

[Organization logo]

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PROCEDURE FOR PURCHASING AND EVALUATION OF SUPPLIERS

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Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

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1. Purpose, scope and users

The purpose of this Procedure is to describe the purchasing process in order to conform to specified purchasing requirements and the receiving inspection process.

This Procedure applies to all processes and/or areas (parts of organization) within the Quality Management System (QMS).

This purchasing process includes, but is not limited to consumables, such as office supplies, hardware needed for product, raw materials, research equipment, and information and communication technology.

This Procedure excludes:

- Utilities (electricity, gas, water, etc.)
- Insurance, legal and audit fees
- Investment services
- Personnel services (benefits, wage and salary administration including employment contracts)
- Other purchases, as approved by the [CFO]; and
- Purchases less than [\$]

Users of this document are [heads of departments, Purchasing Manager and Quality Controllers] of [organization name], as well as internal auditors.

2. Reference documents

- ISO 13485:2016 standard, clauses 4.1.5 and 7.4
- MDR 2017/745, article 10(9) and Annex IX – Chapter I
- IVDR 2017/746
- Quality Manual
- Procedure for Production and Service Provision

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You can find the full text of the MDR on the following link:
<https://advisera.com/13485academy/mdr/>

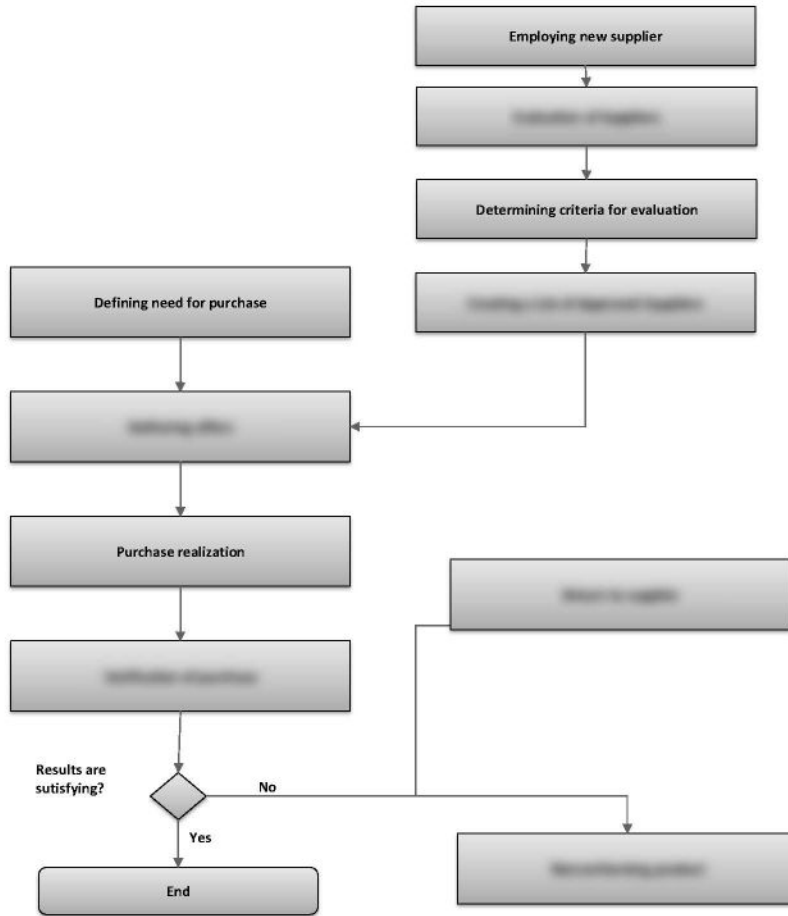
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Commented [AES13]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

3. Evaluation and selection of suppliers

3.1. Process flow



[organization name]

SQ	Shipment Quality	from 0 to 30
P	Price	from 0 to 25
SR	Supplier Reliability	from 0 to 20
TP	Terms of Payment	from 0 to 15
QMS	Quality Management System	from 0 to 10

[Job title] assigns certain number of points for each criterion and sums them.

Commented [AES30]: E.g., Purchasing Manager

3.4.1. Shipment quality

Evaluation of shipment quality considers the following parameters: correctness of delivery documents, delivered quantity of product meets requested quantity,

Commented [AES31]: Modify these criteria to meet

Points	Description
30	No complaints on shipment quality
25	The complaints don't affect shipment quality
20	Complaints significantly affect shipment quality
15	Complaints significantly affect shipment quality
10	Complaints significantly affect shipment quality

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3.4.2. Price

Points	Description
25	Price is under average market price
15	Average market price
10	Price is slightly above market price
5	Price is significantly above market price

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3.4.3. Supplier's reliability

Points	Description
20	Constantly demonstrates willingness for cooperation and professionalism, no complaints regarding cooperation
15	Often demonstrates willingness for cooperation
10	Often demonstrates willingness for cooperation

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3.4.4. Terms of payment

Points	Description
15	Deferred payment 30 days
10	Payment after shipment
5	100% advance payment and 10% after shipment
5	100% advance payment

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3.4.5. Quality Management System

Points	Description
10	Organization has a certified QMS according to ISO 13485:2016 and ISO 9001:2015 or any other applicable standard
5	Organization has a certified QMS, but not according to ISO 13485
5	Organization doesn't have a certified QMS and doesn't plan according to ISO 13485 and ISO 9001

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3.5. Ranking of suppliers

Suppliers are ranked according to the previously defined method.

Rank	Description	Points
A	Exceptional	>95
B	Acceptable	85-95
C	Acceptable with further working	75-85
D	Unacceptable	Below than 75

[Job title] updates this data about suppliers in a Checklist for Evaluation of Suppliers once a year.

Commented [AES37]: E.g., Purchasing Manager

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3.6. Critical suppliers and subcontractors

Critical suppliers are suppliers that deliver materials and components that may influence the safety and performance of the final medical device. With critical suppliers, it is necessary to sign a Quality Agreement, which is stated in the Quality Agreement for Critical Supplier.

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Commented [AES41]: For example, outsourced processes can

Commented [AES42]: E.g., Production Manager, Quality Manager

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which processes need to be subcontracted and what level of control over those processes is necessary. Control over subcontracted processes depends on the risk that the process has on the safety of the final medical product. With subcontractors, it is necessary to sign a Quality Agreement, which is stated in the Quality Agreement for Subcontractors.

Mutual obligations, responsible persons, criteria for supplier's audit, validity of the contract, and ways of communication are explained in those quality agreements. [Job title] prepares these quality agreements and ensures that they are signed and properly maintained.

Commented [AES43]: E.g., Purchasing Manager, QA Manager

4. Purchasing

4.1. Defining need for purchase

According to [inventory status, customer's requests, trends on market and results of design process], [job title] creates an internal purchase request and delivers it to [job title]. Based on the internal purchase request, [job title] creates a Request and Order for Purchasing and chooses a supplier from the List of Approved Suppliers according to section 3.4 of this document.

Commented [AES44]: Write in the reasons for purchasing

Commented [AES45]: E.g., Head of department

Commented [AES46]: E.g., Supply Manager

Commented [AES47]: E.g., Purchasing Manager

If the supplier does not deliver goods or services that meet the requirements of the organization, [job title] reports to [job title], who makes the final decision whether to award the contract to the supplier or to the another supplier.

Commented [AES48]: E.g., Supply Manager

Commented [AES49]: Usually CEO.

4.2. Gathering, selection and approval of offers

[Job title] gathers the offers from approved suppliers by sending them a Request and Order for Purchasing.

Commented [AES50]: E.g., Supply Manager

If the ordered product or service significantly influences the organization's business and quality of product or service, [job title] defines:

- Product specifications
- Requirements for approval of product, processes and equipment
- Requirements for certification of product
- Requirements for quality management system

Commented [AES51]: If supplier is a big company and has a

For long-term purchases or purchases of great value, [job title] signs a contract with the supplier.

Commented [AES52]: Usually CEO.

Commented [AES53]: E.g., Supply Manager

4.3. Realization of purchase

[Job title] monitors the purchasing process and notifies [job title] if problems occur during the purchasing process (shipment delays, nonconforming product, etc.).

Commented [AES54]: E.g., Supply Manager

Commented [AES55]: Usually CEO.

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List of Approved Suppliers	PR11.2			
Registry of Complaints about Suppliers	PR11.3			
Request and Order for Purchasing	PR11.4			
Purchasing Verification Record	PR11.5			
Quality Agreement for Critical Supplier	PR11.6			
Quality Agreement for Subcontractor	PR11.7			

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6. Appendices

- Appendix 1 – Checklist for Evaluation of Suppliers
- Appendix 2 – List of Approved Suppliers
- Appendix 3 – Registry of Complaints about Suppliers
- Appendix 4 – Request and Order for Purchasing
- Appendix 5 – Purchasing Verification Record
- Appendix 6 – Quality Agreement for Critical Supplier
- Appendix 7 – Quality Agreement for Subcontractor

[job title]

[name]

[organization name]

[signature]

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