**Document approval**

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|  | **Name** | **Date** | **Signature** |
| **Author’s designation****e.g., Quality Specialist** |  |  |  |
| **Reviewer’s designation****e.g., Quality Management Director Deputy** |  |  |  |
| **Approver’s designation****e.g., Quality Management Director** |  |  |  |

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# Purpose

This Standard Operating Procedure (SOP) aims to define a regulated procedure for evaluating and handling materials in GMP-regulated areas based on specified quality requirements as to whether a material is suitable for its purpose.

# Scope

This SOP is valid at Company CDE for all Organization. The respective training shall be given in accordance with **SOP-10 CDE Training Management**.

The SOP applies to all materials that:

* are used within a regulated manufacturing process,
* are provided to internal or external Contract Manufacturing Organization (CMOs) where Company CDE is the owner of the material,
* are sold to internal and external customers.

# Responsibilities

Responsible for the content of this SOP is e.g., Quality Management Director.

|  |  |
| --- | --- |
| **Role** | **Definition/Task** |
| Purchasing | * performs ordering of production and laboratory materials for the GMP area,
* considers delivery times and lead time in consultation with production planning,
* clarifies the distribution form per material,
* assigns article numbers for new materials in ERP, and
* orders required sample quantities in consultation with Quality Control.
 |
| Requestor | * prepares initial Material User Requirement Specification (MURS),
* is responsible for the management of the operation and performance qualification process equipment/instruments in their department.
 |
| Quality Organization | * ensures expertise for the materials,
* performs the initial risk assessment of the material,
* defines the requirements for the material,
* acts as an interface between Warehouse & Supply Chain Management and Purchasing,
* authorizes sourcing authority of materials for GMP area,
* is an active member of the Risk Management Team and acts as a material expert in the context of risk analysis and assessment,
* acts as change owner, and
* coordinates the Change Control.
* maintains Material Qualification records
 |
| e.g., Regulatory Affairs Head | * regulates impact assessment for new materials or changes to materials
* conducts the Regulatory Impact Assessment
 |
| Risk Management Team | * Materials experts from the Quality Organization, Manufacturing, Regulatory, Quality Control identify and evaluate materials risks to the manufacturing process and final product quality. They assess whether the material is suitable for the placement purpose.
 |
| Manufacturing | * is an active member of the Risk Management Team to perform risk analysis and assessment regarding the use of the material in production and thus in the manufacturing process.
 |
| Quality Control | * is an active member of the Risk Management Team to perform risk analysis and assessment based on information from suppliers for incoming goods inspection,
* determines whether QC inspections are performed internally or externally,
* performs determination, establishment, and approval of test plans, and
* performs analysis of test samples of the material to be used.
* prepares material specifications
 |
| e.g., QC Head | * reviews, approves, rejects materials (**Material Qualification Status List (MQSL)**)
* approves material specifications
 |
| Warehouse & Supply Chain Management | * checks whether newly requested material is already created in the ERP,
* performs monitoring of the material stock in the ERP,
* performs receipt of the material in the ERP and the warehouse.
 |

# Definitions, terms and abbreviations

|  |  |
| --- | --- |
| **Term/abbreviation** | **Definition at Company CDE** |
| CMO | Contract Manufacturing Organization |
| DP/DS | Drug Product / Drug Substance |
| ERP | Enterprise Resource Program |
| Material Qualification Status List (MQSL) | It is a consolidated list with all GMP relevant materials, their identifier, full name, supplier, manufacturer, dedicated usage, qualification status, and relevant comments. |
| MQ | Material Qualification |
| Ph. Eur. | European Pharmacopoeia |
| USP | United States Pharmacopoeia |

# Workflow

## Checking and purchase ordering

Purchasing checks actual version of **Material Qualification Status List (MQSL)** before placing the order. If there are no quality-related incidents for the materials to be ordered or delivery-time issues, purchasing will order the qualified material. In case of quality-relevant incidents (Change Notifications, memos, or similar), Purchasing consults with Quality Organization and decides on the order ability.

Quality-relevant incidents are evaluated by the members of the Risk Management Team. Based on the existing risk analysis, the risk management team members submit the change request according to **SOP-05 CDE Change Management**, if needed, to determine the measures and whether the material may be obtained from the supplier. In this process, Purchasing is informed by the Risk Management Team.

## New material (or alternative supplier) request

New materials or new suppliers to existing materials, New GMP material requests should be initiated according to **SOP-05 CDE Change Management** to start the Material Qualification. For customized materials, the material requester prepares **Material User Requirement Specification (MURS)** and documents there all specific material related requirements. The material requester is responsible for providing all information, including container sizes and quantities. An overview of documents that may apply is covered in **Documents for the Material Assessment Appendix**.

## Prerequisite for the decision to qualify material

The decision, whether a material to be purchased must be qualified or re-qualified, is made by the e.g., QC Head, Quality Organization and the Risk Management Team based on the following prerequisites:

* new material or changes to existing material,
* new supplier or alternative supplier,
* new manufacturer or change of manufacturer at the supplier’s site, and
* results of re-assessment of a supplier and its quality issues and impact on materials.

The Material Qualification is carried out as a part of **SOP-05 CDE Change Management**.

### Selection of a Supplier

Suppliers/Alternative Suppliers are selected and qualified as described in
**SOP-13 CDE Supplier Management**.

### Initial risk classification of the new material

To determine the initial criticality of the new material from an existing or new supplier to determine the scope of supplier qualification or its requalification (if required) and further measures within the area of Material Qualification, the members of the Risk Management Team perform an initial risk classification of the material. Risk Management Team members with the material requester shall classify initial material-related risk according to **SOP-09 CDE Quality Risk Management** principles and this SOP.

Purchasing inquires about the supply chain of the new material from the supplier and checks whether the supplier has already been utilized in the past (period: <5years) but was rejected as recorded in actual **Supplier Evaluation records**. Likewise, the current delivery time is communicated to Operations for production planning. If the supplier was previously rejected, it must be re-qualified according
 **SOP-13 CDE Supplier Management**.

In the case of a new supplier, refer to **SOP-13 CDE Supplier Management** and leverage the conclusion.

The Risk Assessment Team assigns an initial risk level (low, medium, or high) to the new material based on the potential risk factors, which is increased by one level in the event of an increased delivery time outside the production planning and leads to a bottleneck. Furthermore, the following items raise the risk level and require consideration:

* material criticality class
* results from the initial risk assessment of the supplier based on the questionnaire, which could lead to a negative quality impact,
* a lack of qualified alternative suppliers,
* results from supplier evaluations that show quality issues,
* insufficient feedback from the supplier

Based on this classification, the Risk Management Team decides the scope of the measures based on the risk analysis in the Change Control process.

### Classification of the material

The members of the Risk Management Team determine the classification of the new material in the initial risk classification. In GMP, the criticality is divided into criticality classes 1-4, where 1 is the highest criticality class (see **Table 1**) If a material is used in several process steps, the highest criticality class applies in each case.

|  |  |  |  |
| --- | --- | --- | --- |
| **Class 1** | **Class 2** | **Class 3** | **Class 4** |
| active ingredients starting materials auxiliary materials (part of formulation) primary packaging materialsprinted packaging materialscustomized materials | Auxiliary substances for purificationproduct-contacting sterile materials for aseptic production materials of criticality, as medical devices biological materials for QC materials for microbiological monitoringvalidated sterile cleaning materials | Product-contacting,non-sterile materials for non-aseptic productionsterile materials without contact with final or intermediate productcleaning and detergents/ disinfectantsunprinted secondary and tertiary packaging materials | Auxiliary materials (e.g., gloves)Non-product touching non- sterile materials |

***Table 1: Material criticality classification and examples***

Materials in criticality classes 1-3 are qualified or requalified as part of a Change Control. According to this SOP, materials of criticality class 4 are not qualified and are not subject to Change Control.

### Request documents/certificates from supplier

The members of the Risk Management Teams determine in the initial risk classification of the respective material category which certificates are required for the risk analysis within the Change Control procedure. These are requested from the supplier by Purchasing.

### Determination of measures as part of the Change Control process

The members of the Risk Management Team, together with Quality Organization, e.g., QC Head decide based on the initial risk determined based on the data returned from the supplier whether the material is to be ordered and qualified or must be rejected.

The decision to open and initiate a particular change shall be made **SOP-05 CDE Change Management.** If the material is approved, the Risk Management Team and Quality Organization in the risk classification determine the measures, and a responsible person as action owner is expected to complete the date for the change. The material requester and the members of the Risk Management Team then sign the completed intimate risk classification according to **SOP-09 CDE Quality Risk Management** and submit it to Quality Organization.

In case of rejection, this must be justified in writing in the form by the Risk Management Team.

### Decision making

Quality Organization reviews the information for completeness. e.g., QC Head approves the material for qualification. It assigns a consecutive MQ number according to the **Material Qualification Status List (MQSL)**, or an upgrade in the case of requalification and documents this in the initial risk assessment for new materials or in the change request for already qualified materials.

### Pre-ordering

If required, Purchasing preorders the material, batch-related documents/certificates for qualification purposes.

### Supplier qualification/requalification

After classifying the criticality of the material, the qualification scope is defined. For new materials purchased from an existing supplier, it is necessary to check whether the requirements are covered. The qualification itself is subject to **SOP-13 CDE Supplier Management**. The suitability and approval of the supplier are to be checked before the Material Qualification.

### Risk Assessment

The Risk Management Team assesses whether the material is suitable for its intended use based on the information provided by the supplier. The impact on the process and thus on the final product is assessed.

The assessment covers the potential impact on the product/intermedia, such as extractables & leachables, impurities, etc., which may adversely affect the integrity or shelf life.

According to **SOP-09 CDE Quality Risk Management** Risk Assessment team identifies and assess material related risks to:

* evaluate the impact on the process and the final product due to contamination.
* determine the acceptance criteria and thus prepare the specification.

### Creation of the specification

Based on the Risk Assessment of the material to be used in the GMP area, Quality Control department creates specifications depending on the established criteria.

### Quality Assurance Agreement

The preparation and scope of the **Quality Assurance Agreement** or change notification are based on the criticality of the material and are handled by **SOP-13 CDE Supplier Management** and related **Quality Assurance Agreement Appendix.**

### Final Review

Once all information is complete, Quality Organization verifies the correctness and completeness and the execution of all action items defined in the Change Control.

The most important items are:

* Supplier qualification status and supply chain traceability,
* Risk Assessment,
* Analytical reports and conclusions for material samples
* completed Change Control,
* released Specification (if necessary),
* Quality Assurance Agreement/ change notification,
* correct ERP entries.

### Release of the material

Once all inspection points are completed, Quality Organization enters the material in the **Material Qualification Status List (MQSL)**, with the date and lifecycle, and closes the Change Control. e.g., QC Head approves updated version of **Material Qualification Status List (MQSL).**

### Rejection of the material

Suppose the Risk Management Team stops purchasing the material or blocks new material. In that case, Quality Organization reports the blocking in ERP accordingly to Purchasing and Supply Chain Management.

Quality Organization removes affected material from the **Material Qualification Status List (MQSL)**, e.g., QC Head approves updated version of **Material Qualification Status List (MQSL).**

## Annual materials review

Risk Management Team, Quality Organization, e.g., QC Head review actual **Material Qualification Status List (MQSL)** and latest Risk Assessment records annually.

When reviewing risks, in case of an increase in some risks, the Risk Management Team acts according to the **SOP-09 CDE Quality Risk Management** and initiates required CAPA measures according to **SOP-07 CDE CAPA Management.**

Quality Organization presents the results of this review to senior management as part of Management Review according to **SOP-04 CDE Management Review**.

## Archiving

All documents supporting this procedure are subjects of **SOP-16 CDE Archiving.**

# Applicable documents

SOP-01 (CDE) Documentation Management

SOP-02 CDE Good Documentation Practice

SOP-04 CDE Management Review

SOP-05 CDE Change Management

SOP-09 CDE Quality Risk Management

SOP-10 CDE Training Management

SOP-13 CDE Supplier Management

SOP-16 CDE Archiving

# Appendices

The following appendices are integral part of this SOP:

Appendix Material Qualification Status List (MQSL) Form

Appendix Documents for the Material Assessment Appendix

Appendix Material User Requirement Specification (MURS) Form

# Document revision history

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