# Supplier Controls: FDA Perspective

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# Overview

- Challenges and unique aspects associated with purchasing controls for medical devices
- Quality System (QS) regulation requirements for purchasing controls (21 CFR 820.50)
- Link between purchasing controls and other QS regulation requirements
- Overview and comparison of the GHTF *Guidance on the Control of Products and Services Obtained from Suppliers* and the QS regulation requirements

# Why is FDA Concerned About Purchasing Controls?

- Inspections and FDA authority often extend only to the finished device manufacturer.
  - ... This regulation does not apply to manufacturers of components or parts of finished devices .... [820.1(a)(1)]
    - Finished device means any device or accessory to any device that is suitable for use or capable of functioning whether or not it is packaged, labeled, or sterilized. [820.3(l)]
    - 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)]
  - FDA does have the authority to inspect component manufacturers, but does not issue a FDA-483 for Quality System violations.

# Why is FDA Concerned About Purchasing Controls?

- FDA has seen an increase in
  - Outsourcing of critical components and manufacturing of entire devices.
  - Recalls and product problems associated with purchased components.

# When Does FDA Review Purchasing Controls?

- Inspections
  - Quality System Inspection Technique (QSIT) - Production and Process Controls (P&PC) Subsystem
  - Compliance Program (7382.845) – Inspection of Medical Device Manufacturers
- Premarket Approval Applications (PMAs)
  - Original PMAs
  - Some PMA supplements (Site changes, 30-Day Notices)
- Purchasing Controls Typically NOT Reviewed in 510(k)s

# What is Unique About Medical Devices?

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

# Intent of Purchasing Controls

The intent of Sec. 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**.

Preamble to the 1996 QS Regulation, Comment #106

# Compliance Program ( CP 7382.845)

The **finished device manufacturer bears overall responsibility for the safety and effectiveness of the finished device** and must control all contractors under 21 CFR § 820.50 Purchasing controls and 21 CFR § 820.80 Receiving, in-process, and finished device acceptance ...

... However, **a contract sterilizer/contract manufacturer of finished devices and the finished device manufacturer are all legally responsible for compliance with the Quality System regulation** and for assuring the safety and effectiveness of the finished device.

# When do Purchasing Controls Apply?

- Supplied Product
- Supplied Services (“Contractors”)
  - …FDA believes that all suppliers of such services must be assessed and evaluated, just like a supplier of a product. ... the degree of control necessary is related to the product or service purchased…

    Preamble to the 1996 QS Regulation, Comment #102
- Consultants

# Internal/External Suppliers

... the requirements apply to all product and service 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.

Preamble to the 1996 QS Regulation, Comment #100

- In general, entities not covered by a firm’s internal audits should be treated as suppliers.

# Purchasing Controls – 21 CFR 820.50

- Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.
  - Product includes components, manufacturing materials, in-process devices, finished devices, and returned devices. [21 CFR 820.3(r)]

# Supplier Evaluation – 21 CFR 820.50(a)

- Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

# Supplier Evaluation/Selection – 21 CFR 820.50(a)(1)

- (a)(1) 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.
  - Procedures should be unambiguous about how suppliers are deemed "acceptable."

# Initial Supplier Assessment

... the initial assessment or evaluation, depending on the type and potential effect on device quality of the product or service, should be a combination of assessment methods ...

Preamble to the 1996 QS Regulation, Comment #103

# Supplier Audits

... 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 to the 1996 QS Regulation, Comment #99

- Be cautious of using prior supplier audits as sole basis for decisions; scope of previous audits is important.

# Supplier Audits

- FDA cannot review supplier audits during an inspection

> 820.180(c) Exceptions. This section does not apply to the reports required by 820.20(c) Management review, 820.22 Quality audits, and **supplier audit reports used to meet the requirements of 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions**.

- Supplier information included in CAPA records and other data sources can be reviewed.

# Third Party Certification

… [FDA] cautions manufacturers against relying solely on certification by third parties as evidence that suppliers have the capability to provide quality products or services ... third party certification should not be relied on exclusively in initially evaluating a supplier. If a device manufacturer has established confidence in the supplier's ability to provide acceptable products or services, certification with test data may be acceptable.

Preamble to the 1996 QS Regulation, Comment #103

# 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.

Preamble to the 1996 QS Regulation, Comment #103

- “Action” thresholds should be objective and consistently applied.

# Type and Extent of Control – 21 CFR 820.50(a)(2)

- (a)(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
  - Be mindful of higher risk processes (e.g., those that may require validation) and sub-tier supplier controls.

# Risk Based Decisions

"…. the need for specifications should be based on the criticality of and risk associated with the use of the specific manufacturing material…. 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 …"

Preamble to the 1996 QS Regulation, Comment #115

# Control Over Suppliers

... A finished device manufacturer 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, as appropriate. FDA generally believes that an appropriate mix of supplier and manufacturer quality controls are necessary.

Preamble to the 1996 QS Regulation, Comment #99

# Acceptable Supplier Records - 21 CFR 820.50(a)(3)

- (a)(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

# Purchasing Data - 21 CFR 820.50(b)

- (b) Purchasing data. Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services...
  - Be mindful of informal channels for communicating purchasing data.

# Purchasing Data, cont. – 21 CFR 820.50(b)

- ...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...
  - Beware of over-reliance on notification, especially for suppliers over which the manufacturer has limited control.

# Purchasing Controls Link to Other QS Requirements

- Design Controls (21 CFR 820.30)
  - Product design and associated risks 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. Section 820.50 thus mandates that products be manufactured and services be performed under appropriate quality assurance procedures.

Preamble to the 1996 QS Regulation, Comment #106

# Design Validation – 21 CFR 820.30(g)

Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and **risk analysis** ...

# Purchasing Controls Link to Risk Analysis

... 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 to the 1996 QS Regulation, Comment #99

# Balancing Purchasing Controls and Acceptance Activities

Balance Activities Commensurate with Risk

# Acceptance Activities – 21 CFR 820.80(a)

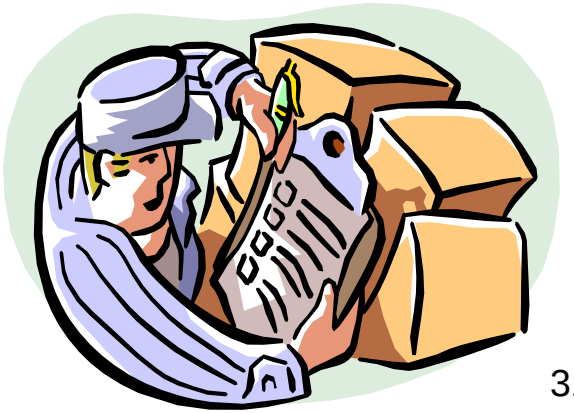
Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities….

# Purchasing Controls Link to Acceptance Activities

Each manufacturer must establish an appropriate mix of assessment and receiving acceptance to ensure products and services are acceptable for their intended uses...

Preamble to the 1996 QS Regulation, Comment #99

- Be cautious of “one size fits all” approaches to balancing supplier controls and assessment activities



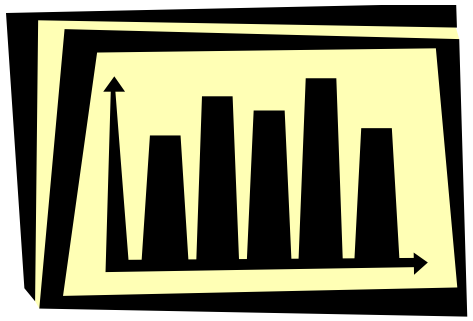
# Purchasing Controls and Acceptance Activities

…while finished device manufacturers are required to assess the capability of suppliers, contractors, and consultants ... **inspections and tests, and other verification tools, are also an important part of ensuring that components and finished devices conform to approved specifications** ...

# Purchasing Controls and Acceptance Activities, cont.

... 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.

Preamble to the 1996 QS Regulation, Comment #106



# GHTF Guidance Document

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

# Guidance vs. Regulation

- Manufacturers are not required to comply with guidance documents.
  - Guidance is voluntary and is a way of doing something that FDA generally recognizes as acceptable.
- Manufacturers are required to comply with the Quality System Regulation.

# GHTF Guidance Document Definitions

- 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.
  - Includes a supplier that may be part of the manufacturer's organization but operates under a separate quality management system.

# GHTF Guidance Document Internal Suppliers

… **if the supplier is not a part of the manufacturer's internal audit** (quality audit) scope, then the supplier is under a separate quality management system and **is considered an internal supplier** … Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same quality management system … Internal suppliers are to be controlled in a similar way as external suppliers are controlled.

# GHTF Guidance
# Internal Supplier Definitions

- 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

# GHTF Guidance Document Manufacturer's Responsibility

The "manufacturer" or entity that has the ultimate responsibility for its quality management system, **cannot relinquish (contractually or otherwise) its obligation and responsibility over any or all functions within the quality management system** … the **responsibility for complying with the quality management system requirements cannot be delegated to any supplier** (internal or external) of products and services.

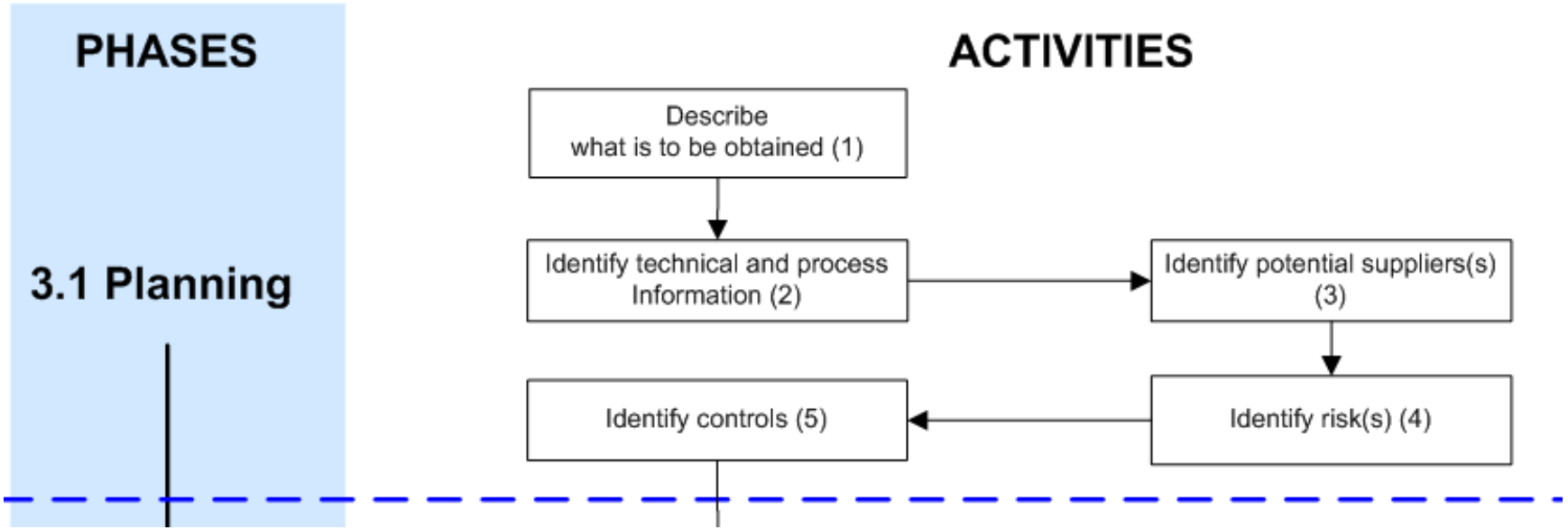
# GHTF Guidance Document Regulated Suppliers

Some suppliers may undergo some form of oversight either by a regulatory authority, or a third-party operating on behalf of a regulatory authority … **This oversight does not relinquish the responsibility of a manufacturer to establish controls and provide evidence for products and services** obtained from suppliers.

# GHTF Guidance
# Six Phases of Supplier Controls

- The process of establishing controls for products and services obtained from suppliers typically comprises six phases, which include:
  - 3.1 Planning
  - 3.2 Selection of potential supplier(s)
  - 3.3 Supplier evaluation and acceptance
  - 3.4 Finalization of controls and responsibilities
  - 3.5 Delivery, measurement and monitoring
  - 3.6 Feedback and communication, including Corrective Action and Preventive Action process

# 3.1 Planning - Steps



# GHTF 3.1, Planning, and the QS Reg.

- 3.1.1, Identify product or service to be obtained from a supplier
  [Objective Evidence: Description or spec for product/service]
- 3.1.2, Develop necessary technical and process information
  [Objective Evidence: Product reqt's/specs, QMS reqt's]
- 3.1.3, Identify one or more potential suppliers
  [Objective Evidence: Name(s)/ contact info for potential suppliers]

- 820.30(d), Establish and maintain procedures for defining and documenting design output
- 820.50(a)/ 820.50(b), (a) Establish and maintain reqt's … that must be met by suppliers, (b) Establish and maintain data that describe or reference specified reqt's.
- 820.50(a)(1), Evaluate and select potential suppliers …

# GHTF 3.1, Planning, and the QS Reg., cont.

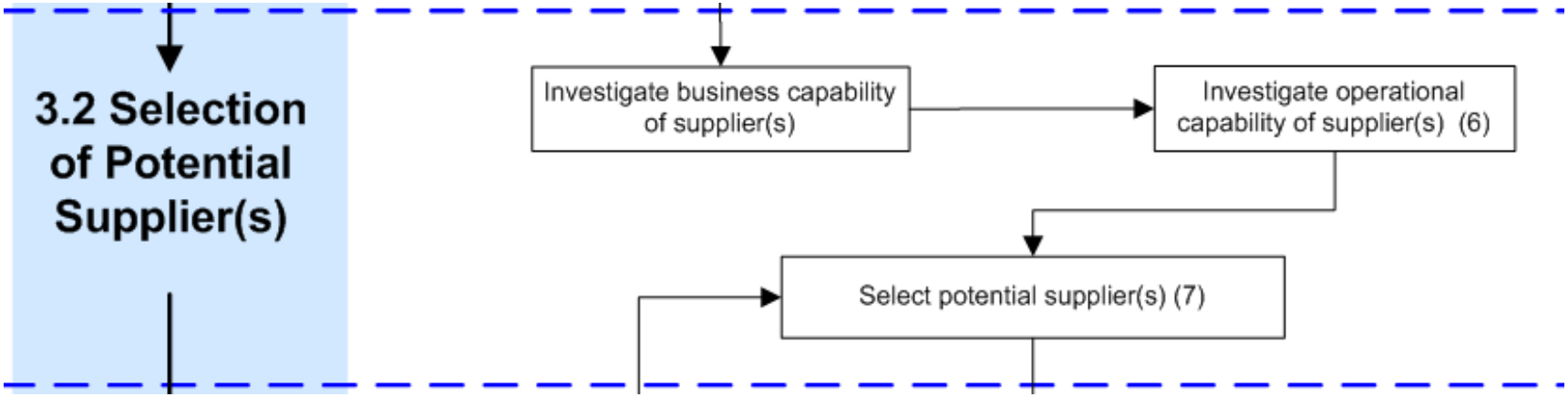
- 3.1.4, Identify risks associated with the product or service to be obtained
  [Objective Evidence: Risks identified]

- 820.30(g), Design validation shall include … risk analysis

- 3.1.5, Identify type and extent of control necessary to control risks
  [Objective Evidence: List of potential controls as a result of identified risks]

- 820.30(g), and 820.50(a)/ 820.50(a)(2), (a) Establish and maintain the reqt's, including quality reqt's, that must be met by suppliers … (a)(2) Define the type and extent of control to be exercised

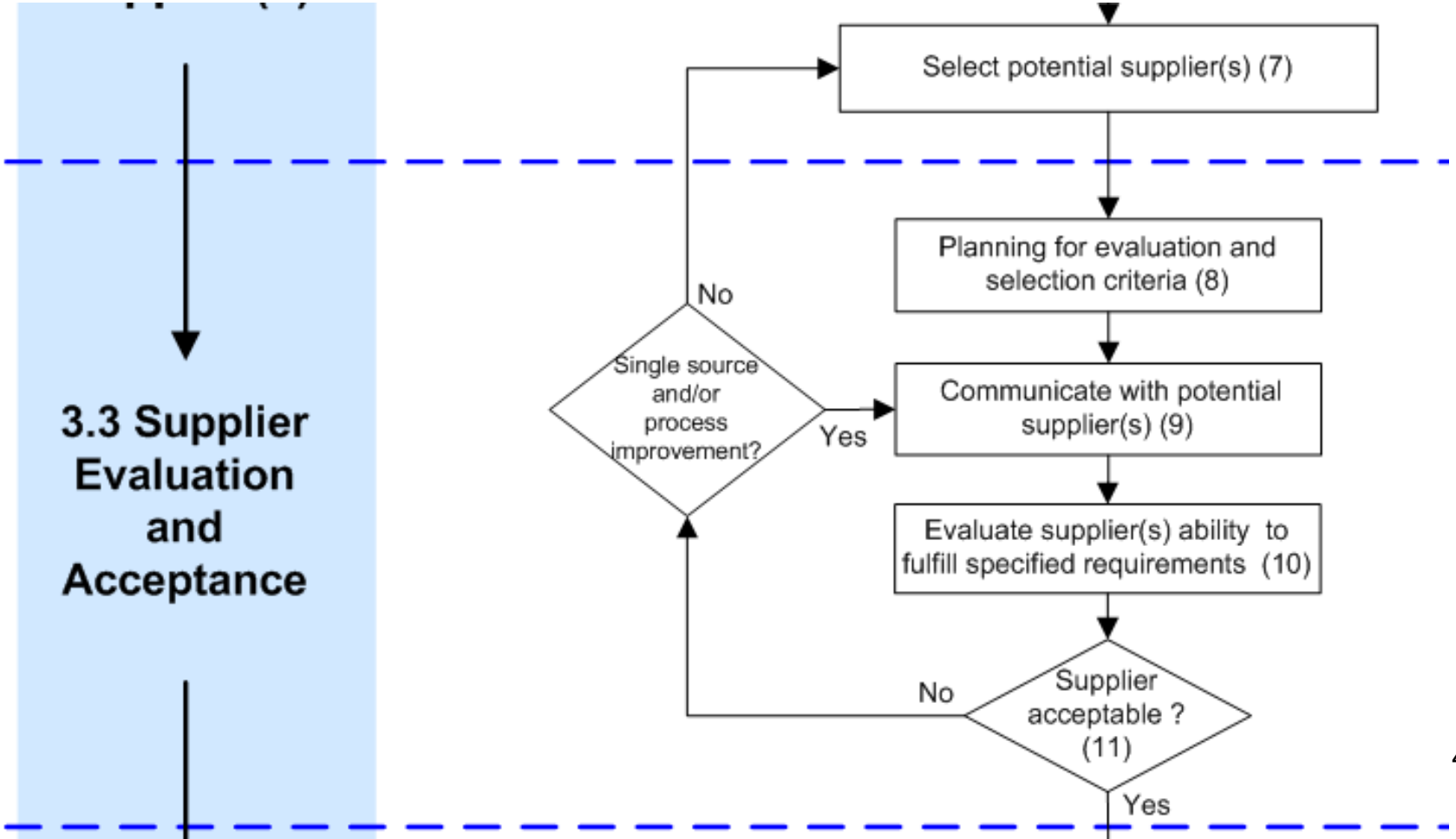
# 3.2 Selection of potential supplier(s)



# GHTF 3.2, Selection of potential suppliers, and the QS Reg.

| | |
|---|---|
| • 3.2.1, Evaluate supplier's business capability (financial viability, etc.) | • N/A |
| • 3.2.2, Evaluate supplier ability to meet operational reqt's, etc. [Objective Evidence: Supplier assessment, Procedures/records provided by the supplier] | • 820.50(a)(1), Establish and maintain reqt's, including quality reqt's, that must be met by suppliers |
| • 3.2.3, Select potential suppliers based on assessments [Objective Evidence: Supplier Documentation, selection criteria and rationale] | • 820.50(a)(1), Evaluate and select potential suppliers … |

# 3.3 Supplier evaluation and acceptance -Steps



# GHTF 3.3, Supplier evaluation and acceptance, and the QS Reg.

- 3.3.1, Define criteria for evaluation of potential suppliers
  [Objective Evidence: Evaluation/ selection criteria]
- 3.3.2, Communicate with potential suppliers, provide specified criteria to supplier
  [Objective Evidence: Initial agreements, documents and records]

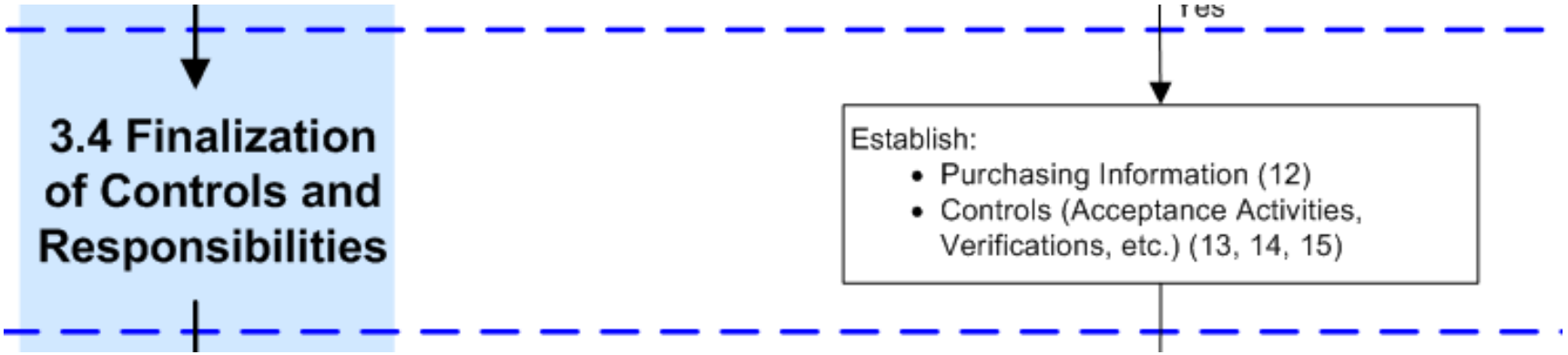
- 820.50(a)(1), Evaluate and select suppliers based on their ability to meet specified reqt's
- 820.50(b), Establish and maintain data that clearly describe or reference specified reqt's …

# GHTF 3.3, Supplier evaluation and acceptance and the QS Reg., cont.

- 3.3.3, Evaluate supplier's ability to meet selection criteria [Objective Evidence: Evaluation activity results]
- 3.3.4, Document acceptance decision for supplier [Objective Evidence: Acceptance decision]

- 820.50(a)(1), Evaluate and select potential suppliers on their ability to meet specified reqt's …
- 820.50(a)(3), Establish and maintain records of acceptable suppliers

# 3.4 Finalization of controls and responsibilities - Steps



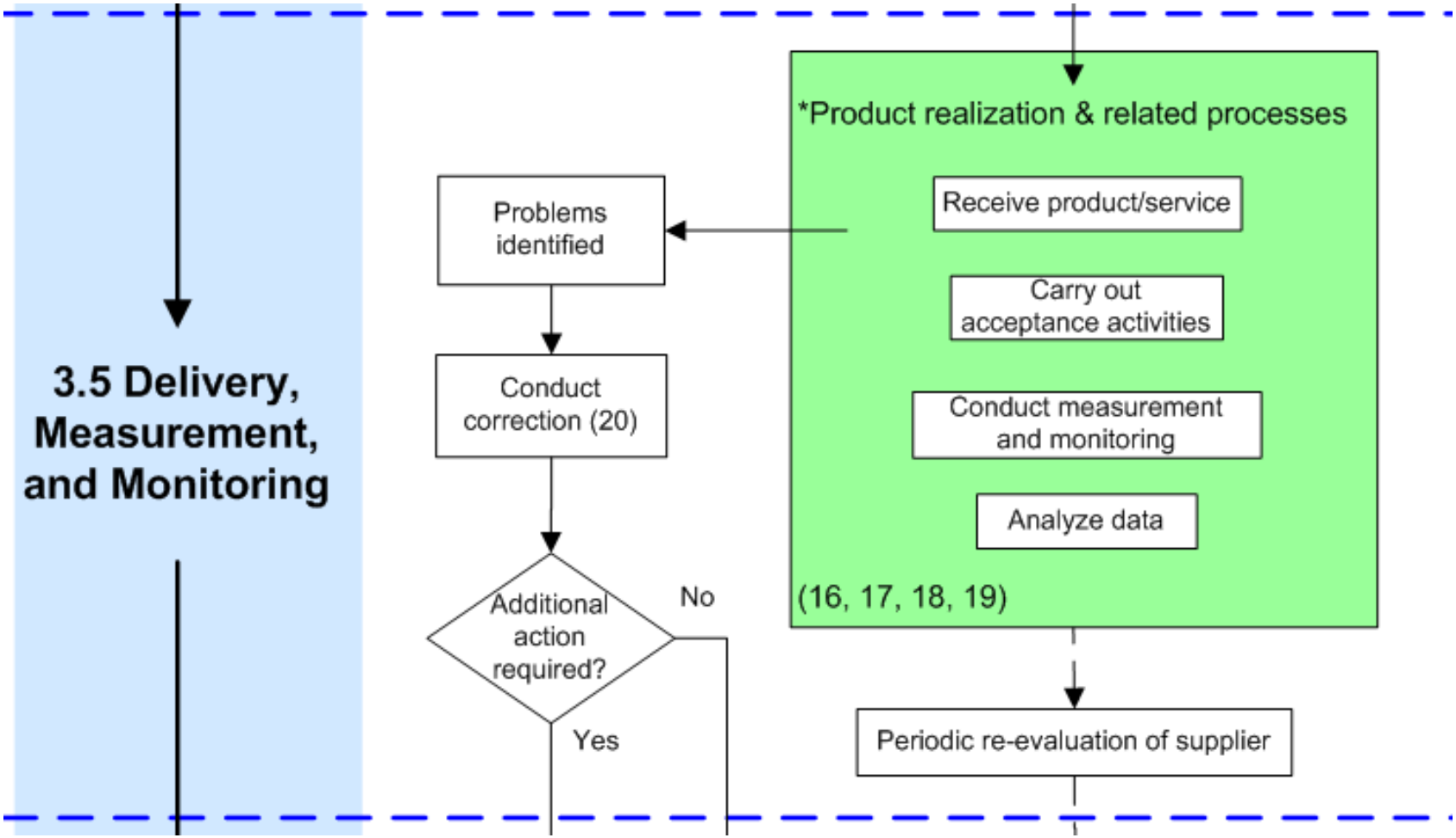
# GHTF 3.4, Finalization of controls, and the QS Reg., cont.

- 3.4, Finalize controls agreed upon by supplier and manufacturer
  [Objective Evidence: Contract/Purchase Order, Acceptance procedures, Specs and reqt's, Records of review and acceptance]

- 820.50(b), Establish and maintain data that clearly describe or reference the specified requirement, including quality requirements …

  820.80(b), … Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements …

# 3.5 Delivery, measurement and monitoring - Steps



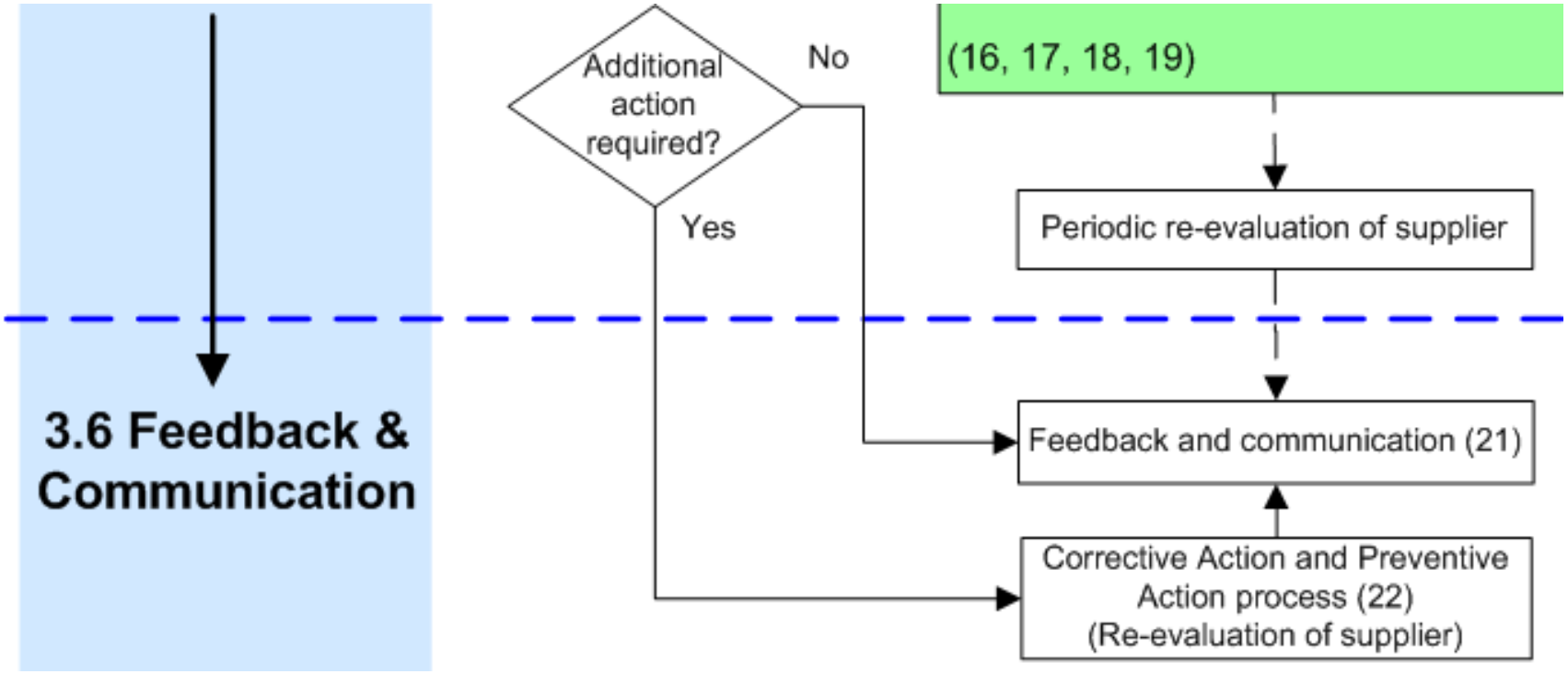
# GHTF 3.5, Delivery, measurement, & monitoring and the QS Reg., cont.

- 3.5, Products delivered, receiving activities performed, and supplier performance monitored
  [Objective Evidence: Receiving, inspection, acceptance records, Records of results of any corrections]

- 820.80(b), … Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements … Acceptance or rejection shall be documented

  820.90, … Control product that does not conform to specified requirements … Notification of the persons or organizations responsible … Define responsibility for review and authority for disposition …

# 3.6 Feedback and communication - Steps



# GHTF 3.6, Feedback and communication, and the QS Reg.

- 3.6, Provisions in place to inform supplier whether expectations are being met and to handle corrections and corrective actions.
  [Objective Evidence: Manufacturer/ Supplier correspondence, Documentation of corrective action and preventive action process.]

- 820.50(a)(2), … Define type and extent of control to be exercised …

  820.100, … Identify existing and potential causes of nonconforming product … Identifying the action(s) needed to correct and prevent recurrence … Verifying corrective and preventive action … Ensuring that information … is disseminated to those directly responsible .

# References

- 21 CFR Part 820
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=820
- Preamble to the QS Regulation Final Rule
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/UCM122806.pdf
- Compliance Program (7382.845) – Inspection of Medical Device Manufacturers
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm
- Quality System Inspection Technique (QSIT)
  - http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm
- "Quality System Information for Certain Premarket Application Reviews: Guidance for Industry and FDA Staff" 2003
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070897.htm
- 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

# Questions?

Thank you!