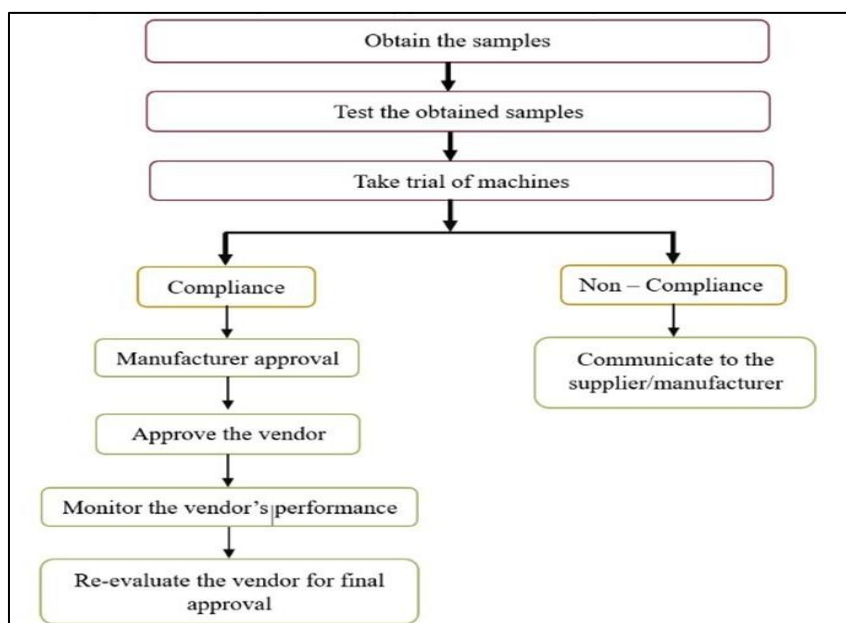


Fig. 2: Procedure for analysis of samples.²

D. Physical audit and Quality agreement:

- A physical audit of critical material vendors, supplying items such as API, excipients, and intermediates, is essential to verify regulatory compliance and ensure adherence to quality standards.
- A vendor site's physical audit provides insight into procedures, facilities, and quality management systems, ensuring alignment with pharmaceutical company standards and regulatory obligations. The audit aims to assess the vendor's quality management system comprehensively, identify and mitigate potential risks related to material quality, and verify industry compliance in material supply.
- Key steps of a conducting a physical audit are:
 - ✓ *Preparation:* Define the audit's objective, goal, scope and criteria. Generate the audit plan that includes the areas that needs to be audited, the audit team framework, and the schedule of the audit.
 - ✓ *On-site audit:* The pre-composed audit team will visit the vendor's site to gather information of vendor's procedures, facilities, conduct interviews with personnels working at vendor's site, review of related documents, and observation of ongoing processes.
 - ✓ *Conclusion of findings and reporting:* After on-site inspection, the audit team compiles findings into a report detailing areas of compliance and non-compliance, associated risks, and proposed corrective and preventive actions for improvement.
 - ✓ *Corrective actions:* If audit identifies deficiencies, the vendor must implement corrective actions to minimize associated risks. Subsequent audits may be conducted to verify the effectiveness of implemented corrective actions.²

E. Quality Agreement

- A quality agreement is a legally binding document outlining responsibilities for ensuring the quality and supply of critical materials, such as APIs and intermediates, meeting pharmaceutical standards. It establishes a mutual understanding on quality and regulatory compliance between the manufacturer and the customer.
- A quality agreement is a major element of the vendor qualification process but, of course, it is not a substitute for the vendor qualification process[including audits, understanding of vendor's procedures, building and facilities, finding and mitigating associated risks etc.¹⁵
- Standard structure of quality agreement includes following components:
 - **Introduction/Purpose/Scope:** This section clearly defines the scope and purpose of quality agreement including the products and services covered, as well as the regulatory requirements that must be met. It further includes:
 - ✓ *Parties to the agreement* - This shows the quality agreement is by and between the supplier and customer and includes supplier's name and location with the customer's name and location.
 - ✓ Products covered under the agreement – includes information about the products listed in the agreement.

- ✓ *Sites involved* – includes sites at which substances are produced, the supplier/vendor's site can also be specified here if required.
- ✓ *Definitions and abbreviations-* An alphabetical list of abbreviations used in the quality agreement should be included to improve the readability and minimizing confusion to the reader.
- **Compliance section:** This section shows how the product or services in relation to quality adhere to the regulatory compliance applies to the rules and regulations, and practices that an organization puts in place for compliance. It also includes:
 - ✓ Certificate of Conformance
 - ✓ Certificate of Analysis
- **General provisions:** This section includes:
 - ✓ *Term of agreement-* The quality agreement takes effect upon final signature and remains valid for two years from the last delivery of critical material, unless a written agreement specifies an extension.
 - ✓ *Assignment* – Neither of the parties shall have the right to assign any of its rights or commitments in the quality agreement without prior written consent of another party.
 - ✓ *Related agreements* – In case of discrepancies, the supplier agreement prevails in non-quality related matters, while the quality agreement takes precedence in all quality-related issues.
 - ✓ *Confidentiality-* A confidentiality agreement is a legal contract preventing the disclosure of sensitive information by outlining how it will be handled and safeguarded by both the supplier and the purchasing company or other involved parties.
 - ✓ *Choice of law:* The choice of law in a supply agreement specifies that the quality agreement is governed and interpreted in accordance with the law applicable to the supply agreement. Typically, the law of the country where the supplier is located is chosen.
 - ✓ *Survival clause:* this subsection relates to the provisions that are intended to be continues after the winding up of the quality agreement, for example-right to audit, maintenance of lot traceability, responses to recalls or complaints, ongoing stability studies, or retention of documents/records/samples.
 - ✓ Signatories
 - ✓ *Quality Contacts:* List all the relevant contact persons of both the parties that are responsible for communication regarding this quality agreement including their details such as name, position, phone number, e-mail.
 - ✓ *List of appendices:* Supplementary materials consists of supporting information that are generally attached to a quality agreement. Appendices may consist of figures, graphs, tables, charts, maps, questionnaires etc...

By integrating physical audits and quality agreements, the organization ensures vendors can consistently supply critical materials, products, and services meeting quality requirements and regulatory compliance. This procedure mitigates potential risks, fostering a robust and trustworthy relationship between the organization and vendors/suppliers.^{2,15}

VIII. VENDOR RATING

Vendor rating, also known as supplier rating, systematically evaluates and assesses a vendor's performance and ability to meet quality requirements and compliance. It involves rating vendors on parameters such as the quality of critical materials, supply cost, delivery

time, material maintenance during transport and storage, efficacy and safety, and responsiveness to emergency orders.

Vendor rating is done according to vendor's performance and can be divided into various groups based on:²

Table 1: Vendor Rating²

RATING	RULES
EXCELLENT	Exceeds company and customer's expectations and no quality issues were found i.e., Zero defects.
GOOD	Meets company and customer's expectations and minor quality issues were found.
ACCEPTABLE	Meets company's requirements
POOR	Doesn't meet customer and company's minimum requirements

- **Approved vendor list:** Is a list of qualified and approved vendor's containing material's code, pharmacopeial status, manufacturer code, vendor code and storage condition of materials.¹⁶

procedures that often depend on individual company requirements.

- To institute a supplier auditing program, it's essential to assess the risk associated with supplied materials, categorizing them as high, medium, or low risk based on their significance to the medicinal product or manufacturing process. For pharmaceutical manufacturers dealing with multiple suppliers, varying levels of evaluation should be applied based on their impact on the final medicinal product.¹⁷
- The ICH Q9 Quality Risk Management guidelines offer essential principles and tools applicable across pharmaceutical quality facets. Within the context of raw material supplier qualification, risk assessment plays a crucial role. Hence, leveraging the ICH Q9 guideline proves invaluable in structuring a robust supplier qualification program.^{19,20,5,17}

IX. RAW MATERIALS

- Pharmaceutical raw materials are input substances or starting materials including both active pharmaceutical ingredient (API) and inactive ingredients or excipients, intermediates and additives.
- Raw materials may be classified according to their use in manufacturing process and the level of effect they impart on quality. On the basis of this raw materials are classified into three categories:
- Starting raw materials – Significant raw materials, crucial to product quality and well-characterized, may be part of the finished drug product or have direct contact with it. Examples include APIs, excipients, reagents, additives, and primary packaging materials.
- ✓ **Key raw materials** – These raw materials significantly impact the process consistency of a quality product but do not directly affect the finished product's quality. Characterization, if needed, is based on risk after risk assessment. Examples include detergents, cleaners, disinfectants, and food-grade lubricants.
- ✓ **Non-key raw materials** – The other categories are not met by these types of raw materials.¹⁷
- Raw material testing is crucial for ensuring the safety, efficacy, potency, and quality of a finished drug product, minimizing rejects and recalls. This testing ensures that all materials used in the manufacturing process are safe, meet specifications, and align with requirements, ultimately resulting in a high-quality finished product.¹⁸
- A diverse array of raw materials, including API, intermediates, excipients, and packaging materials, can influence process performance and product quality. The vendor qualification program serves as a risk assessment tool, ensuring suppliers consistently provide quality raw materials in compliance with requirements.
- Regulatory guidelines emphasize manufacturing practices and raw material evaluation for finished products, but no specific guidance exists for supplier qualification, creating complexity in establishing

Here are the essential procedures/steps involved in executing a supplier qualification program for raw materials:

Table 2: Procedures involved in executing a supplier qualification program for raw materials.²¹

S.No	Procedure	Details/Description
1.	Master plan	It provides overall outlook and basic decisions with their justifications.
2.	Creating and updating specifications	This SOP establishes procedures for creating, approving, assigning unique identifiers, and overseeing the lifecycle of new raw material (RM) specifications.
3.	Procurement of GMP compliant RM's	This SOP provides guidelines for requesting of RM, placement of orders, and management of returns for all items subject to Good Manufacturing Practices (GMP) controls
4.	Receiving GMP compliant RM's	This SOP details the reception process for GMP Raw materials, outlining the location, personnel responsible, and security measures during delivery.
5.	Vendor qualification	This SOP defines the assessment process for suppliers, covering new and established ones based on business, regulatory, and scientific suitability.
6.	Raw material qualification	The procedure of approving a new raw material for utilization in a specific process.
7.	Sampling and inspection	It specifies the methods and utensils used for sampling raw materials (RMs) and addresses whether samples can be combined before testing.
8.	Raw material testing methods	Individual test methods can be found within a compendium specified by the company or documented separately in written procedures.
9.	Documentation and reporting test outcomes	It provides guidance on recording data, rectify mistakes, observe, verify, and assess outcomes, and grant approval for data to be released from the laboratory.
10.	OOS and OOT investigations	Use caution when applying the general Out-of-Specification (OOS) procedure to raw materials (RM), considering unique circumstances.
11.	Handling or management of materials	The quality unit decides material release, rejection, or hold to avoid conflicts.
12.	Deviations and changes	This procedure details QA review for planned and unplanned procedure deviations. It also manages changes in specifications, methodologies, equipment, and software.

X. APPROVAL PROCESS FOR NEW RAW MATERIAL VENDORS:

- The Purchase Department initiates the vendor search based on proximity, technical competence, and commercial considerations.
- New vendors undergo qualification and approval by the Quality Assurance (QA) department before becoming regular suppliers of raw materials.
- The Production Head provides detailed material specifications (IP/BP/USP/In-House) to the Purchase Head as per requirements.
- The Purchase Department, considering proximity and technical aspects, locates potential vendors and obtains details of their products. For existing materials, specifications are provided to the vendor.
- For raw material sources, after the initial assessment, the Purchase Department arranges for the Supplier Questionnaire to be filled by the supplier.
- If the questionnaire evaluation is favourable, the Purchase Department, in consultation with R&D, communicates with the vendor via email. Three initial samples are requested along with Certificates of Analysis (COA), specifications, analysis methods, and regulatory certifications.
- Received samples are logged, and the availability of requested documents is verified. The manufacturing site address is cross-checked with regulatory documents.
- The COA is reviewed against specifications, and samples are sent to Quality Control (QC) for analysis. Vendors failing to meet specifications are rejected.
- If all batches pass QC, and an audit is deemed necessary, the Purchase Head discusses with the vendor to schedule a site inspection.
- The site audit, conducted by a team including QA and representatives from QC, Purchase, and Production, results in an audit report with findings classified as:
 - ✓ *Critical* - An identified issue or deficiency that has the potential to pose a significant risk in producing a product harmful to the patient should be documented or rectified.
 - ✓ *Major* - A non-critical observation or deficiency refers to an issue that if unaddressed, may result in the production of a drug deviating from its marketing authorization. It also includes any observation that could indirectly impact the safety, purity, or efficacy of the drug substance or product.
 - ✓ *Minor* - Observations that cannot be categorized as critical or major, but signify a deviation from Good Manufacturing Practice (GMP).
- The audit report and findings are sent to the vendor for Corrective and Preventive Actions (CAPA).
- Based on findings, vendors are approved, conditionally approved, or rejected, and their status is updated in the approved vendor list.
- Vendors are given 30 days to submit CAPA, which is then verified, and the final decision on approval or rejection is made.
- The vendor is updated as approved in the database, and the next audit/assessment due date is mentioned (within a maximum of 3 years from the last audit).
- After approval, the first three API batches are monitored by QC analysis. Vendor rejection occurs if any batch fails due to Out of Specifications (OOS).
- If API is used for exhibit or pilot scale batches, the vendor is approved based on a self-assessment questionnaire, but a site audit is conducted before releasing the first commercial batch.

- The Quality Assurance Head, based on auditor recommendations and compliance reports, decides on the frequency of re-audits (minimum 6 months to a maximum of 3 years).
- Material requirement specifications provided to the Purchase Head include details such as material name, scientific name, molecular formula, grade (if pharmacopoeial), Material Safety Data Sheet, stability information, category, and additional in-house specifications if any.^{22,23,13,24}
- Ongoing Approval Process for Current Vendors:
- Current vendors remain approved based on past performance and result trends, subject to re-audits approximately every 3 years.
- Re-audits can be conducted at any time or purchase may be halted in the case of critical issues.

The final decision on re-audits and handling critical issues rests with the Quality Assurance Head.

Expected observations should consistently fall within an acceptable range.²

XI. REQUALIFICATION OF VENDORS

Approved vendors maintain their status based on past performance unless a reassessment is necessary.

Vendors listed as approved undergo periodic requalification, achieved through on-site inspections (audits), recent quality systems certification, or self-assessment.

A. Requalification frequency:

- *API*: Every two years
- *Raw materials (excluding API)*: Every four years
- *Packaging material*: Every four years
- Existing vendors introducing additional items from the same facility qualify based on the supply of three separate lots.^{23,25,13}

XII. REQUALIFICATION OF DISQUALIFIED VENDORS

- Disqualified vendors undergo re-qualification as if they were new vendors.
- Requalification follows a change control system.
- Changes to an approved vendor supplying material adhere to the SOP on Change Control Programme.²³

XIII. DISQUALIFICATION OF APPROVED SUPPLIER/VENDOR

Conditions for disqualification include:

- Non-compliance with agreed specifications in the last three consignments
- Delivery of contaminated material adversely affecting product quality
- Inability to address identified audit gaps impacting product quality.

- Disqualification information is communicated to all relevant parties, and the vendor is removed from the approved list.²³

XIV. CONCLUSION

Vendor qualification stands as a cornerstone in ensuring the production of safe and high-quality pharmaceuticals compliant with GMP standards. It encompasses meticulous assessment procedures, annual reassessment protocols, and stringent criteria for vendor selection. Clear communication, prompt action on non-compliance, and subsequent re-evaluation underscore the importance of maintaining quality standards. Additionally, employing effective Vendor Relationship Management strategies enhances the value derived from supplier interactions. Ultimately, a comprehensive and structured approach to vendor qualification is pivotal in upholding pharmaceutical quality and safety standards.

REFERENCES

- [1]. Gaikwad P, Jadhav A, Pathan V, Gujarati N. Review on vendor audit management. *Asian Journal of Pharmaceutical Research and Development* 2018;6:92-6. doi: 10.22270/ajprd.v6i4.391
- [2]. Borra V, Hemanth Kumar S, Patel PR, Gowrav MP. Vendor qualification and evaluation in pharmaceutical industry. *ijrps* 2020;11(2):1987-94. doi: 10.26452/ijrps.v11i2.2129
- [3]. Patel KT, Chotai N. Vendor qualification for pharmaceutical excipients – gmp requirements and approach. *Die Pharmazie - An International Journal of Pharmaceutical Sciences* 2010;65. doi: 10.1691/ph.2010.0146
- [4]. USFDA. U.S. Food and drug administration. 2023.
- [5]. Kiran S. Lpc snapshot dec 2021 - vendor qualification under fda regulations and ich/iso guidelines. 2022.
- [6]. CFR-21. Code of federal regulations - title 21 - food and drugs. FDA; 2023.
- [7]. ICH-Q7Eu. Ich q7 good manufacturing practice for active pharmaceutical ingredients - scientific guideline. 2023.
- [8]. FDA Q. Ich q7 [fda]. 2023.
- [9]. ISO-9001:2015. Iso 9001:2015. 2023.
- [10]. TheFDAgroup. A 5-step guide to qualifying fda-regulated suppliers. The FDA Group; 2022.
- [11]. Frolovs G. The simple guide to supplier qualification in life sciences. 2022.
- [12]. Lewis JM. Building a vendor qualification program for fda-regulated industries. 2018.
- [13]. Maurya. Vendor development 100% good. Abha Maurya; 2016.
- [14]. Bhattacharjee S. Vendor risk assessment questionnaire [with best practices]: Top 40 questions. SignalX; 2022.
- [15]. CEFIC. Quality agreement pdf. 2009. p. 52.
- [16]. Singh BP. Standard operating procedure for vendor qualification. 2020.
- [17]. Rivera E. Supplier qualification program for key raw materials. 2022.

- [18]. Arora S. Pharmaceutical raw material testing & analysis. Auriga Research Pvt. Ltd.; 2009.
- [19]. ICH-Q9EU. Ich q9 quality risk management - scientific guideline. 2023.
- [20]. Center for Drug E, Research,. Q9(r1) quality risk management. FDA; 2023.
- [21]. Shadle PJ. Qualification of raw materials for biopharmaceutical use. 2004.
- [22]. In P. Vendor qualification sop. pharmablog.in; 2022.
- [23]. ResearchSOP. Sop for vendor qualification. 2021.
- [24]. Choudhary A. Sop for qualification of vendors. 2011.
- [25]. Maurya A. Vendor qualification sop. Abha Maurya; 2019.