



Purchasing Controls

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Learning Objectives

- Understand the Intent and Background of Purchasing Controls
- Define Product, Component and Service
- Understand Purchasing Controls Requirements, Voluntary Guidance and Best Practices
- Recognize the Links between Purchasing Controls and other Quality System (QS) requirements such as Design Controls and Acceptance Activities

References

- 21 Code of Federal Regulations (CFR) 820: Quality System Regulation
- 21 CFR 820.50: Purchasing Controls
- Preamble to 1996 Quality System (QS) Regulation

Intent of Purchasing Controls

The intent of § 820.50 is to ensure that device manufacturers select only those suppliers, contractors, and consultants who have the capability to provide quality product and services. As with finished devices, quality cannot be inspected or tested into products or services.

FDA Response to Comment #106 [Preamble to 1996 QS Regulation]

Why Does This Matter?

- Quality of the finished medical device depends on the quality of the raw materials, components and services that went into it.
- Poor Medical Device Quality Can Cause:
 - Injuries from the medical device
 - Recalls
 - Customer dissatisfaction

Why is FDA Concerned about Purchasing Controls?

- Inspections often extend only to the finished device manufacturer.
- FDA does not perform routine inspections of component manufacturers.
- Increasing outsourcing of the manufacturing of critical components and entire medical devices.

What is Unique about Medical Devices?

- Wide range in type of received *products* and *services*
 - Raw materials, Components, Software, etc.
 - Laboratories, Sterilizers, Calibration, Installers and Service Providers, Auditors, Consultants
- Wide range in complexity in received products
 - From components to finished devices

What Else is Unique about Medical Devices?

- Wide range in risk associated with received products and services
 - Same received product or service may have different risks based on use.
 - Same supplier may have different risks for different supplied product or service.

When are Purchasing Controls Applicable?

- Received Products
- Received Services
- Consultants

Definition: Product

Product includes components, manufacturing materials, in-process devices, finished devices, and returned devices.

§ 820.3(r)

Definition: Component

Component 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.

§ 820.3(c)

Definition: Service

Service means parts of the manufacturing or quality system that are contracted to others, for example, plating of metals, testing, and sterilizing...

FDA Response to Comment #102 [Preamble to 1996 QS Regulation]

Requirements and Best Practices

- The Quality System Regulation, 21 CFR 820.50

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=0588847128f3ca65f7192b250f242cc1&mc=true&n=pt21.8.820&r=PART&ty=HTML#sp21.8.820.e>

- Preamble to QS Regulation
- GHTF Guidance: Quality Management System Medical Devices – Control of Products and Services Obtained from Suppliers; SG3; 2008

<http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n17-guidance-on-quality-management-system-081211.pdf>

Requirements for Purchasing Controls

Establish and maintain procedures to ensure that all purchased or ***otherwise received*** product and services conform to specified requirements

Paraphrase § 820.50

Six Steps to Supplier Controls

These six steps are typically involved in establishing controls for products and services obtained from suppliers:

1. Planning
2. Selection of potential supplier/s
3. Evaluation/acceptance of supplier
4. Finalization of responsibilities and controls
5. Delivery, measurement and monitoring
6. Communication including the CAPA process

GHTF Guidance General Principals Section 3.0

Requirements for Purchasing Controls

Establish and maintain requirements, including quality requirements, that suppliers, contractors and consultants must meet

Paraphrase § 820.50(a)

Requirements for Purchasing Controls

Evaluate and select potential suppliers, contractors, and consultants on the basis of their **ability to meet specified requirements**, including quality requirements. The evaluation shall be documented.

§ 820.50(a)(1)

Requirements for Purchasing Controls

- Define the **type and extent of control** to be exercised **over product, services, suppliers, contractors, and consultants** based on the evaluation results.
§ 820.50(a)(2)
- Establish and maintain records of acceptable suppliers, contractors, and consultants
§ 820.50(a)(3)

Control Over Suppliers

... A finished device manufacturer may choose to provide greater in-house controls to ensure that products and services meet requirements, or may require the supplier to adopt measures necessary to ensure acceptability, as appropriate.

FDA Response to Comment #99 [Preamble to 1996 QS Regulation]

Requirements for Purchasing Controls, continued Purchasing Data

- Establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received products and services
- Approve in accordance with Document Controls in § 820.40

Paraphrase § 820.50(b)

Requirements for Purchasing Controls

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 so that manufacturers may determine whether the changes may affect the quality of a finished device.

§ 820.50(b)

Ongoing Supplier Reviews

The capability of the product or service suppliers should be ***reviewed at intervals consistent with the significance of the product or service provided*** and the review should demonstrate conformance to specified requirements.

FDA Response to Comment #103 [Preamble to 1996 QS Regulation]

Ongoing Communication

- Discuss supplier's complaint handling system and any defects in product that could result in problems with the device.
- Discuss supplier's willingness to provide information when the device manufacturer is performing a CAPA where the device defect may be due to the supplier's product.

Purchasing Controls Link to Other Quality System Requirements

Design Controls (21 CFR 820.30)

- Product design drives purchasing decision-making

Acceptance Activities (21 CFR 820.80)

- In-house Acceptance activities complement supplier controls

Purchasing Controls Link to Design Controls

... the quality of a product or service is established during the design of that product or service, and achieved through proper control of the manufacture of that product or the performance of that service...

FDA Response to Comment #106 [Preamble to 1996 QS Regulation]

Specifications

Specifications for the device are determined in Design Controls, (21 CFR 820.30)

- Design Inputs ensure that design requirements relating to the device are appropriate and address intended use
- Design Outputs must contain or make reference to acceptance criteria and identify essential design outputs

Acceptance Activities

- Establish and Maintain Procedures for Acceptance Activities of Incoming Product §820.80
- Acceptance activities include:
 - Inspections, Tests and other Verification Activities
 - Documenting Acceptance or Rejection

Purchasing Controls and Acceptance Activities

... The extent of incoming acceptance activities can be based, in part, on the degree to which the supplier has demonstrated a capability to provide quality products or services.

FDA Response to Comment #106 [Preamble to 1996 QS Regulation]

Summary

- Purchasing controls pertain to received products and services
- Select suppliers based on their capabilities and your manufacturing requirements
- Establish adequate supplier controls
- Documentation is important! Establish and maintain records regarding purchases, data, reviews, etc.
- Following purchasing control requirements is good for business and public health

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