A Basic Model
The GHTF Model
FDA QSR Requirements
ISO 13485:2016 Requirements
QSIT Inspection Tasks
MDSAP Audit Tasks

Supplier Management Models

A Basic Model

Evaluation and Selection

A Supplier provides a product or a service

Evaluation And Selection

Identify the supplier requirements

Identify potential suppliers

Evaluate them on the ability to meet requirements

Select a supplier

Define controls for the selected supplier

Requirements

A Supplier provides a product or a service

Requirements

Document requirements for the product or service
Product or service requirements
Quality requirements
Change requirements

Control the requirements document
Document number and revision

Refer to the requirements document on orders

Acceptance

A Supplier provides a product or a service

Acceptance

Establish a method to determine conformance to requirements

Conduct incoming verification for products
Document the methods
Create forms to generate verification records

Ensure any sampling plans are valid and statistically correct

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Reevaluation

A Supplier provides a product or a service

Reevaluation

Maintain records of the selected supplier

Develop information on the supplier's performance
>   On-time delivery
>   Acceptance rate
>   Corrective action response

Establish a method re-evaluate performance

Maintain records of the reevaluation and the resulting conclusion

Special Cases

- Most supplier management models refer to first-tier suppliers
  - A first-tier supplier receives your purchase order for products or services
  - The purchase order includes the requirements

- There are some special cases to consider
  - Lower tier suppliers
  - Directed procurement

The Supply Chain

We tend to think of the supply chain as linear.

It is more like a web, often 1st tier suppliers may share a 2nd or 3rd tier supplier in common.

Sub-tier Processes

- One of your sub-tier suppliers may perform a critical process in your product.

- A 1st tier supplier provides a sterile component for your finished device.

- The 1st tier supplier uses a contract sterilizer.

- The regulators will hold you responsible for the sterility of a device you market
  - You may never place a PO with the contract sterilizer
  - You may not even know the company's name

Directed Procurement

- You contract with a 1st tier supplier for a component.

- You direct the 1st tier supplier to purchase a certain item from a 3rd party. Perhaps you qualified the 3rd party's material.
  - Example: Your 1st tier supply builds a power supply for your device. You qualified a power transformer manufacturer and direct the procurement

- The risk is lack of visibility. You qualified the supplier and the part, but you never place a purchase order with them

The GHTF Model

GHTF/SG3/N17:2008

Guidance on the control of products and services obtained from suppliers.   GHTF/SG3/N17R9:2008
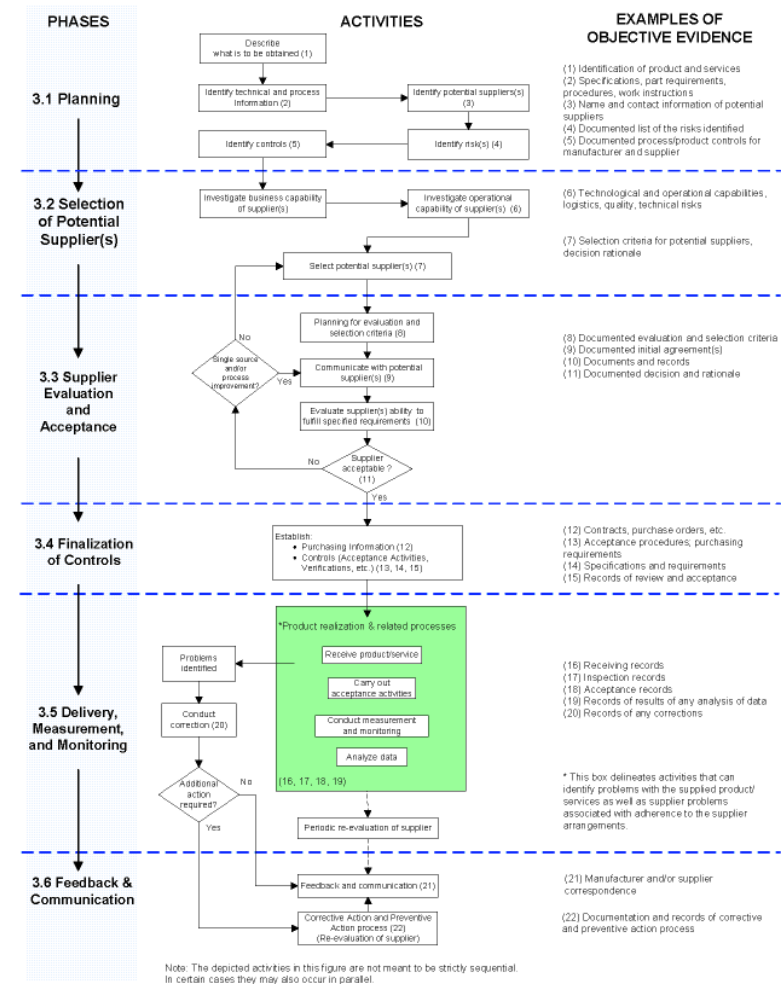
Figure 1

The GHTF model has:
6 Phases
22 Activities

GHTF guidance documents are available at www.imdrf.org

The Major Divisions

Basic Model

GHTF Phases

Evaluation and Selection	Planning
	Selection of Potential Suppliers
	Supplier Evaluation & Acceptance
Purchasing Data	Finalization of Controls
Acceptance Activities	Delivery, Measurement, & Monitoring
Reevaluation	
	Feedback and Communication

FDA QSR Activities

Classification

- §820.50 uses a three attribute classification system

Provider	**Received From**	**Type**
Supplier Contractor Consultant	Purchased Otherwise Received	Product Service

- These twelve possible combinations tell us that one only one selection methodology may not be adequate

- The specific details need to be tailored to the specific application
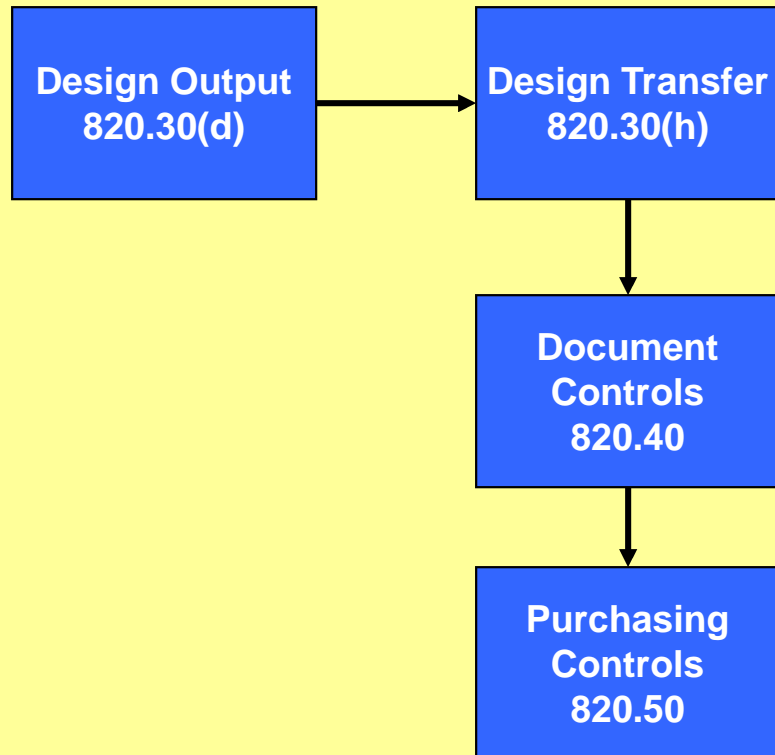
Evaluation and Selection

- Establish and maintain requirements for suppliers, contractors, and consultants [§820.50(a)]

- Evaluate potential suppliers, contractors, or consultants on the ability to meet the requirements [§820.50(a)(1)]
    - Document the evaluation [§820.50(a)(1)]

- Select a supplier, contractor, or consultant on the ability to meet the requirements [§820.50(a)(1)]

- Define the type and extent of control over suppliers, contractors, and consultants based on the evaluation results [§820.50(a)(2)]
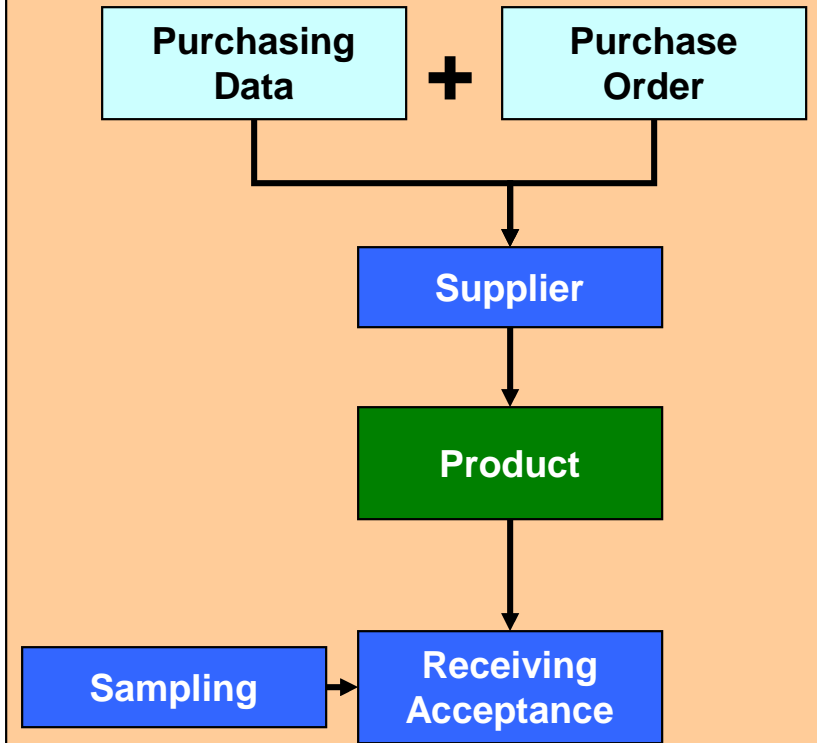
Requirements

- Establish and maintain purchasing data that describes the requirements, including quality requirements, for products and services [§820.50(b)]

- Include, where possible, an agreement to notify the manufacturer of changes in the product or service [§820.50(b)]
  - The manufacturer determines whether the changes affect the quality of a finished device

- Approve the purchasing data in accordance with §820.40 Document Control [§820.50(b)]
  - The requirement is for approval of the purchasing data … on the purchasing document used to purchase a product or service. Thus, each manufacturer must review and approve the purchasing data before release of the data. Approval of each purchasing transaction is not required. [Preamble #113]

The Purchasing Data Flow

Purchasing Data

Design Output 820.30(d) → Design Transfer 820.30(h)

Design Transfer 820.30(h) → Document Controls 820.40

Document Controls 820.40 → Purchasing Controls 820.50

PO Flow

Purchasing Data **+** Purchase Order

Purchasing Data + Purchase Order → Supplier

Supplier → Product

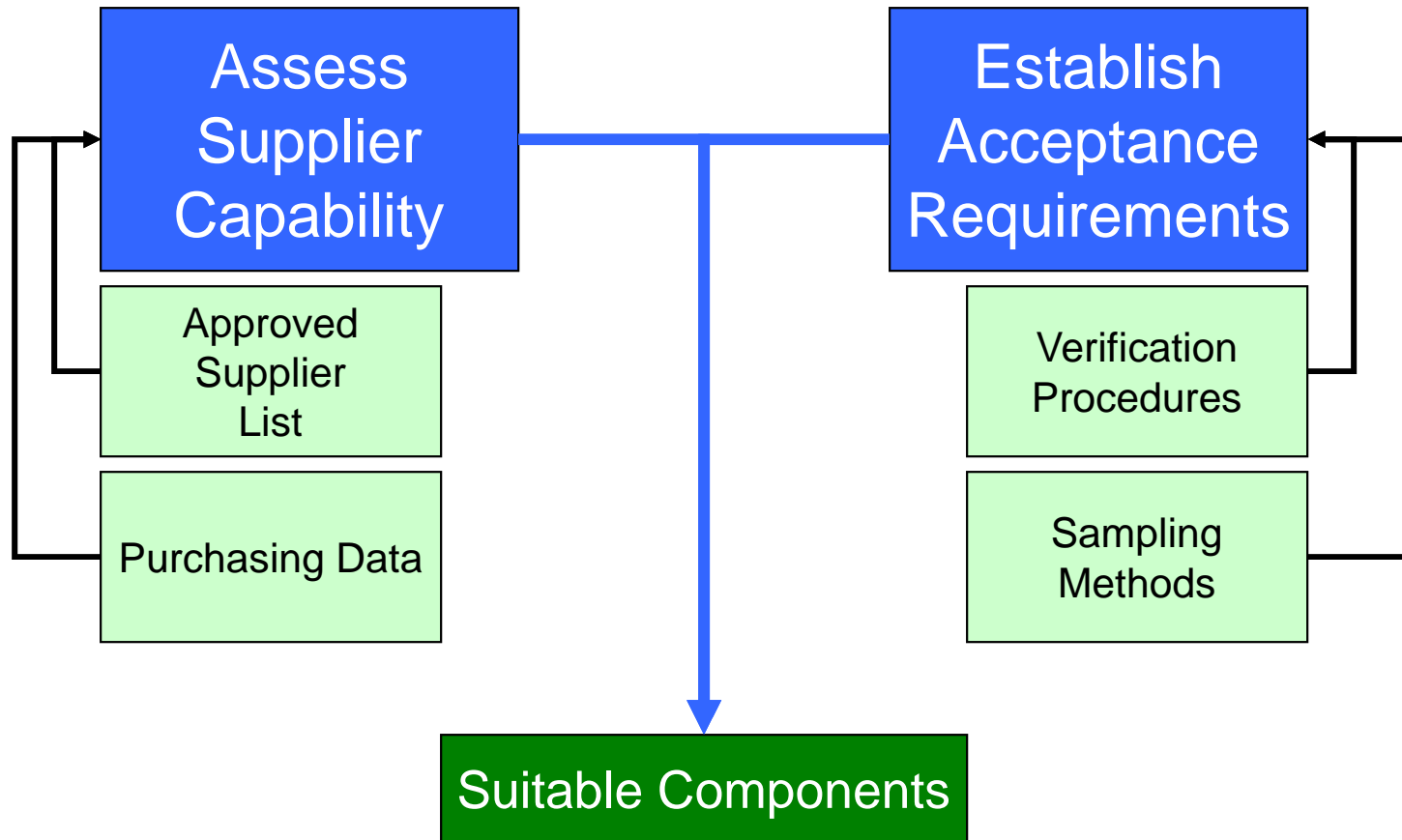Product → Receiving Acceptance

Sampling → Receiving Acceptance

Acceptance

- Establish and maintain procedures for acceptance activities including inspections, tests, or other verification [§820.80(a)]

- Inspect, test, or otherwise verify incoming product [§820.80(b)]

- Document the acceptance or rejection of incoming product [§820.80(b)]

- Document acceptance activities including specified data elements [§820.80(e)]

- Use written sampling plans, based on valid statistical rationale, and adequate for their intended use [§820.250(b)]

- Document sampling activities [§820.250(b)]

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Assuring Suitable Components

Assess Supplier Capability

Establish Acceptance Requirements

Approved Supplier List

Purchasing Data

Verification Procedures

Sampling Methods

Suitable Components

Reevaluation

- FDA QSR does not have an explicit requirement for reevaluation

- However, §820.50(a)(3) requires records of acceptable suppliers, contractors, and consultants

- The implicit requirement recognizes that acceptability could change over time

- A supplier initially evaluated and selected could exhibit deteriorating performance

- Reevaluation detects the potential problem

ISO 13485:2016 Activities

Supplier Management Models

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Definitions

- *Supplier* means an organization that provides a product or a service [ISO 9000:2015, 3.2.5]

- *External Supplier* means a supplier that is not part of the organization [ISO 9000:2015, 3.2.6]

- *Product* means the result of a process [ISO 13485:2016, 3.15]
  - Product includes services, software, hardware, or processed materials

- *Purchased Product* means a product provided by a party outside the organization's quality management system [ISO 13485:2016, 3.16]

Evaluation and Selection

- Establish criteria for supplier evaluation [ISO 13485:2016, 7.4.1]
  - Base the criteria:
  - on the supplier's ability to supply product that meets the organization's requirements
  - on the supplier's performance
  - the purchase product's effect on the quality of the medical device
  - On the risk associated with the medical device

- Record the supplier evaluation results [ISO 13485:2016, 7.4.1]

Evaluation and <u>Selection</u>

- Establish criteria for supplier <u>selection</u> [ISO 13485:2016, 7.4.1]
    - Base the criteria:
    - on the supplier's ability to supply product that meets the organization's requirements
    - on the supplier's performance
    - the purchase product's effect on the quality of the medical device
    - On the risk associated with the medical device

- Record the supplier <u>selection</u> results [ISO 13485:2016, 7.4.1]

Requirements

- Purchasing information describes or references the product to purchase [ISO 13485:2016, 7.4.2]

- Purchasing information includes, as appropriate:
  - product specifications
  - requirements for product acceptance, procedures, processes, or equipment
  - requirements for the qualification of supplier personnel
  - requirements for the QMS

- Purchasing information includes, as applicable, a written agreement that the supplier notifies the organization of purchased product changes that affect the ability to meet requirements before implementing the changes. [ISO 13485:2016, 7.4.2]

- Ensure the purchase requirements are adequate before communicating them to the supplier. [ISO 13485:2016, 7.4.2]
  - This not require document control

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Requirements – Outsourced Processes

- Monitor and control outsourced processes that affect product conformity [ISO 13485:2016, 4.1.5]

- The controls are proportional to the risks and the external party's ability to meet the requirements in 7.4 Purchasing [ISO 13485:2016, 4.1.5]

- The organization retains responsibility for outsourced process as required by ISO 13485:2016, customer requirements, and applicable regulatory requirements [ISO 13485:2016, 4.1.5]

- The outsourced process controls include written quality agreements [ISO 13485:2016, 4.1.5]

Acceptance

- Establish and implement inspection, or other activities, to ensure the purchased product meets requirements. [ISO 13485:2016, 7.4.3]

- Base the extent of verification activities on the supplier evaluation results. [ISO 13485:2016, 7.4.3]

- The extent of verification activities is proportionate to the risk associated with the purchased product. [ISO 13485:2016, 7.4.3]

- Plan and implement monitoring and measurement to demonstrate product conformity including statistical techniques and the extent of their use [ISO 13485:2016, 8.1]

Acceptance – Change

- Purchasing information includes, as applicable, a written agreement that the supplier notifies the organization of purchased product changes that affect the ability to meet requirements before implementing the changes. [ISO 13485:2016, 7.4.2]

- When learning of a change to a purchased product, determine whether the change affects the product realization process. [ISO 13485:2016, 7.4.3]

- When learning of a change to a purchased product, determine whether the change affects the medical device. [ISO 13485:2016, 7.4.3]

Reevaluation

- Plan supplier monitoring [ISO 13485:2016, 7.4.1]
  - Monitor supplier performance in meeting purchased product requirements
  - Record the results of supplier monitoring
  - Record any necessary actions resulting from supplier monitoring

- Plan supplier re-evaluation [ISO 13485:2016, 7.4.1]
  - Use the supplier monitoring results as an input to supplier re-evaluation
  - Record the results of supplier re-evaluation
  - Record any necessary actions resulting from supplier re-evaluation

- Address non-fulfillment of purchasing requirements with the supplier
  - The method of addressing supplier non-fulfillment of purchasing requirements is proportionate to the risk associated with the purchased product

QSIT Inspection Tasks

Production and Process Controls

- 1. Select a process for review

- 2. Review the specific procedures for the manufacturing process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored

  – This verification must include a review of the purchasing controls and receiving acceptance activities regarding at least one component or raw material (preferably determined essential for the proper functioning of the device)

Production and Process Controls

- 1. Select a process for review
- 5. If the process is software controlled, confirm that the software was validated
  - An important linkage to consider at this point is Material Controls (§820.50 Purchasing Controls). For example, for software developed elsewhere, confirm that appropriate software and quality requirements were established and provided to the vendor and that purchasing data (and validation results) support that the requirements were met.

Sterilization Process Controls

- 2. Review the specific procedures for the sterilization process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored.

  – Your evaluation must also include a review of the firm's purchasing controls and receiving acceptance activities regarding at least one component, material or service. Examples include: the sterilant, sterilization indicators, and services provided by contract sterilizers or contract laboratories.

Sterilization Process Controls

- 4. If the sterilization process is software controlled, confirm that the software was validated

  - An important linkage to consider at this point is Material Controls (§820.50 Purchasing Controls). For example, for software developed elsewhere, confirm that appropriate software and quality requirements were established and provided to the vendor and that purchasing data (and validation results) support that the requirements were met.

MDSAP Inspection Tasks

Supplier Management Models

Purchasing Process

- The MDSAP Audit Model covers seven processes, including purchasing

- Purpose:
  - Verify that the processes ensure the products conform with the specified purchase requirements

- Outcomes:
  - There are defined, documented, and implemented procedures for purchasing
  - There are criteria for evaluation, selection, and re-evaluation of suppliers
  - Supplier have been appropriately evaluated and selected
  - Re-evaluation determines continued supplier suitability
  - Appropriate controls are determined and implemented

Purchasing Audit Tasks

- Verify that planning activities identify products and processes
  - §820.20, §820.50, 4.1.2, 4.1.3, 4.1.5, 7.1, 7.4.1, 7.4.2, 7.4.3
- Select one or more supplier evaluation files to audit
- Verify established and documented procedures for conformance of purchased product
  - §820.50, 7.4.1
- Verify established criteria for supplier selection, evaluation, and re-evaluation
  - §820.50, 7.4.1
- Verify suppliers are selected based on their ability to meet requirements
  - §820.50(a), 4.2.1, 7.1, 7.4.1
- Verify effective controls over suppliers and product
  - §820.50(a), 7.4.1

Purchasing Audit Tasks

- Verify that supplier re-evaluation is performed at intervals consistent with the significance of the product on the finished device
  - §820.50(a), 7.4.1
- Verify that purchase requirements are adequate before going to the supplier and include product change notification
  - §820.50(b), 4.2.1, 7.4.1
- Verify documented purchasing information includes, where appropriate, approval of product, procedures, processes, equipment, qualification of personnel, and sterilization services. Verify consistency with traceability.
  - §820.50(b), §820.65, §820.160, 7.4.2, 7.5.9
- Verify that purchased product verification activities are adequate and produce records
  - §820.50, §820.80(b), 4.2.1, 7.1, 7.4.3
- Verify the data is a source of quality data for measurement, analysis, and improvement
  - §820.100, 8.4

Supplier Management Models

Nonconformance Grading

- Impact
  - Clauses 4.1 through 6.3 enable the QMS and have <u>indirect</u> influence on safety and performance
  - Clause 6.4 through 8.5 have <u>direct</u> influence on safety and performance
  - Impact is judged at the X.X clause of the standard
- Occurrence
  - <u>First</u> means not observed in the two previous QMS audits that evaluated the same sub-clause
  - <u>Repeat</u> means observed in either of the two previous QMS audits that evaluated the same sub-clause
  - Occurrence is judged at the X.X.X clause of the standard

	First	Repeat
Indirect	1	2
Direct	3	4

Supplier Management Models

Nonconformance Grading

- Grade Escalation
  - Add 1 point to the grade for each of:
    - Absence of a documented process or procedure
    - Release of a nonconforming medical device
  - The maximum grade is 5

- Action
  - For a grade 4 or 5, the manufacturer provides correction and corrective action plans to the AO within 30 days
  - For one or more grade 5, more than two grade 4, a public health threat, any fraudulent activity, or a counterfeit product, the AO informs the Regulatory Authorities within 5 working days

Exercise

- This exercise provides an opportunity to grade nonconformances using the MDSAP grading system