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**Add the following:**

## ^⟨1083⟩ SUPPLIER QUALIFICATION

### 1. INTRODUCTION

The manufacturers of pharmaceuticals primarily source their required ingredients, materials, components, and services through external local and global suppliers. External suppliers also provide services such as research and development, manufacturing, assembly, analysis, packaging, warehousing, transportation, and distribution, etc. The expectations on the part of regulatory authorities, healthcare professionals (including medical practitioners, nurses, dentists, and pharmacists), and consumers are that pharmaceutical products will be fitted for their intended use and be of the required quality. This means that active ingredients, excipients, components, other raw materials, and packaging components used in the end product have been manufactured to the appropriate standards and comply with regulations, pharmacopeial monographs, and/or all approved specifications. It also means that the processes in the supply chain for a material or service will also be compliant and do not increase risks to the product.

Reliable suppliers provide benefits through established risk management processes. Supplier qualification is a process to systematically evaluate suppliers based on i) the risk to the quality of the product or service supplied; ii) compliance of their quality systems to applicable regulations and requirements of the supply contract or quality agreement, and iii) the reliability of the supplier to avoid quality deviations and shortages of components and/or products.

This chapter provides a quality risk-based approach on how to select, assess, approve, and monitor suppliers of ingredients, packaging materials, and other components and services.

### 2. SCOPE

This chapter applies to organizations involved in identifying, selecting, assessing, approving, and monitoring suppliers of:

- Materials (e.g., active pharmaceutical ingredients, excipients, other materials, and components)
- Packaging materials (e.g., primary, secondary, and tertiary packaging)
- Service providers (e.g., contract manufacturing, packaging, and repackaging; logistic providers for warehousing and transportation; software; calibration and qualification services; and analytical services)

The principles discussed in this chapter apply to the different types of suppliers for pharmaceutical manufacturing companies and compounding pharmacies, to establish supplier reliability in providing appropriate materials and services. In this context, the fundamental principles of supplier qualification are the same for all such organizations. However, the details depend on the type of material or service, the stage of development, and the intended use of the product. This general chapter will focus on the high-level elements of supplier qualification that apply to all organizations.



Figure 1. Examples of some suppliers that should be qualified.

[Figure 1](#) shows types of suppliers for which the general concepts of this chapter may be applicable.

### 3. SUPPLIER QUALIFICATION LIFE CYCLE: STEPS FOR A SUPPLIER QUALIFICATION

The following sections provide expectations and the rationale of tasks for each step in the supplier qualification life cycle. Each activity in the supplier qualification life cycle should be documented and justified. The level of effort, formality, and documentation of each step should be commensurate with the risk level of material or service to be supplied, risk effect, and the availability of mitigation strategies. The supplier qualification life cycle is described in [Table 1](#).

**Table 1. Supplier Qualification Life Cycle: Steps and Tasks**

Step	Tasks
1. Preparation	<ul style="list-style-type: none"> <li>• Nominate a supplier qualification process owner</li> <li>• Build a cross-functional team</li> <li>• Identify material and/or service requirements</li> <li>• Establish material and service criticality</li> </ul>
2. Identification and selection	<ul style="list-style-type: none"> <li>• Establish supplier requirements</li> <li>• Identify potential suppliers</li> <li>• Sign confidentiality and nondisclosure agreements</li> <li>• Make a risk assessment</li> <li>• Select suppliers for evaluation</li> </ul>
3. Evaluation and acceptance	<ul style="list-style-type: none"> <li>• Perform evaluation based on risk and criticality of the material and supplier and may include the following: i) documentation review; ii) audit; and iii) sample request for analysis</li> <li>• Establish central location(s) for referencing supplier qualification (e.g., qualification database, list, or spreadsheet)</li> </ul>

Step	Tasks
	<ul style="list-style-type: none"> <li>Update supplier qualification status in the central list of suppliers, central location, or spreadsheet</li> </ul>
4. Performance monitoring	<ul style="list-style-type: none"> <li>Establish and share key performance indicators (KPIs) as necessary</li> <li>Monitor the supplier performance against the contract and/or quality agreement</li> <li>Evaluate the supplier performance at regular intervals</li> <li>Make decisions based on the evaluation, e.g., ask for corrective action and preventive action (CAPA), quality agreement review, contract termination</li> </ul>
5. Disqualification	<ul style="list-style-type: none"> <li>Document the circumstances</li> <li>Update the supplier database</li> </ul>
6. Conditional approval of an existing supplier	<ul style="list-style-type: none"> <li>Explanation and measures to mitigate the risk</li> </ul>

### 3.1 Preparation

#### TEAM BUILDING

The involvement of subject matter experts (SMEs) with relevant experience is necessary to balance departmental objectives with goals of the overall organization. For a successful supplier qualification program, a cross-functional collaboration is required and a process owner should be nominated.

The objective of building cross-functional teams is to provide a forum to address supplier identification and selection, uncover risks and opportunities, qualify and if necessary, quantify those risks, and establish potential mitigation strategies, allowing all functional areas to align on critical requirements and assumptions to make appropriate decisions.

Functional areas to be considered for membership of a supplier qualification cross-functional team include (as needed):

- Technology development (e.g., research, development, concept, design, engineering)
- Technology launch and commercial support (e.g., pharmaceutical technology, engineering, industrial engineering, technical services, technology operations, process technology)
- Quality (e.g., quality compliance, quality assurance, quality control)
- Regulatory affairs and compliance
  - The regulatory framework will vary from region to region and country to country
- Environment, health, and safety
- Sales, marketing, business development, and customer service
- Commercial manufacturing, production, operations, packaging
- Purchasing, procurement, supply management, strategic sourcing, commodity management, category management
- Management of external contractors
  - Supply chain
  - Supplier management
  - Vendor relationship management
  - Strategic sourcing management
- Information technology, including customer and supplier data exchange
- Logistics, including warehouse

#### MATERIAL AND/OR SERVICE REQUIREMENTS AND CRITICALITY

The identification and characterization of material and/or service requirements are important first steps in the product development process. Development teams identify materials and/or services needed for the finished product and begin studies to understand what requirements are necessary to support consistent product performance. These requirements can be further defined using a cross-functional development team to best identify supply chain partners.

Once the final product attributes and desired material performance are defined, the company teams should align on the material criticality needed to meet the final product specification. For this, the cross-functional development team agrees on material criticality in alignment with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines Q8

(Pharmaceutical Development), Q9 (Quality Risk Management), Q10 (Pharmaceutical Quality System), and Q12 (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management).

Similar to the identification of material characteristics, service requirements should also be described by the organization, specifying what is required from the service suppliers. Storage conditions, category of product, licensing needed for handling a specific product, transportation modes, duration of trips, and types of shipping containers are some examples of topics that should be evaluated first to build service requirements for storage and transportation providers. For other services, such as contract manufacturing, analytical, calibration, or qualifications services, and service requirement, specification is also needed and is written according to the scope and risks of service that should be provided.

### 3.2 Identification and Selection of Supplier for Materials and Services

Once the material and/or service requirements are identified, the cross-functional team can then establish supplier requirements. After determining requirements, the team can identify potential suppliers that should be considered for each material or service while assuring the procurement process is manageable and cost effective.

#### SUPPLIER REQUIREMENTS

Appropriate requirements for material or service suppliers may include, but are not limited to:

- Ability to meet market demands, including regular lead times and responses to changes in demand
- Operational and financial viability, such as future manufacturing capacity, global presence, alternate sourcing options, and ability to manage supply chain risks
- Willingness and ability to communicate
- Quality systems and regulatory compliance are appropriate
- Controls are in place for material traceability and control of their own supply chain
- Possession of technical capability and expertise for the characterization of both the material or service and the manufacturing process
- The supplier has appropriate systems in place to prevent the introduction of falsified, diverted, or counterfeited products into the supply chain during the procurement, manufacturing, storage, transportation, disposal of waste, and destruction activities

#### POTENTIAL SUPPLIER IDENTIFICATION

Once the material, service and supplier requirements are identified and aligned, the company can identify potential suppliers that meet the defined requirements.

First, the company defines a list of potential suppliers, and then engages with them to share subject matter expertise and verify expectations. Engagement with potential suppliers provides the best opportunity for improving understanding of the material or service in question such that it meets the criteria for the intended use, e.g., performance, variability, and impact on the quality attributes of the finished product.

The company should be able to provide the supplier with the critical information (such as intended use of the material or service, critical quality attributes of the product, storage conditions, technical capabilities needed from the supplier, and a provisional forecast) that will enable both the supplier and the company to support the finished product successfully.

Before exchanging information with suppliers, confidentiality and nondisclosure agreements should be signed.

#### CONFIDENTIALITY AND NONDISCLOSURE AGREEMENTS

If needed, appropriate confidentiality agreements should be executed to allow for the exchange of confidential information needed for supplier qualification. When the information exchange moves beyond public knowledge, interacting with suppliers will necessitate a confidentiality or nondisclosure agreement. Suppliers operate in a competitive environment where compromised confidential knowledge of manufacturing processes, equipment, capacity, raw materials, process testing, facility layout, and other site-specific information could result in the loss of an economic advantage for the supplier or the gain in an economic advantage for their competitor. For suppliers where the portion of products sold into markets is relatively small, the risk of losing sensitive trade secrets may outweigh the benefit of selling to customers who require such information. Likewise, for a product manufacturer, compromised confidential information regarding a new product, existing formulations, material specifications, or production processes could have an adverse economic impact on their company. For these reasons, confidential information should only be shared and requested when necessary for ensuring the manufacturing, safety, and quality of the finished product.

#### RISK MANAGEMENT

Risk assessment and control should be integrated into supplier qualification taking into account quality and patient safety. The supply chain's risk assessment process involves identifying the internal and external risks and evaluating their potential impact on the finished product, third party materials and services, and internal systems. This risk assessment effort is not a one-time event but rather a periodic recurring process to communicate and review risks.

It is not the aim of this chapter to provide a list of risk and mitigation strategies because risks are perceived differently and depend on experience and the services and materials that could be supplied. Instead, this section is meant to stimulate discussion and highlight points to be considered when assessing and controlling risks to select potential suppliers.

**Table 2. Points to Be Considered When Assessing and Controlling Risks**

Risk Category	Points to Consider
Material-related risks	<ul style="list-style-type: none"> <li>• Use in patient and/or business critical products (irrespective of material cost)</li> <li>• Degree of use across product lines (irrespective of material cost)</li> <li>• Available inventory (internally and/or externally) irrespective of material cost</li> <li>• Consider supplier's reject and discard rate</li> <li>• Consider variability in process capability impacting the final product</li> <li>• Material performance based on information supplied by supply chain intelligence</li> <li>• Financial impact: cost of material and/or service, cost and time of the alternate source</li> <li>• Product sensitivity                             <ul style="list-style-type: none"> <li>◦ Sterility, temperature sensitivity, light sensitivity, etc.</li> </ul> </li> <li>• Impact of primary and secondary packaging on material integrity</li> </ul>
Capability	<ul style="list-style-type: none"> <li>• Manufacturing                             <ul style="list-style-type: none"> <li>◦ Pharmaceutical: biologic, vaccine, sterile, nonsterile, etc.</li> <li>◦ Device: Class III, Class II, Class I, etc.</li> </ul> </li> <li>• Service                             <ul style="list-style-type: none"> <li>◦ Familiarity with changing regulations in all countries of service</li> <li>◦ Upgrade capabilities</li> <li>◦ Package, delivery, and route qualification and traceability</li> </ul> </li> </ul>
Stock-out risk to patients	<ul style="list-style-type: none"> <li>• New product</li> <li>• Orphan product</li> <li>• Availability of alternates</li> </ul>
Financial risk to the business	<ul style="list-style-type: none"> <li>• High cost of discards, loss of market share, impact to shareholders, etc.</li> </ul>
Location and supply chain complexity	<ul style="list-style-type: none"> <li>• Physical distance</li> <li>• Political boundaries and regulations</li> </ul>

Each company needs to develop priorities based on the impact on all stakeholders: patient, public, employees, and shareholders. When measuring impact, it is important to focus on the effects on safety, efficacy, continuity of supply, and business and financial performance, and not only on the cost or volume.

For more information on risk and mitigation strategies related to storage and transportation of finished drug products, please see [Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products \(1079\)](#). For further information on quality risk management, please see ICH Q9.

SUPPLIER SELECTION

This selection process is intended to identify a short list of suppliers that will be evaluated further. The selection may include, but is not limited to, consideration of the following key points.

- **Supplier product and process technical and operational capability:** The supplier has the specific technical expertise, acceptable process capabilities, extensive experience with the material, service in question, and a defined process for improvements to afford future economies of scale.
- **Quality and regulatory compliance system:** The supplier has controls in place for material traceability, acceptable quality control, and control over their supply chain.

- **Relationship alignment and business capability:** The supplier is socially responsible, shares market intelligence, and meets the strategic needs of the company culture (e.g., commitment, trust, and reputation and promotes financial stability).
- **Supplier operating systems and business continuity:** The supplier supports speed to market, meets lead time demands, and responds to any changes in a timely manner.

There is no ranking implied and there may be different emphasis of importance depending on each company's needs. The organization could submit a questionnaire to the supplier in order to obtain initial feedback on these key points.

### 3.3 Evaluation and Acceptance

Based on the information gathered during the supplier selection stage, the selected supplier(s) are then further evaluated. The evaluation criteria are based on the risk assessment of the materials and services to be supplied. For example, the tolerable risk from a supplier and/or reagent used in an early process step of an active drug substance synthesis is usually higher than a supplier and/or an excipient used in the finished drug product. Similarly, the tolerable risk for an early development analytical service is usually higher than that for a registration stability program. In general, the closer you get to the finished product, the higher the risk from goods and services obtained from suppliers.

With an established risk assessment, the suppliers could be evaluated for their technical capability and quality system compliance. The evaluation may include, but is not limited to:

#### 1. Documentation review:

- Authorizations, permits, or licenses for the intended service (e.g., manufacturing license, good practice regulations (GxP) certificates)
  - Site master file or drug master file references (where applicable)
  - A recent audit report, if possible
  - Recent supplier qualification report (between both organizations involved in the audit)
  - Recent regulatory inspection reports, if available
  - Quality management system (QMS) review (e.g., deviation handling, change control system, customer complaints handling, recall, product rejection and return handling)
  - Trend data for potential critical material attributes and compendial tests (if appropriate)
  - For service providers, examples may include design, operational, and performance qualification protocols and reports.
- Additional documentation for lane studies and applicable performance as appropriate

- Audit:** An audit could be necessary or required to verify and qualify the information obtained during the documentation review. It also provides the opportunity to engage with the supplier in a more detailed discussion to gain firsthand knowledge of the QMS, as well as the technical capabilities, such as personnel, equipment, facility, etc. When an on-site audit is not feasible, the use of remote or virtual audits should be taken into consideration and a third party's certification may be acceptable for the assessment of the supplier's QMS and conformance to GxP.
- Sample request:** For each material supplier, tests of at least three batches of materials should be performed to evaluate if the supplier can consistently provide the material with the quality suitable for the intended use. Information of data trending for potential critical material attributes or compendial test can also be provided. For labeling verification, one proof is acceptable.

With a satisfactory evaluation outcome, the contract and quality agreement negotiation will be initiated with the supplier. The following elements (not all-inclusive) should be included in the contract or quality agreement:

- Mode of transport and delivery
- Roles and responsibilities
- Good manufacturing practices (GMP) requirements
- Technical requirements
- Product and service quality monitoring
- Rejection, deviation, complaint, etc.

The organization should have a central location for referencing a supplier's qualification (e.g., qualification database, list, or spreadsheet) that shows those who were qualified, with their status, and important dates (initial qualification, requalification, monitoring, disqualification, etc.), which is continuously updated. Additionally, the date a supplier is first approved should be included in this location.

### 3.4 Performance Monitoring

The supplier's performance should be appropriately monitored and recorded at receipt and/or use against the contract and/or quality agreement, key performance indicators (KPIs), and relevant external standards (e.g., International Organization for Standardization (ISO) standards, industry standards, GxP). The KPIs should reflect the most critical quality parameters for the supplied product or service. The following are examples of KPIs. [NOTE—Some of these may not apply in all cases and other KPIs may be considered.]

- The quality of the supplied product or service
- The timeliness of the supply and service
- Flexibility in response to unexpected and urgent requests and response to urgent issues and matters
- Response time of resolving audit observations, deviations, or customer complaints
- Effectiveness and timeliness of communication
- The ability to provide supplies and services without any interruption

## EVALUATION OF SUPPLIER PERFORMANCE AND PERFORMANCE MONITORING

At regular intervals, the supplier performance should be evaluated and documented based on the results of the continuous monitoring detailed above. The frequency of the evaluation is based on the criticality of the supplied product or service; it is recommended to be at least once a year. Root cause analysis, severity, and frequency of unfulfilled KPI(s) should be included in the evaluation. Furthermore, the validity of the supplier's required certificates and authorizations, as well as the financial viability of the supplier, should be checked. Any trends in the supplier's performance should be identified and investigated. In addition, the quality agreement should be reviewed and updated as necessary on a regular basis.

Depending on the nature of any contract breach, unfulfilled KPI(s), or deviating trend(s), the supplier may be contacted with the request for improvement, corrective and preventive actions, or even termination of the contract in certain cases. The organization should consider how the deficiencies can be mitigated either at source or in-house.

### 3.5 Supplier Disqualification

There are many reasons to remove or disqualify a supplier. The removal of a supplier must be thoroughly evaluated to minimize the impact on product quality and disruption of supply. The circumstances surrounding the disqualification of a supplier must be documented through a change control program.

When a supplier can no longer meet the criteria that were determined during the approval process, the supplier should be disqualified and removed from the supplier list.

A supplier is removed based on documented actions as follows:

1. Undertake an investigation to determine the root cause
2. Determine a timeline for supplier removal
3. Establish agreement of completion of tasks prior to being disqualified
4. Establish a procedure to audit the current status of the project
5. Establish a process to retrieve outstanding work and samples
6. Establish a risk mitigation strategy and determine the impact of the supplier disqualification on product quality
7. Implement the changes necessary
8. Remove the supplier's name from the approved supplier's list

### 3.6 Conditional Approval of an Existing Supplier

When an existing supplier's performance is not considered satisfactory, but their disqualification would adversely impact the patient, the organization should implement measures to mitigate the risk. This can either be by working with the supplier to improve their quality systems, etc., or by establishing and implementing further controls needed to assure the required quality is achieved and maintained. If the supplier agrees to work to improve their quality systems, there should be an agreed-upon action plan with criteria and timelines to be met.

## GLOSSARY

**Material:** Any active pharmaceutical ingredient, excipient, component, packaging, or other raw material that is intended to be included as part of the product or used in its manufacture.

**Organization:** In the context of this chapter, an organization is the company that needs to purchase a material or outsource a contract service. It may also be referred to as company or supplier's customer. It is the entity that will perform the steps to qualify a supplier.

**Other raw materials:** In the context of biological products, other raw materials are defined as any other substances different from starting materials that are used for manufacturing or extracting the active substance(s) but from which this active substance is not directly derived (starting materials). Other raw materials could be reagents, culture media, fetal calf serum, additives, and buffers used in the production of a product.

**Product:** Any tangible output from the organization or service provider.

**Quality agreement:** A negotiated and comprehensive written agreement between the organization and the material supplier or service provider that defines and establishes each party's activities, the common understanding about materials or services, quality specifications, responsibilities, guarantees, and communication mechanism, providing key contacts for both parties.

**Service:** Activity related to manufacturing, quality, storage, or distribution of a product or material.

**Specification:** A list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. "Conformance to specifications" means that the purchased material, when tested according to the listed analytical procedures, will meet the listed acceptance criteria.

**Supplier:** In the context of this chapter, a supplier is the entity that will provide a service or material to the organization. It may also be called a vendor.

**Supplier qualification:** Supplier qualification is a process to systematically evaluate suppliers based on i) the risk to the quality of the product or service supplied, ii) compliance of their quality systems to applicable regulations and requirements of the supply contract or quality agreement, and iii) the reliability of the supplier to avoid quality deviations and shortages of components and/or products. ▲ (USP 1-Aug-2023)

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