SOP Purchasing

ISO 13485:2016 Section	Document Section
7.4	All

Summary

This SOP describes requirements for the purchasing of goods and services by the organization. It includes initial supplier evaluation, budget approval and continuous supplier surveillance. It ensures that only high-quality goods and services are purchased in order to guarantee the manufacturing of high-quality products for own customers.

Process Owner	*<enter role of process owner>*
Key Performance Indicators	*<enter KPIs to be tracked for the Management Review>*

General Considerations

1.1 Supplier Qualification

Goods and services that can impact the quality of the organization's medical devices are only purchased from qualified suppliers.

Initial supplier evaluation is carried out by following the Supplier Evaluation Checklist.

1.2 List of Qualified Suppliers

Suppliers which are deemed critical and which underwent initial supplier evaluation are added to the List of Qualified Suppliers. The list is also used to document continuous supplier surveillance and the latest evaluation status of every supplier.

1.3 Supplier Criticality

A supplier is classified as critical:

- If the purchased goods or services could have a direct impact on the safety of the organization's medical devices; OR:
- If the purchased goods or services could have a direct impact on the performance of the organization's medical devices; OR:
- If the purchased goods or services could have a direct impact on the regulatory compliance of the organization's medical devices; OR:
- If the organization is not able to manufacture its medical devices without the supplier's goods or services; AND:

- If there is no alternative and equivalent supplier for these goods or services.

If a supplier could have an *indirect impact* on the safety, performance or regulatory compliance of the organization's medical devices, it is up to the QMO to determine the supplier's criticality on a case-by-case basis depending on their impact on product safety and performance.

A supplier is classified as non-critical if the purchased goods or services have no impact on the safety, performance or regulatory compliance of the organization's medical devices.

1.4 Supplier Evaluation

Suppliers are evaluated according to the evaluation categories described below:

Quality of Products/Services	Quality is assessed based on the number of identified nonconforming purchases and reported reclamations, also taking into account delivery.
Timeliness / Punctuality	Timeliness is assessed based on the number of delayed purchases.
Cooperation	Cooperation is assessed e.g. based on the availability for follow-up questions and responses to complaints.
Payment Terms	Payment terms are assessed e.g. based on pricing and discounts, payment options, overdue fees and return policies compared to alternative suppliers.

Suppliers are evaluated along with these categories by assigning a score value to each category. Score values are as follows:

- 0: unacceptable
- 1: moderate
- 2: good
- 3: excellent

In order to complete the evaluation, an average score is calculated from all categories. The quality value is weighted double.

The overall score results in the following evaluation outcome:

- Average score 2 - 3: supplier can be approved.
- Average score 1 - 2: supplier can be approved, provided that surveillance measures are in place (see step 2.5 of this process).
- Average score 0 - 1: supplier cannot be approved and is marked as blocked in the List of Qualified Suppliers.

Process Steps

2.1 Preliminary Regulatory Assessment

Before purchasing any product or service, employees are required to check compatibility with the organization's quality standards.

Employees therefore first check if the supplier is approved in the List of Qualified Suppliers. If it is listed, they can continue with step 2.3.

If the supplier is documented as blocked in the List of Qualified Suppliers, the employee looks for an alternative supplier.

If the supplier is not mentioned in the List of Qualified Suppliers, employees need to request regulatory approval for the purchase from the QMO. The QMO checks the supplier's criticality, i.e. the impact of its goods and services on the quality of the organization's medical devices, by reviewing against the criteria described in section 1.3. The QMO can decide that a supplier is obviously uncritical and that no further supplier evaluation is needed. If so, the process continues with step 2.3.

If the supplier is not mentioned in the List of Qualified Suppliers and not deemed obviously uncritical, the QMO first conducts an initial supplier evaluation.

Participants	Purchasing employeeQMO
Input	Preliminary regulatory assessmentList of Qualified SuppliersSupplier Checklist
Output	Regulatory approval for purchaseor: need for initial supplier evaluation

2.2 Initial Supplier Evaluation

The QMO conducts the initial supplier evaluation by completing the Supplier Checklist. They can therefore request additional information from the supplier. Only the QMO decides on the approval of a critical supplier.

If the supplier is deemed critical and the initial supplier evaluation is completed successfully, the supplier is added to the List of Qualified Suppliers and the process continues with the next step. Based on the supplier's criticality for the quality of the organization's medical devices, the QMO may define additional measures for supplier surveillance which are also documented as part of the List of Qualified Suppliers.

If the supplier is deemed critical and the evaluation is unsuccessful (meaning, the supplier cannot be qualified for purchasing), the supplier is also added to the List of Qualified Suppliers, but marked as blocked. In this case, the order cannot be placed and the employee looks for an alternative supplier.

Blocked suppliers can be approved by repeating this process step and conducting a new supplier evaluation.

Participants	QMO
Input	Purchase needList of Qualified Suppliers
Output	Completed supplier evaluationUpdated List of Qualified SuppliersRegulatory approval

2.3 Budget Approval

The employee requests their supervisor for budget approval for the respective purchase. The supervisor reviews the purchasing costs against the organization's budget plan and approves or denies the request. Upon approval, the employee places the order.

Participants	Purchasing employeeSupervisor
Input	Documented regulatory approval
Output	Documented budget approvalOrder placement

2.4 Verification

The purchasing employee verifies that the received services or goods match the order and fulfill expected quality standards.

In case sub-standard quality or in any other way nonconforming services or goods, the QMO is notified to document the purchase's effect on continuous supplier evaluation (next step). A complaint is sent to the supplier and defective products are returned if applicable.

Invoices and receipts are attached to expense records and archived accordingly.

Participants	Purchasing employeeQMO
Input	Received services or goods
Output	Archived reclamation records (if applicable)Updated List of Qualified Suppliers (if necessary)Invoices processed

2.5 Supplier Surveillance

> NOTE: for class II or higher, the annual re-evaluation of suppliers should be completed prior to the Management Review.

The QMO can decide to undertake various surveillance measures such as:

- **Supplier Certification**: a supplier can be requested to provide valid and ongoing certification as proof of its quality management system's efficacy. In this case, the QMO keeps a copy of the current supplier certificates with the organization's QM records. The validity of supplier certification is checked at least once per year as part of the annual supplier evaluation.

- **Quality Assurance Agreement (QAA)**: a supplier can be requested to sign a QAA as a commitment to specific quality assurance measures.
- **Supplier Audits**: supplier audits and site visits can be requested where previous supplier documentation (records, certification) did not establish sufficient objective evidence of a supplier's QM system efficacy and compliance. The QMO is responsible to conduct supplier audits. As part of conducting a supplier audit, an audit plan and audit report are created following the organization's process for Internal Auditing. Additionally, the QMO may decide to set up a continuous audit program for the supplier.

2.5.1 Continuous Supplier Surveillance Supplier evaluations are updated continuously in the context of every new purchase, but at minimum once per year. Surveillance measures are carried out continuously as considered appropriate and documented in the List of Qualified Suppliers.

Any new information about a supplier can lead to an update of the supplier's evaluation status. Following a decrease in a supplier's evaluation status, the QMO can decide over appropriate measures, such as opening a CAPA, further surveillance measures or blocking a supplier in case of a significant decrease in quality standards. Opening a CAPA is always required in case of a decrease by one grade according to the evaluation criteria outlined in step 1.3.

Participants	QMO
Input	New supplier records
Output	Updated List of Qualified Suppliers

2.5.2 Annual Supplier Evaluation At minimum once per year, the QMO reviews all available information (incl. public records such as complaints, ratings, certificates) to update the evaluation status of suppliers listed in the List of Qualified Suppliers.

Following a decrease in a supplier's evaluation status, the QMO can decide over appropriate measures, such as opening a CAPA, further surveillance measures or blocking a supplier in case of a significant decrease in quality standards. Opening a CAPA is always required in case of a decrease by one grade according to the evaluation criteria outlined in step 1.4.

Participants	QMO
Input	Supplier recordsList of Qualified Suppliers
Output	Updated List of Qualified Suppliers