**Document approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Author’s designation**  **<QualityDesignee2>** |  |  |  |
| **Reviewer’s designation**  **<QualityDesignee1>** |  |  |  |
| **Approver’s designation**  **<QualityOrganizationHead>** |  |  |  |

|  |  |
| --- | --- |
| **Effective Date** | **<EffectiveDate>** |

**Table of Contents**

[1 Purpose 2](#_Toc95307591)

[2 Scope 2](#_Toc95307592)

[3 Responsibilities 2](#_Toc95307593)

[4 Definitions, terms and abbreviations 2](#_Toc95307594)

[5 Workflow 3](#_Toc95307595)

[6 Applicable documents 3](#_Toc95307596)

[7 Appendices 3](#_Toc95307597)

[8 Document revision history 3](#_Toc95307598)

# Purpose

This Standard Operating Procedure (SOP) aims to establish the <SuppliersTitle> process used to evaluate and qualify Suppliers against the internal, customer, and regulatory agency-specified requirements.

# Scope

This SOP is valid at <CompanyName> for all Organization. The respective training shall be given in accordance with **<TrainingCode> <TrainingTitle>**.

This SOP process applies to all Suppliers <CompanyName> receives quality-relevant goods and services. This includes but is not limited to:

* + Raw Materials (Active Substances and excipients),
  + Intermediate Products,
  + Packaging Materials (primary and secondary packaging Materials),
  + High complexity equipment, particularly if it was customized at <CompanyName> request,
  + Outsourced activities (e.g., contract laboratories, maintenance and calibration, cleaning services).

# Responsibilities

Responsible for the content of this SOP is <QualityOrganizationHead>.

| **Role** | **Definition/Task** |
| --- | --- |
| **Quality Organization** | * Is responsible for this SOP and management of the <SuppliersTitle>, * Coordinates activities related to Supplier Qualification, including approval and disqualification of Suppliers, * Signs <SupplierQAA>, * Presents status updates of Suppliers and <SuppliersTitle> at <ManagementReviewTitle>, * Performs the risk analysis as part of the Supplier Qualification process, * Manages Supplier Audits, * Ensures Supplier re-qualification is conducted on time following the Supplier risk classification, * Communicates Events (e.g., shipping complications, deviations, OOS results) to the relevant Line Managers and Purchasing, as necessary * Supports the corrective action associated with any Supplier Events, and * Owns the <SuppliersList> and ensures it is up-to-date. |
| **Line Managers (or designee)** | * Ensures that the <SuppliersTitle> process is carried out in their Team/Department, * Takes part in the choice and qualification of potential Suppliers, * Compiles “technical data” including a detailed description (e.g., process instructions, SOP, user requirement Specification, Material user requirement Specification) of the service the Supplier will provide, * Evaluates Product / Material samples regarding their technical suitability and processing properties, as applicable, * Communicates Events (e.g., shipping complications, Deviations, Nonconformances, OOS results) to Quality Organization, * Responds appropriately to quality issues and complications involving the Supplier as part of an Event. |
| **Purchasing Team** | * Primary liaison with the Supplier, * Takes part in the choice of potential Suppliers, * Ensures that agreements are signed and countersigned by the appropriate parties, * Collects the necessary documents for Supplier Qualification, * Verifies the Supplier is categorized as qualified before each new order/purchase, * Forwards information from the Supplier regarding planned or existing changes and other quality-relevant information to Quality Organization and the impacted Line Managers, * Communicates Events (e.g., shipping complications, Deviations, Nonconformances, OOS results) to Quality Organization, the Line Manager. |

# Definitions, terms and abbreviations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Term/abbreviation** | | | **Definition at <CompanyName>** | | |
| **Master Purchase Agreements (MPA) or Master Service Agreement (MSA)** | | | A framework agreement that deals with the general legal terms of the Supplier relationship. It regulates the framework conditions of the legal relationship, such as rights and obligations, and is specified in later individual contracts and orders. | | |
| **Material** | | | A general term refers to Raw, Starting Materials and packaging Materials. | | |
| **Non-Disclosure Agreement (NDA)** | | | General agreement regarding the confidential treatment of data and information. | | |
| **Product** | | | Collective term for intermediate Products. | medicines, Raw | Materials, and |
| **Quality (QAA)** | **Assurance** | **Agreement** | Contractual definition of the general framework and processes and an individual detailed delimitation of liability between <CompanyName> and the Supplier are necessary to achieve the desired quality target. | | |
| **Raw Material** | | | Every Material is employed in producing a drug (Active Substance and excipient), except for the packaging Material. | | |
| **Supplier** | | | Organization that provides a product or a service | | |
| URS | | | User Requirement Specification | | |

# Workflow

## Documenting Requirements for a Supplier

The responsible Line Manager defines and documents the service or Products/Materials and quality standards expected from either a new Supplier or an existing and qualified Supplier providing a new Product, Material, or service.

The documentation may include:

* A User Requirement Specification (URS)
* Another form of Specification
* A draft of an agreement
* An extract of the catalog of the Supplier (e.g., for sample orders)
* The names of known Suppliers who can provide the Product, Material, or service

The Line Manager sends the documents to Purchasing to evaluate whether there is an existing qualified Supplier who can provide the Material or service.

If there is no existing qualified Supplier, Purchasing initiates the Supplier selection and qualification process. If there is a current qualified Supplier, Purchasing notifies Quality Organization for re- evaluation of the risk assessment for the new Product, Material, or service be supplied.

## Selection of a (new) Supplier

Purchasing selects a potential Supplier or Suppliers and initiates the communication with the Supplier, sending the documentation provided by the Line Manager that describes the service or Materials needed.

The selection of a new supplier and any significant changes to approved suppliers shall be a subject of <ChangeManagementTitle> procedure. All involved persons shall follow principles of **<ChangeManagementCode> <ChangeManagementTitle>**.

For Materials, Purchasing may request that the potential Supplier utilize a shipping company that is an existing and qualified shipping Supplier of <CompanyName>.

The Purchasing Team and the Line Manager may also request Material samples from the potential Supplier.

An Non-Disclosure Agreement (NDA) is necessary for Suppliers who receive sensitive or proprietary information with <CompanyName>. Before the provision of the documentation or after the condition of the initial request but before additional discussions with the potential Supplier. Depending on the nature of shared information, Purchasing will align with the Line Manager if confidential information is shared, which requires implementation of an NDA. and at what point in the communication process it needs to be executed.

An NDA is not necessary for Suppliers who do not receive sensitive or proprietary information with <CompanyName>.

## Supplier Self-Assessment

After selecting the potential Supplier and, if applicable, signing the NDA, Purchasing, in conjunction with Quality Organization, prepare a **<SupplierSelfAssessment> draft according to <SupplierSelfAssessment> Form.** In the case of a valid ISO 9001 or ISO 13485 in conjunction with a GMP certificate, only mandatory sections of **<SupplierSelfAssessment> Form** are required.

The responsible Line Manager, Quality Organization, and/or Purchasing may request additional documents to aid in the qualification process, such as:

* GMP certificates
* Information on other certifications (e.g., compliance to DIN, EN, ISO)
* Lists of references of other companies that the potential Supplier currently provides Materials or services to
* Any additional technical information that may be required to conduct the qualification decision process
* If applicable, results of quality tests performed to assess the samples of materials
* A list of the potential Supplier’s Audits/inspections and performance of Audits/inspections (e.g., FDA or other government inspections, ISO Audits, etc.)

The completed **<SupplierSelfAssessment> Form** and associated documents provided by the potential Supplier are evaluated by Quality Organization. In consultation with the Line Manager and other internal parties, Quality Organization will determine whether a candidate is suitable for further evaluation. The decision is recorded by Quality Organization on the last page of the **<SupplierSelfAssessment> Form**.

## Technical Visit and/or Audit (optional)

The Line Manager and Quality Organization may determine that a technical visit is necessary to evaluate the potential Supplier further. Suppose the responsible Line Manager and Quality Organization decides to do a technical visit. In that case, Purchasing will agree on a first visit with the potential Supplier (after initial evaluation of the Supplier Self-Assessment Form by Quality Organization).

The technical visit aims to:

* Clarify general questions of purchase, e.g., capacities and resources (infrastructure, equipment, personnel),
* Clarify the technical feasibility and methodical competence of the candidate, and
* Discuss questions of the candidate regarding the User Requirement Specification.

The results of the technical visit are recorded in the potential Supplier’s file. The Line Manager and Quality Organization decide whether the candidate is appropriate to continue the qualification process.

Depending on the Material or service being supplied, Quality Organization may determine that an Audit is necessary before performing the qualification process. Suppose it is determined that the potential Supplier requires both a technical visit and an Audit. In that case, the Audit may be performed at the time of the initial visit or before/after the technical visit.

Audits should be performed for:

* Contract laboratories,

Suppliers of:

* Raw Materials
* Excipients rated as critical

The results of the Audit are recorded in the potential Supplier’s file. The Line Manager and Quality Organization decide whether the candidate is appropriate to continue the qualification process.

## Risk Assessment and Classification

After evaluation of the completed **<SupplierSelfAssessment> Form** and conduction of any technical visits or Audits, as necessary, Quality Organization and material / service requestor perform risk assessment and classification and record the results in **<SupplierEvaluation> record** according to **<SupplierEvaluation> Form**. All risk assessment participants must follow the principles and requirements of **<QRM\_Code> <QRM\_Title>.**

***For existing and qualified Suppliers, the current risk assessment is re-evaluated for any new/additional service or Material, as the provision of the new service or Material may entail other risks not contemplated in the initial risk assessment.***

Risk assessment shall take into consideration the following:

* The risk of the Material or service to be outsourced, including <CompanyName>’s dependence on the Material or service to meet internal deadlines
* Whether the Supplier outsources any of their work to other third parties
* The Supplier’s expertise and level of experience.
* The Supplier’s ability to provide:
* Prompt availability and flexibility,
* Punctuality and adherence to delivery dates, and
* Rapid response to queries from customers
* The experience of the potential Supplier with GMP and the maturity of their quality system, including the following:
* Existence of and compliance with quality standards,
* Ability to comply with the requirements of <CompanyName>,
* Existence and maturity of a QMS,
* Reliable shipping and adherence to delivery dates,
* Professional and technical suitability and competence,
* Sufficient resources (e.g., infrastructure, equipment, personnel),
* If applicable, a valid Production permit, a valid GMP certificate, or another certificate of lawfulness specific to the area (e.g., ISO certificates),
* Regulatory authority monitoring, if applicable, and

Based on the risk assessment, Quality Organization assigns each Supplier a Risk class:

**Risk class 1**

For Suppliers with high risk, the assessment and evaluation of the Supplier are based on written reports (e.g., Self-Assessment Form), the performance of quality tests, e.g., assessment of Product / Material samples, and additional Audits. Suppliers of Risk class 1 are requalified **every year**.

**Risk class 2**

For Suppliers with medium risk, the assessment and evaluation of the Supplier are based on written reports (e.g., Self-Assessment Form) and the performance of quality tests (e.g., assessment of Product / Material samples). Suppliers of Risk class 2 are requalified **every three (3) years**.

**Risk class 3**

For Suppliers with low risk, the assessment and evaluation of the Supplier are based on their shipping history and a verification of their quality-relevant documents (e.g., <SupplierSelfAssessment> Form). Suppliers in risk class 3 are requalified **every five (5) years**.

The results of the risk assessment are recorded in <SupplierEvaluation> record and <SuppliersList>.

## Contractual Agreement and procurement

Suppliers classified as Risk class 1 and 2 require implementing a basic contractual agreement, a Master Purchase Agreement (MPA), upon the issue of any order. Class 3 Supplier implementation of an MPA is not required; Materials and Services can be appointed by formal purchase order only, based on a Supplier quote, offer, or similar.

The MPA can be a standard agreement created by <CompanyName> or the Supplier. <CEO> or person with appropriate power of attorney signs MPA after consultations with Material / service requestor and Quality Organization. If required, <SupplierQAA> shall be signed jointly with MPA.

In the case of Suppliers that are already qualified and take on an additional activity, the existing contract may need to be revised and updated. Purchasing will initiate this.

Before the first order is issued, Purchasing verifies that the MPAs (for Risk class 1 and 2 only), the NDA, if applicable, <SupplierQAA>, and any other agreements are signed, as necessary, and that the Supplier status has been updated to “qualified.”

An order can be based on:

* Contractual agreements,
* A Product or Material Specification approved by <CompanyName> and confirmed by the Supplier’s quote or offer,
* A Specification for customer requests approved by <CompanyName> and confirmed by the Supplier’s quote or offer,
* An order number from an official catalog of the Supplier, and
* An offer/performance Specification.

Before any order placement, Purchasing ensures that the procedures and approvals per <CompanyName>’s purchasing process are completed.

## Quality Agreement

**<SupplierQAA>** is a general agreement in which the quality standards of both contract partners are defined in writing (see **<SupplierQAA> Appendix)** <SupplierQAA>s are required for Class 1 Suppliers. Class 2 Suppliers may have <SupplierQAA>or change notification (which ensures notification at encountering major or critical incidents), and Class 3 Suppliers do not require a <SupplierQAA> or change notification. <SupplierQAA> is generally standardized but is adapted in particular for each Supplier depending on the Products, Materials, or services supplied. <SupplierQAA> includes, but is not limited to, the following:

* Primary contacts,
* General regulations regarding the scope of the contract and the processing of orders,
* Obligation of the Supplier to not forward order or outsource work to third parties without the permission of <CompanyName>,
* Right to Audit the Supplier,
* Obligation to inform, particularly regarding Audits or inspections by regulatory authorities,
* Compliance with the Specifications, SOPs, WIs, and testing instructions defined by <CompanyName>,
* Assurance of preparation and archival of documents, specifically in the case of closure or acquisition of the Supplier
* Handling of Events, including quality defects and complaints, and
* Liability, scope, and termination.

<SupplierQAA>s must be accepted and signed by both parties before initiating a service, shipping, or a formal transfer of technical data or methods. <SupplierQAA>s are re-evaluated at re-qualification based on the Supplier’s risk classification and constitute a separate agreement next to the subsequent.

As soon as the <SupplierQAA> is signed by both parties and thereby legally binding, Quality Organization assigns the Supplier status of “qualified” on the <SuppliersList>. In the case of previously qualified Suppliers, Quality Organization updates the Risk classification as necessary based on the provision of new Products, Materials, or services.

## Transfer of technical data (optional)

The responsible Line Manager collects all relevant data and necessary information in the area that the Supplier needs to fulfil the specialized tasks. In particular, this includes precise information on technology transfers, method transfers, work safety, and possible problems or risks in infrastructure, equipment, personnel, or subsequent Products/Materials, elated to the Product/Material or the task.

The responsible Line Manager assumes responsibility for the comprehensiveness of the technical transfer documentation. The Line Manager shall coordinate with Quality Organization to ensure the technical transfer documentation is complete, accurate, and by work described in the MPA and <SupplierQAA>.

The transfer of this data must be done promptly so that any resulting questions related to the documentation can be discussed before fulfilment of impacted orders.

## Requalification of the Supplier

The performance of the Supplier is continuously monitored by Quality Organization. The requalification of the Supplier is performed per the frequency defined by the Risk Class.

The requalification process assesses the following:

* Overall competence and ability to fulfill the contractually agreed requirements (e.g., order quantities),
* Current validity of the <SupplierQAA> and MPA,
* Audit results
* Results of regulatory authority inspections of the Supplier, if applicable,
* Event data history and associated correspondence (CAPAs, deviations, OOS results, detected trends, complaints, transport damage, other non-conformances, or discrepancies), Note: Events are stored in the Event database. Event information can be extracted per Supplier for Supplier requalification and <ManagementReviewTitle>.
* Ability to communicate effectively and responsiveness to <CompanyName> queries,
* Adherence to schedule for order delivery dates and CAPAs (e.g., timelines for implementing corrective action)
* Adherence to schedule and the quality/completion of documents (e.g., raw data, certificates, and reports)

If the Supplier continues to comply with the above requirements, it remains a qualified Supplier and the <SuppliersList> is updated with the date of requalification.

If the requalification assessment was not successful or if quality issues occur before the requalification process, Quality Organization contacts the Supplier to discuss the issues and possible corrective and preventive measures. Depending on the results of the requalification or other Events, Quality Organization may increase the Audit frequency for the Supplier or define other subsequent actions or controls.

Documentation of the requalification is documented in the Supplier’s file.

## Disqualification

If during Audits, requalification, or in ongoing monitoring of shipping or services, severe flaws are found (e.g., repeated complaints and recalls while failing to implement CAPAs an other Events) and the Supplier has not taken sufficient measures and regularly failed to deliver a satisfactory performance, Quality Organization and, the Line Manager may decide to disqualify the Supplier based on quality or business risks.

Suppose the Line Manager and Quality Organization decide to disqualify a Supplier. In that case, Quality Organization must document the disqualification status in the Supplier’s File (including the justification for disqualification), remove the Supplier from the <SuppliersList>, and notify Purchasing to prevent future orders from the Supplier.

## Suppliers review

Quality Organization evaluates the Supplier data every year and creates a status update report for Management Review. The report includes, but is not limited to:

* initial Supplier qualifications,
* re-qualification and
* any Supplier Events that may impact the business.

## Supplier Documentation

Quality Organization maintains the <SuppliersList>, ensuring Purchasing has access to the documentation to check Supplier status before placing orders. The <SuppliersList> includes, at minimum, the following information:

* Name of qualified Suppliers,
* Risk Classification,
* Date of qualification, and
* Date of re-qualification (per risk classification).

In addition to the Supplier database, the following Supplier documents are maintained by <CompanyName>:

|  |  |
| --- | --- |
| **Title / Type of Document** | **Owned / Maintained By** |
| Supplier database | Quality Organization |
| Supplier Self-Assessment and Associated qualification documents (e.g., copies of certifications) | Quality Organization |
| Technical Visit Results | Quality Organization |
| Audit Results | Quality Organization |
| Risk Assessment Results (including Risk Classification) | Quality Organization  Purchasing Manager  Line Manager |
| Master Purchase Agreement | Purchasing Manager and Line Manager |
| Non-Disclosure Agreement (NDA) | Purchasing Manager and Line Manager |
| Quality Assurance Agreement (QAA) | Quality Organization |
| Purchase Orders | Purchasing |
| Requalification Results | Quality Organization |
| Disqualification Results | Quality Organization |
| Supplier-related Events (Deviations, OOS, complaints, non-conformances, CAPAs, exceptions, etc.) | Quality Organization |

Contracts and applications necessary for the Supplier Qualification are registered as follows:

* NDA-YYYY-No.: NDA, dash, , the year (YYYY), dash, and a serial number in the format 000, e.g., NDA-2022-001 for the first non-disclosure agreement (NDA) registered.
* MPA-YYYY-No.: MPA, dash, , the year (YYYY), dash, and a serial number in the format 000, e.g., MPA-2022-001 for the first Master Purchase Agreement registered.
* QA-YYYY-No.: QA, dash, the year (YYYY), dash, and a serial number in the format 000, e.g., QA-2022-001 for the first <SupplierQAA> in 2022).

# Applicable documents

<DocMngmtCode> <DocMngmtTitle>

<ChangeManagementCode> <ChangeManagementTitle>

<CAPA\_Code> <CAPA\_Title>

<AuditsInspectionsCode> <AuditsInspectionsTitle>

<QRM\_Code> <QRM\_Title>

<MaterialManagementCode> <MaterialManagementTitle>

# Appendices

The following appendices are integral part of this SOP:

Appendix <SupplierSelfAssessment> Form

Appendix <SupplierEvaluation> Form

Appendix <SuppliersList> Form

Appendix <SupplierQAA> Appendix

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |