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[Organization name]

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PROCEDURE FOR PURCHASING AND EVALUATION OF SUPPLIERS

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

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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

Commented [AES4]: Adapt to the organization's needs.

Commented [AES5]: Write in other exclusions that organization finds appropriate.

Commented [AES6]: Adapt to the organization's practice.

Commented [AES7]: Write in the amount.

Commented [AES8]: Adapt to the organization's practice.

Commented [AES9]: Include the name of your organization.

 $\label{lem:commented} \begin{tabular}{ll} \textbf{Commented [AES10]:} & \textbf{Delete this if your organization does not} \\ \textbf{need to be compliant with MDR.} \\ \end{tabular}$

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

Commented [AES11]: Delete if your medical device is not an in vitro diagnostic medical device.

Commented [AES12]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

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

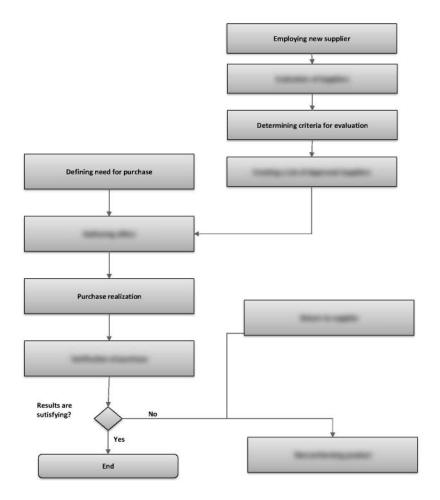
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3. Evaluation and selection of suppliers

3.1. Process flow



Employing new suppliers 3.2.

In the case of hiring a new supplier, [job title] gathers samples of products or supplier's references.

Commented [AES14]: E.g., Purchasing Manager

Parameters needed for consideration in risk assessment are:

- information on off-the-shelf or custom-made device/part
- specification of raw material or service
- information on complexity of device/part

According to gathered data, [job title] conducts an evaluation of the supplier using criteria described below. [Job title] should send a questionnaire to the supplier that is delivering critical parts and materials.

Commented [AES15]: These bullets represent the minimum

Commented [AES16]: E.g., Purchasing Manager Commented [AES17]: E.g., Purchasing Manager

Commented [AES18]: E.g., Purchasing Manager Commented [AES19]: E.g., Purchasing Manager

Commented [AES20]: E.g., sterilization, gluing, welding

Commented [AES21]: Include the name of your organization.

Commented [AES22]: Process validation is the analysis of data

Commented [AES23]: Include the name of your organization. Commented [AES24]: E.g., Purchasing Manager

Commented [AES25]: The greater the effect of the product on

Commented [AES26]: Adapt to organization's practice; other

Commented [AES27]: Adapt the method to the organization's

Commented [AES28]: E.g., Purchasing Manager

In the case of special processes, [organization name] must perform a validation of processes, because they cannot be regularly monitored and measured.

3.3. **Evaluating suppliers**

of Suppliers

[Job title] conducts evaluations of suppliers by analyzing:

previous purchasing of goods and services

Criteria for selecting suppliers

technical documentation, catalogs, demo versions, prospectus, and other relevant documents about goods and services

Status of supplier performance and certification is monitored during the year and at the end of each

year, suppliers are re-evaluated and ranked.

[Job title] conducts the evaluation of suppliers according to the following criteria:

Symbol Range of points

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Commented [AES29]: These are suggested criteria and range

SQ	from 0 to 30
P	from 0 to 25
SR	from 0 to 20
TP See See See See See See See See See Se	from 0 to 15
QMS	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,

Points	Description
30	No complaints on shipment quality
25	The complaints don't affect shipment quality
100	up of sergions with end office or disprove quality
-	constants against affect stipment quality
-	frigment's sturned facts oracognotic stipment quality

Commented [AES31]: Modify these criteria to meet

Commented [AES32]: Adapt to the organization's needs.

3.4.2. Price

Points	Description
25	Price is under average market price
15	Average market price
-	Proxity agenty above memor princi-
	Proxit age/forms above monter prior

Commented [AES33]: Adapt to the organization's needs.

3.4.3. Supplier's reliability

Points	Description	
20	Constantly demonstrates willingness for cooperation and professionalism, no complaints regarding cooperation	
*	Mine constant specifiq manufacture	
-	The organic species consisted	

Commented [AES34]: Adapt to the organization's needs.

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3.4.4. Terms of payment

Points	Description
15	Deferred payment 30 days
10	Payment after shipment
	Whatever agreet and 10h after stigment
	SSR above payment

Commented [AES35]: Adapt to the organization's needs.

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
	Experience has a serifical SME, but only according to SE 900.
*	Trigonisation deposit force a sentitled SMS and deposit and exceeding to

Commented [AES36]: Adapt to the organization's needs.

3.5. Ranking of suppliers

Suppliers are ranked according to the previously defined method.

Rank	Description	Points
Α	Exceptional	>95
В	Acceptable	85-95
	Recognition with family	To dis
	(Proportional Co.	Name Nati

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

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

Commented [AES38]: Adapt to the organization's practice.

Commented [AES39]: Delete if your organization doesn't have

Commented [AES40]: If the organization does not have critical

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.

Commented [AES41]: For example, outsourced processes can

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

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[organization name]

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

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

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

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

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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[organization name]

Managing of purchasing will be proportionate to the risk associated with the medical device and impact of the product on the quality of the medical device.

4.4. Verification of purchased product/service

4.4.1. Verification of products

[Job title] confirms receiving agreed quantity of goods by signing the supplier's delivery documents that include attests and other evidences of product or service quality and entering the information into the Purchasing Verification Record. In cases when it's necessary to wait for results of aboratory testing, [job title] must put purchased product in an appropriate place and label such product with PRODUCT ON TESTING – FORBIDDEN USE.

Commented [AES56]: E.g., Warehousing Manager

Commented [AES57]: Adapt to the organization's practice

Commented [AES58]: E.g., Warehousing Manager

When the organization becomes aware of any changes to the purchased product, [job title] must determine whether these changes affect the product realization process or the medical device, and start appropriate actions if needed.

Commented [AES59]: E.g., Purchasing Manager

Commented [AES60]: Include the name of your organization.

Commented [AES61]: E.g., QA Manager, Management

4.4.2. Verification of services

[Job title] conducts service verification by acquiring evidences from the supplier (references,

Commented [AES62]: E.g., Purchasing Manager

5. Managing records kept on the basis of this document

Record name	Code	Storage		
		-	-	-
Checklist for Evaluation of Suppliers	PR11.1	C passing	(office of Management Representation	gas-enc.

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[organization name]

List of Approved Suppliers	PR11.2	Digestri.	joffice of Monagement Monagement Monagement	(parentes)
Registry of Complaints about Suppliers	PR11.3	(Fallent)	julificacusi Management Magementation	(parentee)
Request and Order for Purchasing	PR11.4	Especia	(office of Management Management	gas resc
Purchasing Verification Record	PR11.5	Statement.	(effice of Monagement Representative)	jun muc
Quality Agreement for Critical Supplier	PR11.6	CONTRACTOR OF THE PARTY OF THE	Jaffres of Sections Manager Section Manager Section Manager Section Manager Section Manager Section	(parente)
Quality Agreement for Subcontractor	PR11.7			parms

Commented [AES63]: Adapt to the organization's practice.

Commented [AES64]: Adapt to the organization's practice.

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

[job title] [name]

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[organization name]	
[signature]	Commented [AES65]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.