Purchasing Controls & Acceptance Activities

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Objectives

- Understand the requirements for purchasing controls or product/services provided by a supplier
- Understand the relationship between purchasing controls, acceptance activities and risk analysis
- Be aware of the GHTF document on this topic and what that means to FDA

QS Regulation Definition: Product

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

§820.3(r)

Component Manufacturers

- FDA decided not to regulate component manufacturers under the Quality System regulation in light of the Purchasing Controls Requirements in 820.50 and the requirements for Receiving Acceptance Activities in 820.80(b).

Purchasing Controls

- Applies when products and/or services are obtained from:
  - Suppliers
  - Contractors
  - Consultants

§820.50(a)

Procedures for Purchasing Controls

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

§820.50

The Preamble on Purchasing Control Requirements

- FDA emphasizes that the requirements apply to all product and services received from outside of the finished device manufacturer, whether payment occurs or not. Thus, a manufacturer must comply with these provisions when it receives product or services from its “sister facility” or some other corporate or financial affiliate. “Otherwise received product” would include customer supplier product … but would not apply to “returned product” from the customer.

Preamble, Comment 100

Purchasing Controls

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

§820.50(a)

Evaluation and Selection

- Evaluate and select potential suppliers, contractors, and consultants on the basis of their **ability to meet specified requirements**, including quality requirements
- Document evaluation

§820.50(a)(1)

The Preamble on Supplier Evaluations

- … finished device manufacturers who conduct product quality control solely in-house must also assess the capability of suppliers to provide acceptable product. Where audits are not practical, this may be done through, among other means, reviewing historical data, monitoring and trending, and inspection and testing

Preamble, Comment 99

The Preamble on Degree of Supplier Control

- … the degree of supplier control necessary to establish compliance may vary with the type and significance of the product or service purchased and the impact of that product or service on the quality of the finished device.

Preamble, Comment 99

Control

- Define **type and extent of control** to be exercised **over product, services, suppliers, contractors, and consultants** based on the evaluation results.

§820.50(a)(2)

The Preamble on Control Over Products and Services

- ... manufacturers must clearly define in the procedures the type and extent of control they intend to apply to products and services. Thus, 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.

Preamble, Comment 99

Records

- Establish and maintain records of acceptable suppliers, contractors, and consultants

§820.50(a)(3)

Purchasing Data

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

§820.50(b)

Purchasing Data

- Include, where possible, an agreement that suppliers, contractors, and consultants will notify the manufacturer of changes in the product or service so the manufacturer can determine the effect of changes on the finished device

§820.50(b)

Risk Analysis

Using Risk Analysis and striking a balance for controlling supplied product and service through a combination of purchasing controls and acceptance activities.

Purchasing Controls
Risk Analysis

- The extent of the specification detail necessary to ensure that the product or service purchased meets requirements will be related to the nature of the product or service purchased, taking into account the effect the product or service may have on the safety or effectiveness of the finished device, among other factors.

  – Preamble comment 115

Acceptance Activities

- Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

§820.80

Acceptance Activities

- Purchasing controls require device manufacturers to assess the capability of suppliers, contractors, & consultants to provide quality products and services.

- Inspection, tests, and verification activities are important in ensuring components and finished devices meet approved specifications.

Acceptance Activities

- For Receiving, In-process, Finished device acceptance each manufacturer shall:

- Establish and maintain procedures for acceptance activities.

Receiving Incoming Product

- Establish and maintain procedures for incoming acceptance of product.
- Inspect, test, or verify product conforms to specification.
- DOCUMENT acceptance or rejection.
  - 21 CFR 820.80(b)

GHTF Final Guidance Document

Title: Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers.

http://www.ghtf.org/documents/sg3/sg3final-N17.pdf

Supplier Controls
GHTF Guidance Document

- A product or service is one which is purchased or otherwise received by the manufacturer

- A supplier is anyone that is independent from the manufacturer's quality management system

Supplier Controls
GHTF Guidance Document

- Internal supplier
  - Part of the manufacturer's organization
  - Operates under a separate quality management system
  - Not part of the manufacturer's internal audit scope (quality audit)

- Internal suppliers are to be controlled in a similar way as external suppliers

Supplier Controls
GHTF Guidance Document

- FDA intends to adopt through the FDA Good Guidance Practice process.

Outsourced Processes Requiring Validation

- Finished device manufacture is ultimately responsible for ensuring the device meets all requirements.
- Sterilization and packaging processes require validation.
- Need to be able to demonstrate the process has been validated.

Outsourced Processes Requiring Validation

- Purchasing control agreements should clearly identify the responsibilities of both parties.
- Changes to product or processes need to be exchanged and evaluated to determine if revalidation is needed.
- 21 CFR 801.150(e) – contract sterilization.

Questions?

Thank you!