Supplier Management Comparative Analysis

Supplier Management is an overarching QMS element that includes process that can be broken down into activities. (They would be boxes on a flowchart.) For each activity, the table identifies the requirement from the identified standard.

Processes
Supplier evaluation and selection
Supplier monitoring and re-evaluation
Control of purchasing data
Outsource processes
Placing a purchase order
Receiving the product

Definitions

Standard	Product	Risk	Notes
QSR	Product means components, manufacturing materials, in-process devices, finished devices, and returned devices. [820.3(r)]	Not defined	--
ISO 13485:2003	A product is the result of a process [ISO 9000:2005, 3.4.2]	Not defined	--
ISO 13485:2016	A product is the result of a process [ISO 13485:2016, 3.15]	Risk is the combination of the probability of occurrence of harm and the severity of that harm [ISO 13485:2016, 3.17]	When the term “risk” is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements. [ISO 13485:2016, 0.2]

Supplier evaluation and selection

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Establish and maintain procedures to ensure conformance to requirements	Establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [820.50]	Establish documented procedures to ensure that purchased product conforms to specified purchase requirements [7.4.1]	Document procedures to ensure that purchased product conforms to specified purchasing information [7.4.1]
Establish criteria for supplier selection	Establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants [820.50(a)]	Criteria for selection and evaluation shall be established [7.4.1]	Establish criteria for the evaluation and selection of suppliers [7.4.1] {See the notes to this section}
Evaluate a potential supplier's ability to satisfy the criteria	Evaluate … potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements [820.50(a)(1)]	Evaluate suppliers based on their ability to supply product in accordance with the organization's requirements. [7.4.1]	--
Create and maintain records of the evaluation	The evaluation shall be documented [820.50(a)(1)]	Records of the results of evaluations shall be maintained [7.4.1]	Records of the results of evaluation … shall be maintained [7.4.1]
Select the supplier	[Select] suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements [820.50(a)(1)]	Select suppliers based on their ability to supply product in accordance with the organization's requirements [7.4.1]	--
Create and maintain records of the selected supplier	Establish and maintain records of acceptable suppliers [820.50(a)(3)]	--	Records of the results of … selection … shall be maintained [7.4.1]

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Create and maintain records of actions required from the evaluation	--	Records of any necessary actions arising from the evaluation shall be maintained [7.4.1]	Records of … any necessary actions arising from [evaluation] shall be maintained [7.4.1]
Create and maintain records of actions required from the selection	--	--	Records of … any necessary actions arising from [selection] shall be maintained [7.4.1]
Define the supplier controls	Define the type and extent of control to be exercised over the … suppliers, contractors, and consultants, based on the evaluation results [820.50(a)(2)]	The type and extent of control applied to the supplier … shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. [7.4.1]	--
Define the product controls	Define the type and extent of control to be exercised over the product [and] services … based on the evaluation results [820.50(a)(2)]	The type and extent of control applied to the … purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. [7.4.1]	--

Notes:
The criteria [for evaluation and selection] shall be:
a) based on the supplier's ability to provide product that meets the organization's requirements;
b) based on the performance of the supplier;
c) based on the effect of the purchased product on the quality of the medical device;
d) proportionate to the risk associated with the medical device.

Supplier monitoring and re-evaluation

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Plan supplier monitoring	--	--	Plan the monitoring … of suppliers [7.4.1]
Establish criteria for monitoring	--	--	Supplier performance in meeting requirements for the purchased product shall be monitored [7.4.1]
Create and maintain records of the monitoring	--	--	Records of the results of … monitoring … of supplier capability or performance shall be maintained [7.4.1]
Create and maintain records of the actions resulting from the monitoring	--	--	Records of … any necessary actions arising from [monitoring] shall be maintained [7.4.1]
Plan supplier re-evaluation	--	--	Plan the … re-evaluation of suppliers [7.4.1]
Establish criteria for re-evaluation	--	Criteria for… re-evaluation shall be established. [7.4.1]	The results of the monitoring shall provide an input into the supplier re-evaluation process [7.4.1]
Create and maintain records of the re-evaluation	--	Records of the results of [re-evaluations] … shall be maintained. [7.4.1]	Records of the results of … re-evaluation of supplier capability or performance … shall be maintained [7.4.1]
Create and maintain records of the actions resulting from the re-evaluation	--	Records of any necessary actions arising from the [re-evaluations] shall be maintained. [7.4.1]	Records of … any necessary actions arising from [re-evaluation] shall be maintained [7.4.1]

Control of purchasing data

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Establish and maintain data that describes to procured product or service	Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements … for purchased or otherwise received product and services. [820.50(b)]	Purchasing information shall describe the product to be purchased [7.4.2]	Purchasing information shall describe or reference the product to be purchased [7.4.2]
Include any product specifications	--	--	Purchasing information shall include as appropriate product specifications [7.4.2.a]
Include any requirements for product, procedures, processes, and equipment approval	--	Purchasing information shall [include] where appropriate requirements for approval of product, procedures, processes, and equipment [7.4.2.a]	Purchasing information shall include as appropriate requirements for product acceptance, procedures, processes, and equipment [7.4.2.b]
Include any requirements for personnel qualification	--	Purchasing information shall [include] where appropriate requirements for qualification of personnel [7.4.2.b]	Purchasing information shall include as appropriate requirements for qualification of supplier personnel [7.4.2.c]
Include any requirements for the supplier's quality management system	Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements including quality requirements … [820.50(b)]	Purchasing information shall [include] where appropriate quality management system requirements. [7.4.2.c]	Purchasing information shall include as appropriate quality management system requirements [7.4.2.d]

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Include, where possible, an agreement to notify the manufacturer of changes to the product or service	Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service … [820.50(b)]	--	Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. [7.4.2]
Determine if the changes may impact the finished device quality	[N]otify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device [820.50(b)]	--	When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect … the medical device. [7.4.3]
Determine if the changes may impact the product realization process	--	--	When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process … [7.4.3]
Ensure the purchasing requirements are adequate before sending them to the supplier	--	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. [7.4.2]	The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. [7.4.2]

Activity	QSR	ISO 13485:2003	ISO 13485:2016
For verification at the supplier's site, include the arrangements in the purchasing information.	--	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. [7.4.3]	When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. [7.4.3]
Place the data under document control	Purchasing data shall be approved in accordance with §820.40. [820.50(b)]	--	--
Maintain relevant information for traceability	--	To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, *i.e.*, documents and records. [7.4.2]	To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents and records. [7.4.2]

Outsource processes

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Ensure control of outsourced processes	--	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. [4.1]	When the organization chooses to outsource any process that affects product conformity to requirements, it shall … ensure control over such processes. [4.1.5]
Identify the outsourced process controls	--	Control of such outsourced processes shall be identified within the quality management system (see 8.5.1). [4.1]	--
Controls are proportionate to the risk involved	--	--	The controls shall be proportionate to the risk involved … [4.1.5]
Controls are proportionate to the external party's ability to meet them	--	--	The controls shall be proportionate to … the ability of the external party to meet the requirements in accordance with 7.4 – Purchasing. [4.1.5]
Controls include written quality agreements	--	--	The controls shall include written quality agreements. [4.1.5]
Monitor the outsourced process	--	--	When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor … such processes. [4.1.5]

Placing a purchase order

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Purchasing documentation includes, where possible, an agreement to notify the manufacturer of changes to the product or service	Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service … [820.50(b)]	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. [7.4.2]	Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. [7.4.2]
Ensure the purchasing requirements are adequate before communicating them to the supplier.	Purchasing data shall be approved in accordance with §820.40. [820.50(b)]	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. [7.4.2]	The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. [7.4.2]

Receiving the product

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Establish and maintain procedures to accept incoming product	Each manufacturer shall establish and maintain procedures for acceptance of incoming product. [820.80(b)]	--	--
Inspect, test, or otherwise verify incoming product	Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. [820.80(b)]	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. [7.4.3]	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. [7.4.3]
Base acceptance activities on the supplier evaluation results.	--	--	The extent of verification activities shall be based on the supplier evaluation results … [7.4.3]
Base acceptance activities on the risks associated with the purchased product.	--	--	The extent of verification activities shall be … proportionate to the risks associated with the purchased product. [7.4.3]
Document the acceptance or rejection of incoming product.	Acceptance or rejection shall be documented. [820.80(b)]	--	--

Activity	QSR	ISO 13485:2003	ISO 13485:2016
Create quality records of incoming acceptance activities.	These records shall include: (1) The acceptance activities performed; (2) the dates acceptance activities are performed; (3) the results; (4) the signature of the individual(s) conducting the acceptance activities; and (5) where appropriate the equipment used. [820.80(e)]	Records of the verification shall be maintained (see 4.2.4).	Records of the verification shall be maintained (see 4.2.5).
Include incoming acceptance activity records in the DHR.	These records shall be part of the DHR. [820.80(e)]	--	--
For verification at the supplier's site, include the arrangements in the purchasing information.	--	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. [7.4.3]	When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. [7.4.3]