

# **Purchasing Controls at a Glance**

**FDA Small Business Regulatory Education for Industry (REdI)**

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# Why Purchasing Controls?



**RECALL**

# Harmonized



**Quality System (QS) Regulation**

**International Organization for  
Standardization (ISO)  
13485:2016**

# Learning Objectives

- Define key terminology associated with purchasing controls requirements
- State the importance and goals of purchasing controls
- State QS regulation and ISO 13485:2016 requirements for Purchasing Controls
- Identify similarities and differences in QS regulation and ISO 13485:2016 requirements for Purchasing Controls

# Definitions

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- **Product** 820.3(r) - includes components, manufacturing materials, in-process devices, finished devices, and returned devices
- **Component** 820.3(c) - means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device

# Definitions

- **Manufacturing material** 820.3 (p) – means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer

# Definitions

- **Product** (Clause 3.15) – result of a process.
  - Note 1: Four generic product categories:
    - Services (e.g., transport)
    - Software (e.g., computer program, dictionary)
    - Hardware (e.g., engine mechanical part)
    - Processed materials (e.g., lubricant)
  - Note 2: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible.
- **Purchased product** (Clause 3.16) – product provided by a party outside the organization's quality management system



# **Importance and Goals of Purchasing Controls**

# Importance

- Quality of finished medical device depends on quality of raw materials, components and services
- Companies outsource a lot of product manufacturing and quality services
- Quality cannot be ensured by product testing alone

# Goals

- Purchasing controls ensure that device manufacturers:
  - Establish and maintain requirements that suppliers, contractors and consultants must meet
  - Select only suppliers, contractors, and consultants who have capability to provide quality product and services

# **QS Regulation and ISO 13485:2016 Purchasing Control Requirements**

# Purchasing Controls Requirements

## 21 CFR 820.50

- Ensure all purchased product and services conform to specified requirements
- Establish requirements that must be met by suppliers
- Evaluate suppliers on the basis of their ability to meet specified requirements
- Define the type and extent of control to be exercised over suppliers

# Purchasing Controls Requirements

## 21 CFR 820.50

- Establish records of acceptable suppliers
- Establish purchasing data
- Obtain an agreement to provide a notification of changes in the product or service

# Purchasing Controls Requirements

## ISO 13485: 2016, Clause 7.4.1 Purchasing process

- Ensure purchased product conforms to specified purchasing information
- Establish criteria for the evaluation & selection of suppliers
- Plan the monitoring and re-evaluation of suppliers
- Address non-fulfillment of requirements with the supplier proportionate to risk
- Maintain records

# Purchasing Controls Requirements

## ISO 13485: 2016, Clause 7.4.2 Purchasing information

- Purchasing information shall describe or reference the product to be purchased
- Include a written agreement that the supplier notify the organization of changes
- Maintain relevant purchasing information



# Purchasing Controls Requirements

## ISO 13485: 2016 , Clause 7.4.3 Verification of purchased product

- Establish inspection or other activities to ensure purchased product meets requirements
- Verification activities based on the results of the supplier evaluation and proportionate to the risks
- Determine whether any changes in purchased product affect the product realization process or the medical device

# Purchasing Controls Requirements

## ISO 13485: 2016 , Clause 7.4.3

- Document the intended verification activities and product release method
- Maintain records

# Knowledge Check

**Purchasing Controls apply only to the purchasing of components for the finished medical device.**

**A. True**

**B. False**

# Knowledge Check

**The type and extent of the control over suppliers is based on:**

- A. The evaluation results**
- B. Commensurate with risk of the supplied product**
- C. Supplier quality historical data**
- D. All of the above**

# **Purchasing Controls Requirements: Similarities and Differences**

# Similarities

## Similarities

- Require documented procedures for purchasing controls
- Require that evaluations of suppliers are based on determining suppliers' ability to meet requirements
- Extent of control over suppliers is based on risk of product or service to be received and evaluation results

# Similarities

## Similarities

- Records of acceptable suppliers must be maintained
- Require documented specified requirements for purchased product and/or services
- Require an agreement with suppliers to provide notification of any changes to the product or service

# Differences

Differences	
21 CFR 820.50	ISO 13485:2016
<ul style="list-style-type: none"> <li>Requirement is specific to evaluate, select, and control contractors and consultants</li> </ul>	<ul style="list-style-type: none"> <li>Does not point out “contractors” and “consultants”, but rather simply refers to “purchased product” from any supplier</li> </ul>



# Differences

Differences	
21 CFR 820.50	ISO 13485:2016
<ul style="list-style-type: none"> <li>• Evaluation of suppliers is based on               <ul style="list-style-type: none"> <li>➤ suppliers' ability to meet specified requirements, including quality requirements</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Evaluation of suppliers is based on               <ul style="list-style-type: none"> <li>➤ supplier's ability to provide product that meets organization's requirements</li> <li>➤ performance of supplier</li> <li>➤ effect of purchased product on quality of medical device</li> <li>➤ and proportionate to risk associated with medical device</li> </ul> </li> </ul>

# Differences

Differences	
21 CFR 820.50	ISO 13485:2016
<ul style="list-style-type: none"> <li>Does not specify re-evaluations of suppliers</li> </ul>	<ul style="list-style-type: none"> <li>Requires a plan for monitoring and re-evaluation of suppliers</li> <li>Requires companies to address non-fulfillment of purchasing requirements with the supplier based on risk</li> </ul>

# Differences

Differences	
21 CFR 820.50	ISO 13485:2016
<ul style="list-style-type: none"> <li>Does not name specific purchasing data/information</li> </ul>	<ul style="list-style-type: none"> <li>Purchasing information shall include, as appropriate:               <ul style="list-style-type: none"> <li>➤ Product specifications</li> <li>➤ Requirements for product acceptance, procedures, processes and equipment</li> <li>➤ Requirements for qualification of supplier personnel</li> <li>➤ QMS requirements</li> </ul> </li> <li>Purchasing information relevant to traceability is required</li> </ul>

# Differences

Differences	
21 CFR 820.50	ISO 13485:2016
<ul style="list-style-type: none"> <li>• Verification of purchased product is not mentioned explicitly, but covered in 820.80(b)</li> <li>• Does not specify the effect of changes</li> </ul>	<ul style="list-style-type: none"> <li>• Verification of purchased product is defined based on supplier evaluation results and proportionate to its risks</li> <li>• Determine the effect of changes to purchased product</li> <li>• Purchasing information includes on-site verification and product release activities</li> </ul>

# Resources

Slide Number	Cited Resource	URL
3	Quality System Regulation (21 CFR 820.50)	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&amp;showFR=1&amp;subpartNode=21:8.0.1.1.12.5">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&amp;showFR=1&amp;subpartNode=21:8.0.1.1.12.5</a>
3	Proposed Rule-Medical Devices, Quality System Regulation Amendments	<a href="http://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments">www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments</a>
10 and 19-23	Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation	<a href="http://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation">www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation</a>
24	AAMI Quality Systems White Paper- Comparison of 21 CFR Part 820 to ISO 13485:2016-2018	<a href="http://www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf">www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf</a>
24	AAMI Technical Information Report 102 (TIR 102)	TIR102:2019 (U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016)
	CDRH Learn Module: Purchasing Controls	<a href="http://fda.yorkcast.com/webcast/Play/083de1ef7cfb40169e2451492a32ed1e1d">fda.yorkcast.com/webcast/Play/083de1ef7cfb40169e2451492a32ed1e1d</a>
	Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers	<a href="http://www.imdrf.org/sites/default/files/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n17-guidance-on-quality-management-system-081211.pdf">www.imdrf.org/sites/default/files/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n17-guidance-on-quality-management-system-081211.pdf</a>

# Summary

- Purchasing controls are an extremely important process
- Purchasing controls ensure that device manufacturers select only suppliers who have capability to provide quality product and services
- Companies can out-source their device design and manufacturing activities, but there is one thing a company cannot out-source...RESPONSIBILITY!

# Questions

