



Purchasing Controls

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Learning Objectives

- Define Product, Component, Service
- Background on Purchasing Controls
- Explain Requirements and Best Practices
- Note Links Between Purchasing Controls and Other QS Requirements
- Review Compliance Data

When are Purchasing Controls Applicable?

- Supplied Products & Components
- Supplied Services
- Consultants

[§ 820.50](#) - *Purchasing Controls.*



Definition: Product

Product means 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)

There are no “FDA approved” materials

Components ≠ accessories

Definition: Service

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

-Preamble, Comment #102

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.

-Preamble, Comment #106

Goal: Provide quality products beyond what can be achieved through inspection and testing

Why Does This Matter?

Quality of the finished medical device depends on the quality of the components, raw materials and services

Poor Quality Can Cause:

- Injuries from the medical device
- Recalls
- Customer dissatisfaction

Why is FDA Concerned about Purchasing Controls?

- FDA authority applies to the finished device manufacturer
- Outsourcing of critical components and manufacturing of medical devices

FDA does *not* perform routine inspections of component manufacturers

What is unique about medical devices?

Wide range in type of supplied *products* and *services*

- Raw materials, Components, Software
- Laboratories, Sterilizers, Calibration, Installers and Service Providers, Auditors, Consultants

What else is unique about medical devices?

Wide range in risk associated with supplied products and services

- Same supplied product or service may have different risks based on use
- Same supplier may have different risks for different supplied product or service

Supplier

- **Internal (In house)** – only when the supplier is under the same Quality System internal quality audit.
 - **External** – supplier is not under the same Quality System internal quality audit.
 - Affiliated companies – supplier affiliated with the device manufacturer, a “sister company,” or another division
- **Need to qualify external suppliers**

Purchasing Controls Apply Regardless of Monetary Transaction

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

- § 820.50

Supplier Requirements

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

Best Practice:

- Ensure consultants have the right experience.

Purchasing Evaluation & Selection

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)*

Best Practices:

- Create contractual agreements regarding supplier expectations

Type/Extent of Control & Records

- 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)*

Best Practices:

- Keep lists of both qualified and disqualified suppliers

Control Over Suppliers

... may choose to provide greater in-house controls to ensure that products and service meet requirements... or may require the supplier to adopt measures necessary to ensure acceptability...

-Preamble , Comment #99

For example: audits, review historical data, monitoring, trending, inspection testing

Purchasing Data

Each manufacturer shall establish and maintain data that clearly describe or reference specified requirements, including quality requirements, for purchased or otherwise received products and services. § 820.50(b)

- Approve in accordance with Document Controls in § 820.40

Best Practice:

- Ensure that all staff are aware of the requirement(s)

Purchasing Data

*Purchasing documents shall include, where possible, an **agreement** that 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)



Best Practice:

- Ensure that suppliers notify manufacturers about changes *prior* to implementation

Ongoing Supplier Reviews

...Product or service suppliers should be reviewed at intervals consistent with the significance of the product or service provided ...demonstrate conformance to specified requirements.

-Preamble , Comment # 105

FDA reviews procedures for supplier audits, not actual results of supplier audits.

Best Practice:

- If your procedures state that audits are conducted at a particular frequency, stick to it!

Ongoing Communication

- Supplier's complaint handling system - identify defects in product that could result in problems with the device
- Supplier's willingness to provide information during investigation of a Corrective and Preventive Action (CAPA)

GHTF QMS - Medical Devices - Guidance on Control of Products and Services Obtained from Suppliers

- Good reference document
- Contains flowchart of activities



Purchasing Controls Link to other Regulations

- *Design Controls* *§ 820.30*
 - Product design drives purchasing decision-making
 - Quality established through design and proper manufacturing
- *Acceptance activities of incoming product* *§ 820.80*
 - Inspections, tests and other verification activities

2014 FDA Inspectional Data

FDA 483 Observations

Time frame 1/1/2014 to 12/31/2014

- **3,740** observations cited for 21 CFR 820
- **1,197** observations cited for Production and Process Controls (e.g. Receiving device acceptance, traceability, etc.)
- **54 Warning Letter citations for 21 CFR 820.50**

Commonly Cited Issues, § 820.50 Supplier Evaluations

- No documentation of supplier evaluations
- Inadequate requirements for suppliers
 - e.g., control over validated processes, reliance on supplier self-assessments*

Example Warning Letter Citation

- Failure to clearly define the type and extent of control to be exercised over suppliers.
 - For example, your Supplier Approval Procedure & Process Map states you will perform ongoing monitoring of Level 1 suppliers. The procedure does not define the frequency and type of monitoring required for these suppliers.*
- Failure to evaluate potential contractors.
 - For example, you did not evaluate the company who conducted steam sterilization validation studies for the XYZ Screw System to ensure they could conduct the validation studies in accordance with the specified standard.*

Injunction Example

–Shutdown Letter to Firm

- .. failed to establish and maintain adequate procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR §820.50.
- ... *relies on its PCB supplier to perform a comparison (verification) between electronic design files ... and the manufacturing files ... the requirement that this verification be performed and appropriately documented was not specified in XXX purchasing documentation or supplier agreement.*
- ... *relied on the supplier to perform its own First Article Inspection, but failed to established any criteria for the supplier to conduct the verification ...*
- ... *continues to have solder flux contamination issues from a supplier even after implementing previous corrective actions. ... has not implemented procedures to adequately control the products from this supplier or to inspect incoming products to detect contamination*

Summary

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

Providing Industry Education

Three Resources

1. CDRH Learn – Multi-Media Industry Education

- over 80 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices

<http://www.fda.gov/Training/CDRHLearn>

2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance>

3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30 pm EST)
- Web: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>

Questions?

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