Supplier Quality Agreements

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Outline

- QSR Requirements for Purchasing
- Supplier Quality Agreement
  - Administrative Elements
  - Compliance
  - Manufacturing, Packaging, and Labeling
  - Documentation and Records
  - Storage and Shipment
  - Change Control
  - Non-Conformance, CAPA, and Complaints
  - Auditing
- Summary and Conclusions
- Questions

QSR Requirements for Purchasing

Regulations and Preamble

- The Regulations
  - Supplier management is found in 21 CFR §820.50, Purchasing Controls
  - We will examine the regulations in detail and extract the structure

- The Preamble
  - When FDA issued the regulations, they offered comments to help explain their thinking.
  - The comments are in the preamble, and each comment has a number. We look at some of the comments to illuminate the regulation.
  - The preamble and regulation were published in the Federal Register: October 7, 1996 (Volume 61, Number 195), Pages 52601-52662.

21 CFR 820.50
Purchasing Controls

Purchasing Controls

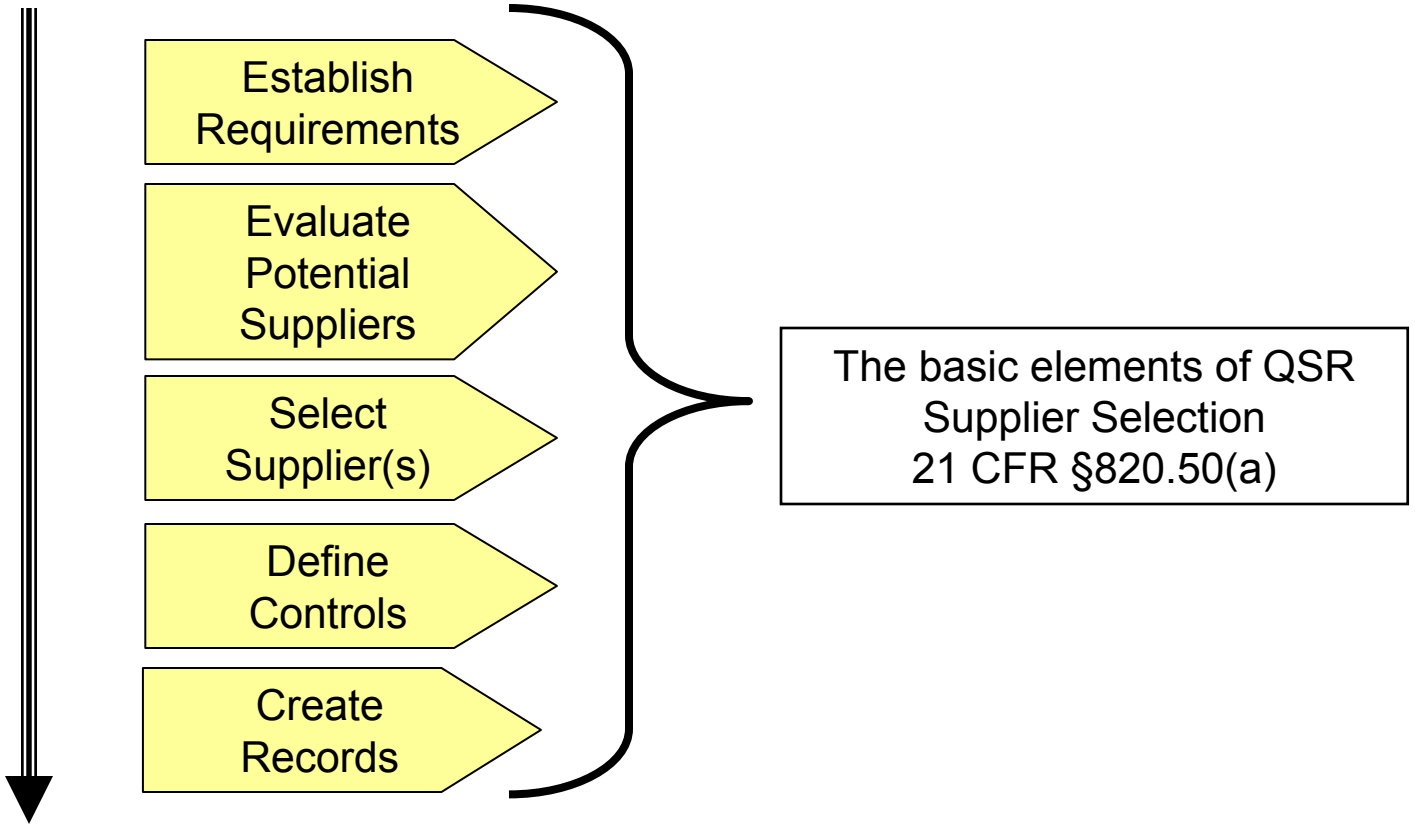
Requirement 820.50
Each manufacturer shall ESTABLISH and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

Preamble #100
[The phrase "purchased or otherwise received product and services" conveys the meaning "product and services which were purchased or processed in some manner by other organizations".] FDA emphasizes that 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 #102
First, as used in the regulation, "service" means parts of the manufacturing or quality system that are contracted to others, for example, plating of metals, testing, and sterilizing, among others. Second, FDA believes that all suppliers of such services must be assessed and evaluated, just like a supplier of a product. As always, the degree of control necessary is related to the product or service purchased.

ESTABLISH means define, document (in writing or electronically), and implement.

Supplier Selection
QSR Approach §820.50(a)



Establish Requirements

Establish Requirements

Requirement 820.50(a)
Each manufacturer shall ESTABLISH and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants

Preamble #104
[O]ver the years FDA has observed that a surprising number of firms hire consultants who have no particular expertise in the area in which the firm is seeking assistance. Section 820.50 addresses this problem by ensuring that a consultant's capability for the specific tasks for which he or she is retained be assessed and documented.

Discussion
- Establish the requirements before you start the selection process.
- The requirements you establish will form the basis for the supplier agreement.
- The requirements will be different depending on the product or service, as well as the role (supplier, contractor, or consultant).
- Unlike other QMS requirements, QSR explicitly names consultants.

ESTABLISH means define, document (in writing or electronically), and implement.

Evaluate Potential Suppliers

Evaluate Potential Suppliers

Requirement 820.50(a)(1)
Each manufacturer shall – [e]valuate … potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

Preamble #109
The term "quality requirements" means the quality control and quality assurance procedures, standards, and other requirements necessary to assure that the product or service is adequate for its intended use.

Discussion
- Identify potential suppliers, and evaluate them based on your established requirements, *i.e.,* the requirements you determined in the previous step.
- For each potential supplier, compare their capability and capacity against your requirements.
- Keep quality records of the comparison between your requirements and each potential supplier.

Select the Supplier(s)

Select Supplier(s)

Requirement 820.50(a)(1)
Each manufacturer shall – select … suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

Preamble #105
Suppliers, contractors, and consultants selected by manufacturers of medical devices should have a demonstrated capability of providing products and services that meet the requirements established by the finished device manufacturer.

Discussion
- Having evaluated potential suppliers, contractors, or consultants, you will select one to provide the required product or service. (You may select more than one, but current thinking keeps the supplier base small.)
- You will have a draft of the supplier agreement, based on your requirements, and your selected supplier should be able to meet all the requirements.
- Of course, you may not have a supplier that meets everything, but you select the best.

Define Controls

Define Controls

Requirement 820.50(a)(2)
Each manufacturer shall – [d]efine the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

Preamble #99
Under the requirements, 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.

Discussion
- You established requirements, developed a draft agreement, and evaluated potential suppliers.
- You selected the best fit to your requirements, but that doesn't mean your choice satisfied every requirement.
- You have a gap analysis, the output of the evaluation, of each supplier's ability.
- You will establish controls based on the results of your evaluation. The controls will be a combination of supplier requirements and in-house controls.

Create Records

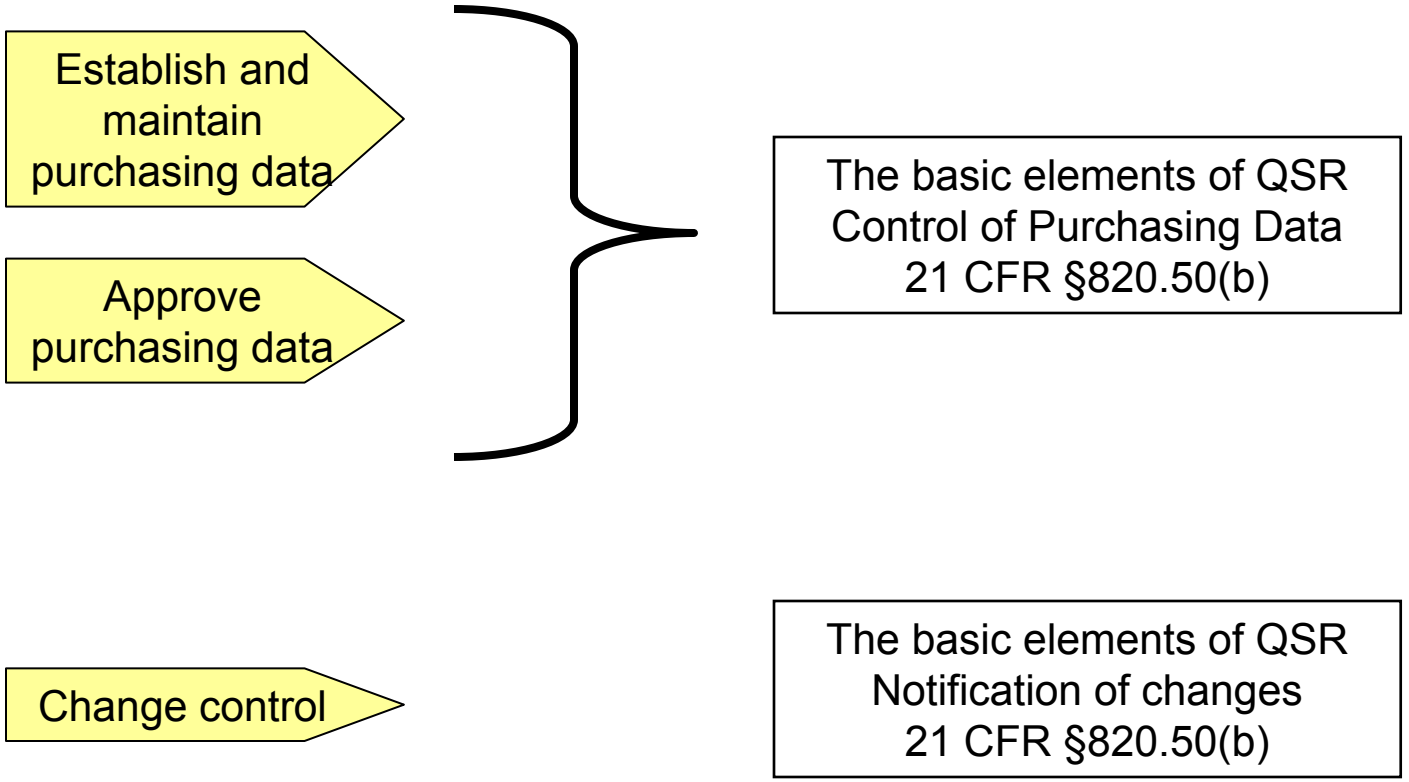
Create Records

Requirement 820.50(a)(3)
Each manufacturer shall – [E]STABLISH and maintain records of acceptable suppliers, contractors, and consultants.

Discussion
• Any activity you performed to evaluate, select, monitor, measure, *etc*. should be reflected in a record.
• Records include any supplier audits you performed. You do not have to provide supplier audit reports to the FDA (21 CFR §820.180(c)) but you may be asked to certify in writing that supplier audits were performed and documented.

ESTABLISH means define, document (in writing or electronically), and implement.

Purchasing Data
QSR Approach §820.50(b)



Establish Purchasing Data

Establish and maintain purchasing data

Requirement 820.50(b)

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.

Preamble #110

- FDA … does not believe that Sec. 820.50(b) prohibits the use of drawings or prints, assuming that the documents contain data clearly describing the product or service ordered, and that the specified requirements are met.
- Sec. 820.50(b) … requires manufacturers to establish purchasing "data". This provides manufacturers with the flexibility to use both written and electronic means to establish purchasing information.

Discussion

- You must have a document that describes or refers to the requirements for the product or service you receive.
- The information can be in any format you choose.

ESTABLISH means define, document (in writing or electronically), and implement.

Establish Purchasing Data (cont.)

Establish and maintain purchasing data

Requirement 820.50(b)

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.

Preamble #115

FDA agrees that the specifications for many [components] may be so well established that the trade name of the product may be sufficient to describe the material needed. For other materials, specific written specifications may be necessary to ensure that the desired materials are received. 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.

Discussion

The required scope and complexity of the documentation depends on the product or service. It could range from a simple specification of a trade name to a complex multi-page document defining the product or service.

Approve Purchasing Data

Approve purchasing data

Requirement 820.50(b)
Purchasing data shall be approved in accordance with 820.40.

Preamble #113
- The requirement is for approval of purchasing data or information 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.

Discussion
- 820.40 is the document control section of QSR.
- Documents must be reviewed and approved by designated individuals prior to being issued.
- Changes to documents must be reviewed and approved by designated individuals from the same function or organization that initially approved the document.

Change Control

Change control

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

Preamble #111
• FDA still believes that this change information is very important to the manufacturer, and that the manufacturer should obtain information on changes to the product or service.
• Where a supplier refuses to agree to provide such notification, depending on the product or service being purchased, it may render him an unacceptable supplier. However, where the product is in short supply and must be purchased, the manufacturer will need to heighten control in other ways.

Discussion
• When the product or service is made exclusively for you to your specifications, change control will not be an issue.
• If you purchase or otherwise receive a product or service you should include a requirement to be notified of changes.
• You must evaluate each notification to determine if it impacts the quality of the finished device. Your evaluation should produce a quality record.

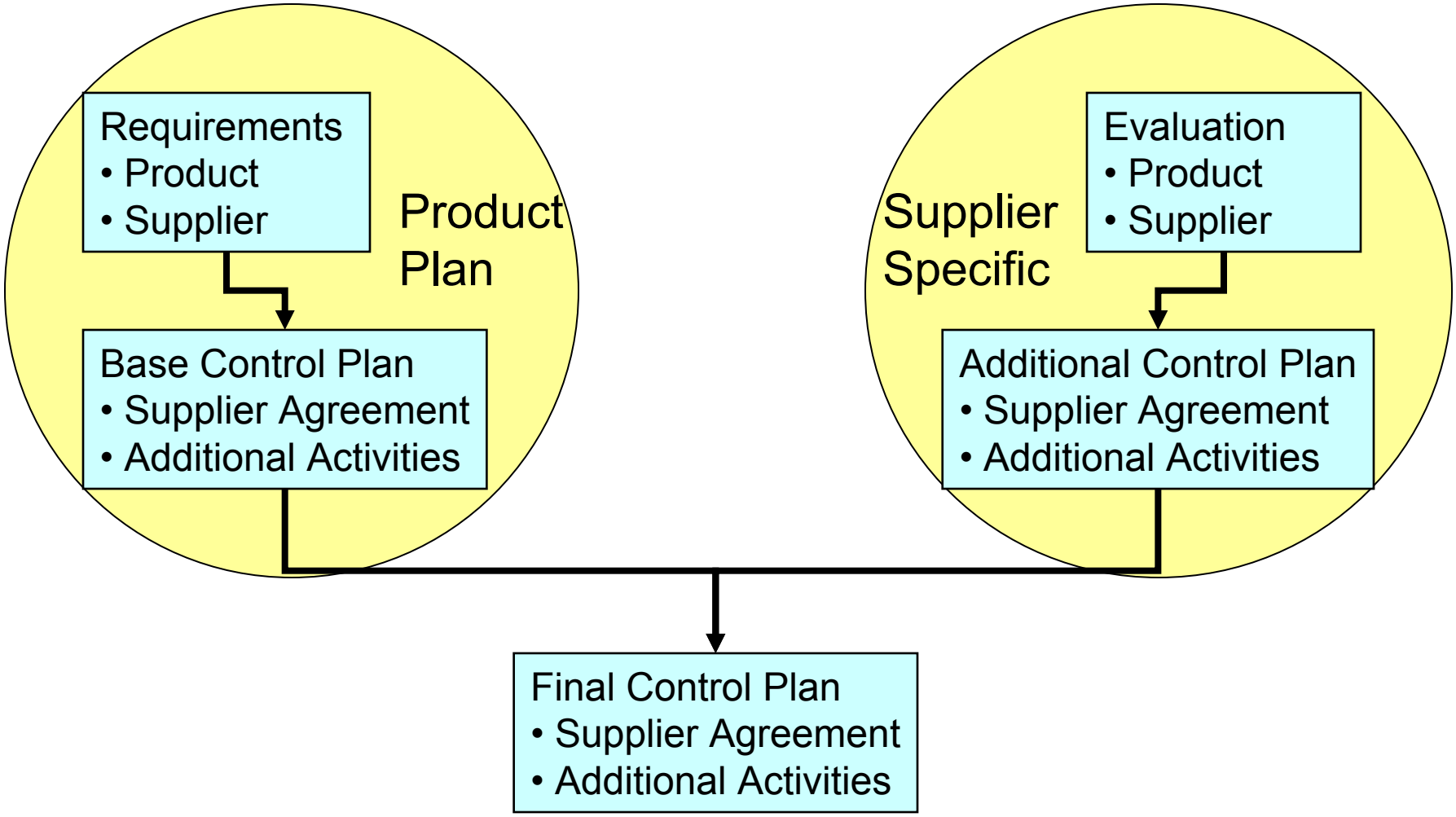
Classification

- FDA has developed a classification based on three dimensions

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

- These twelve possible combinations tell us that one generic Supplier Agreement will not be sufficient.
- Any generic agreement needs to be tailored for the specific application.

Overall Structure

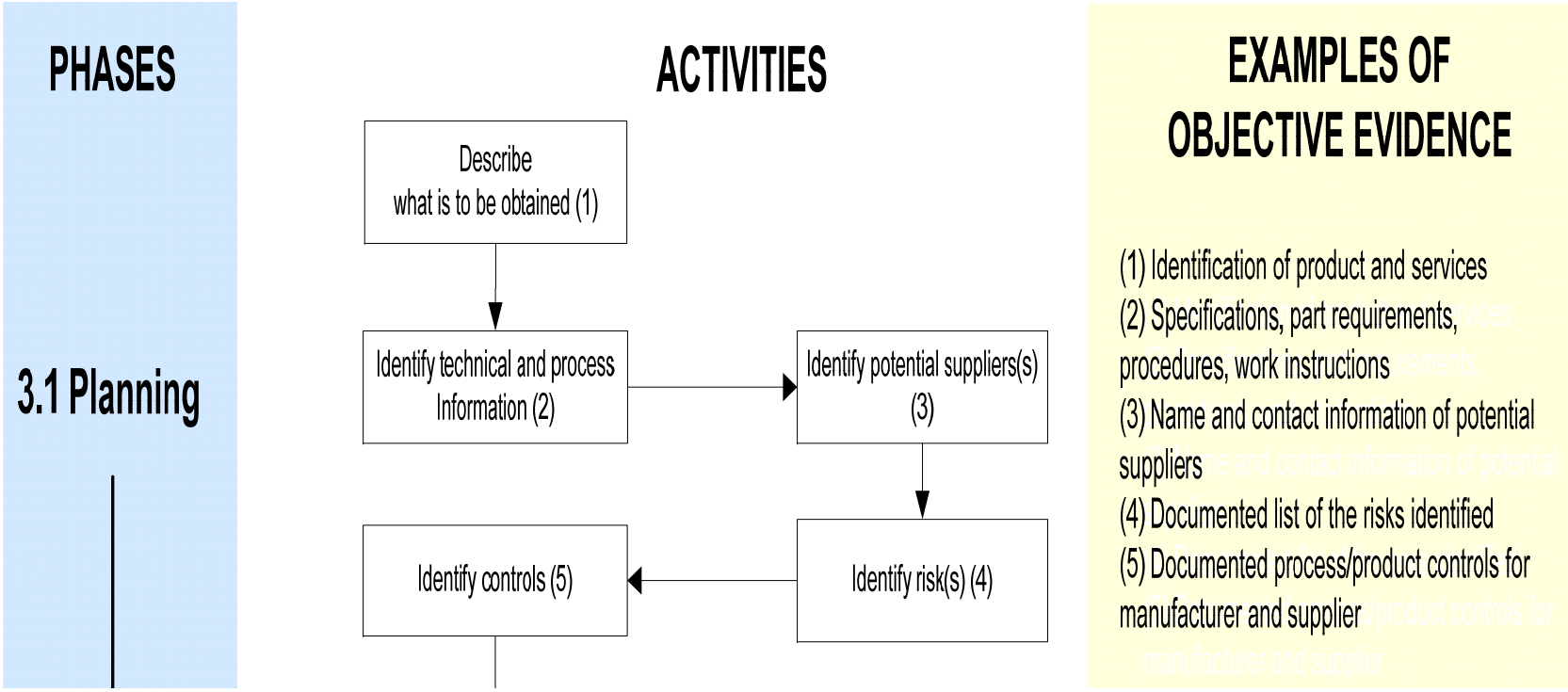


GHTF Flow Chart

Planning Phase

Planning

Guidance 3.1
Planning provides the direction for establishing the extent of controls for product and services obtained from suppliers. These plans are typically documented and approved, as part of the QMS.

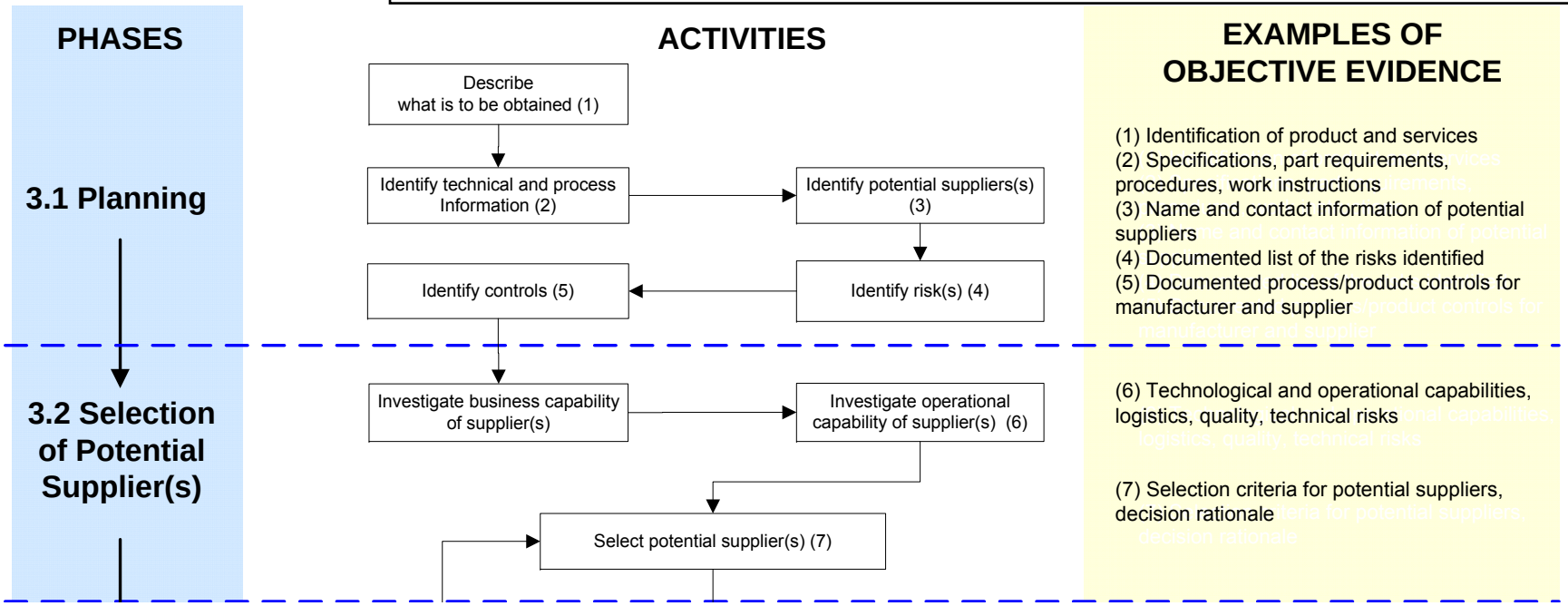


Potential Supplier Selection Phase

Selection of Potential Supplier(s)

Guidance 3.2

When selecting potential suppliers the manufacturer should investigate their business and operational capability, which may include technological capability, to ensure that the supplier can provide the necessary quality, safety, performance, and reliability of the products and services.

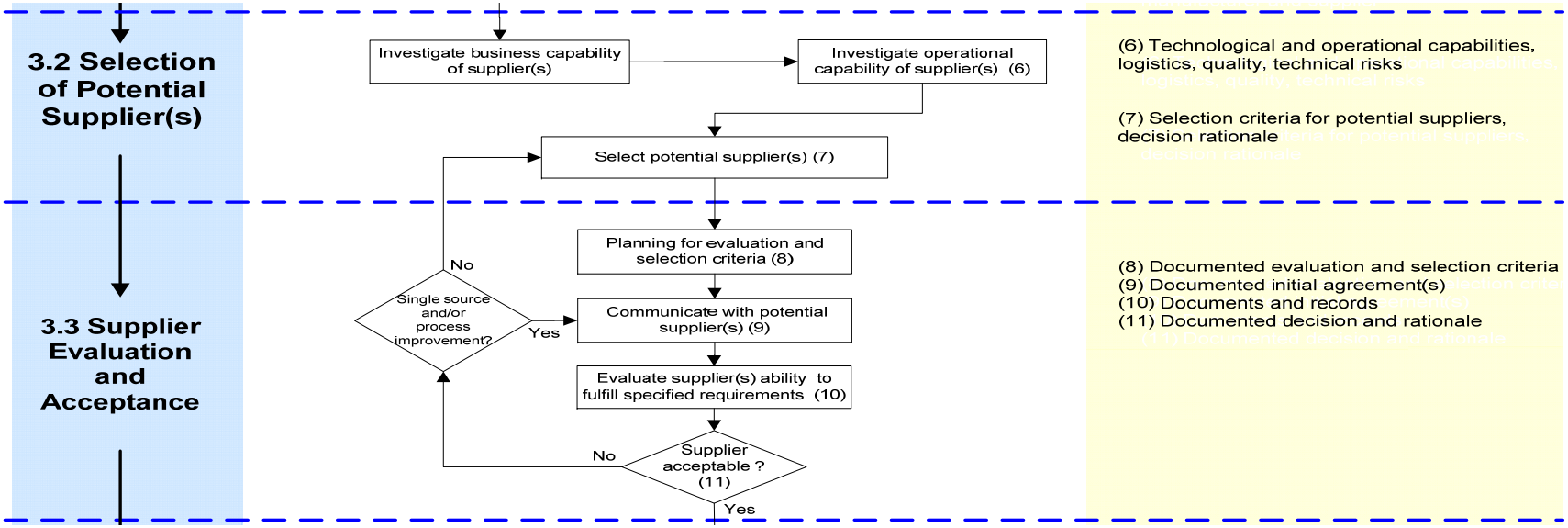


Supplier Evaluation and Acceptance Phase

Supplier Evaluation and Acceptance

Guidance 3.3

This [phase] provides guidance on the process by which the manufacturer evaluates that the selected potential supplier is actually capable of supplying product or service in accordance with the manufacturer's requirements. The extent of evaluation and acceptance activity performed should be in proportion to the identified risk of the procured product, and/or services, on the safety and effectiveness/performance of the final product.

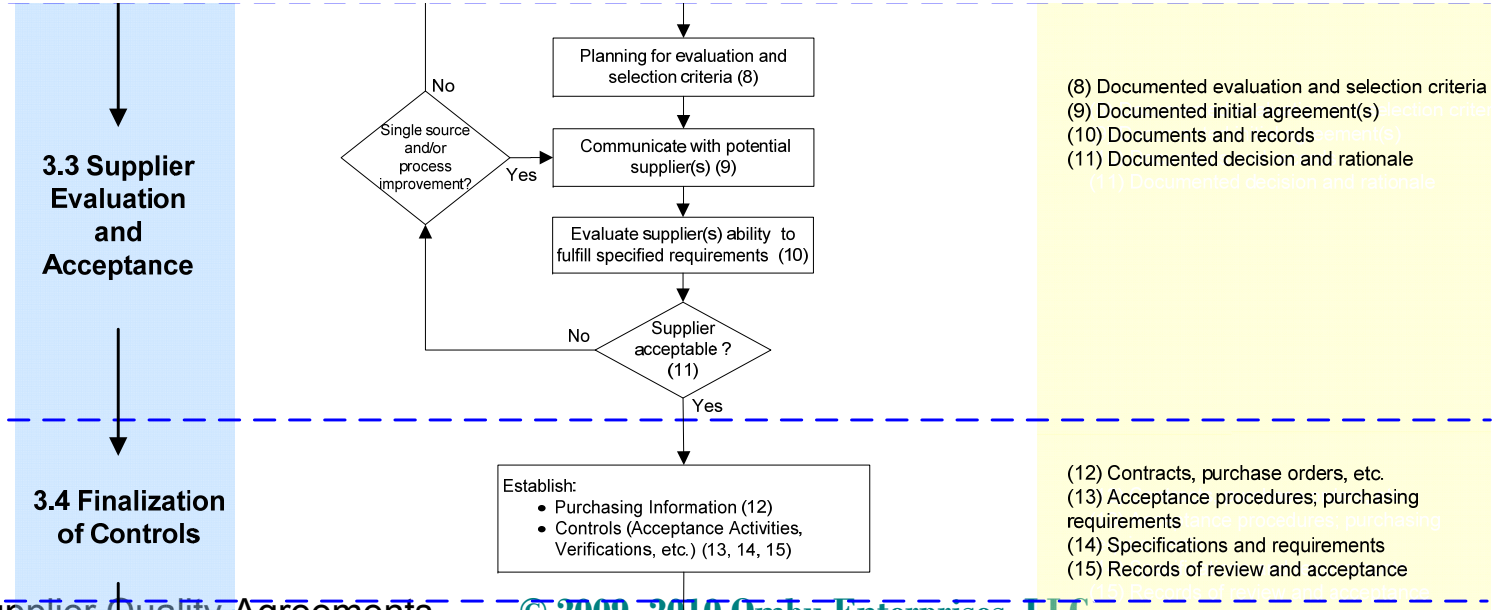


Finalization of Controls Phase

Finalization of Controls

Guidance 3.4

This section provides guidance for the finalization of the controls that are mutually agreed upon by the manufacturer and the supplier. Determining the extent and degree of controls, as well as defining clear lines of responsibilities, should be defined by the manufacturer. As a result of the supplier evaluation and acceptance, the controls need to be finalized as previously defined in the planning process.

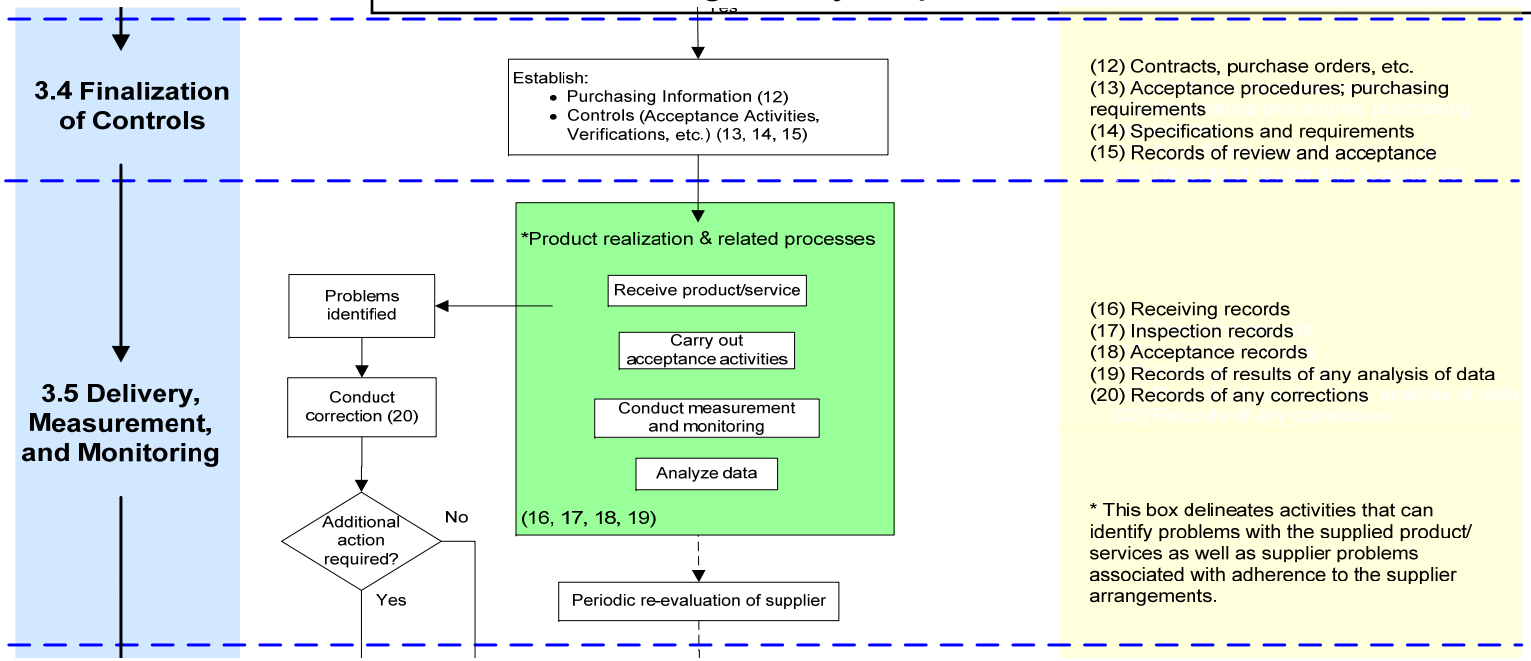


Delivery, Measurement, and Monitoring Phase

Delivery, Measurement, and Monitoring

Guidance 3.5

In this phase the accepted supplier will deliver products/service according to the agreed arrangements and these products will be used by the manufacturer in the product realization process. Within the product realization process the manufacturer will establish checkpoints to monitor the supplier's performance to ensure that customer and regulatory requirements continue to be met.

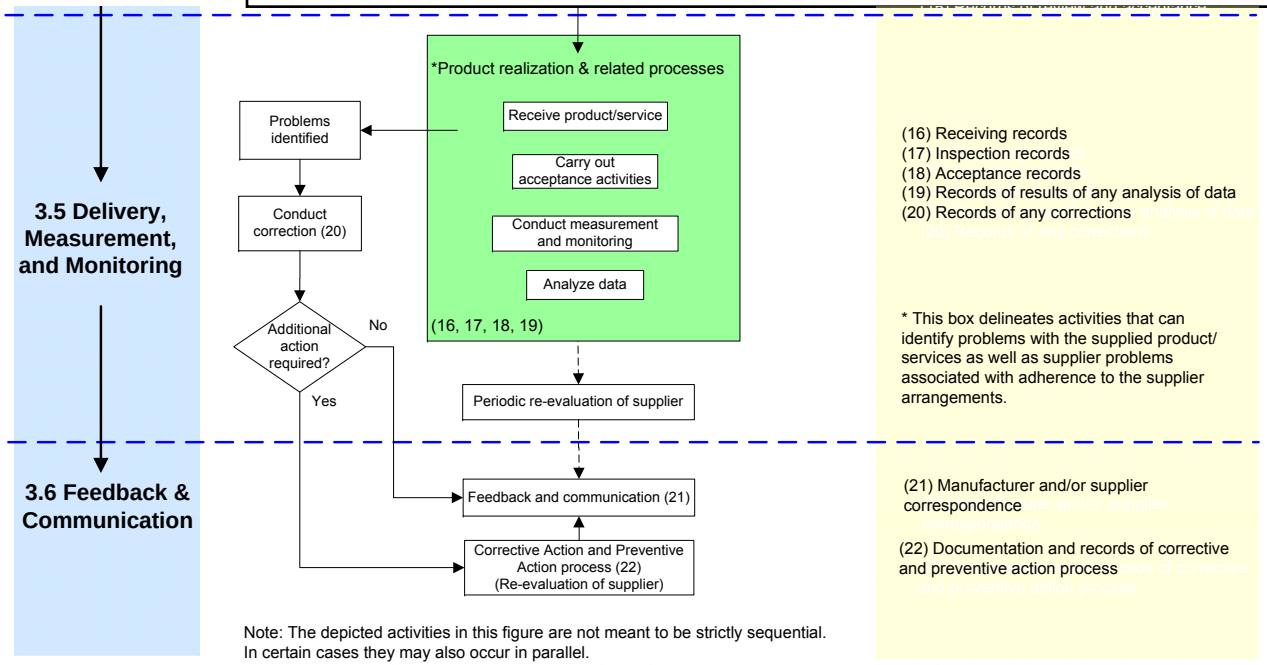


Feedback and Communication Phase

Feedback & Communication

Guidance 3.6

Provisions should be in place for the manufacturer to inform the supplier of whether the manufacturer's expectations are being met. Feedback should be both positive and negative. The manufacturer should ensure that there are effective lines of communication open to both parties to discuss problems/complaints or other matters. It is important that trust be developed between parties so that any problems can be resolved quickly in a cooperative way.



Note: The depicted activities in this figure are not meant to be strictly sequential. In certain cases they may also occur in parallel.

Supplier Quality Agreement

When Do You Need One?

- You should have a formal policy that defines the type of Product or Supplier that needs a Supplier Quality Agreement
  - Contract manufacturers and contract sterilizers clearly qualify
  - Suppliers of critical components will qualify
  - Common material purchased in large quantities often qualify (Class A Items in inventory analysis)
  - Services that don't impact your product won't apply
    - The company that stripes your parking lot could be left out

When Do Need One?

- You should complete the Base Supplier Agreement as part of requirements planning.
- When you have the short list of potential suppliers, send them a copy.
- Their response will be a major component in supplier evaluation

The Supplier Agreement

- We will review a Supplier Agreement Template
- We don't make any claim of completeness
  - In fact, you will need to add specific information based on the supplier, product, and relationship.
- We don't include the additional activities you need as part of the control plan.
  - You may ask for a Certificate of Analysis in the Supplier Agreement
  - You may send a sample to an independent lab as part of your receiving acceptance activities

Administrative Elements

Scope
Definitions
Products
QMS
Assignment

Parties
Referenced Documents
Sites
Third Parties

Scope

- A good scope statement defines both what is “in” and what is “out”.
  - It defines the boundaries of the “box”
- The “ins” and “outs”
  - Commitment and cooperation are “in”
  - Forecasting, ordering, delivery, and pricing are “out”
  - Product specifications are “out”.
- The “outs” are covered in other places, just not here.

Parties

- In this part there are two parties to the agreement, the Customer and the Supplier
  - The section on Parties identifies them by name, place of business, *etc*.

- Two issues will arise in subsequent sections
  - Where do the first two parties conduct business
  - What is the control of Third Parties who become involved

Definitions

- Define the technical terms that appear in the agreement
- Use the definitions from standards when possible
  - 21 CFR Part 820
  - ISO 9000:2005
  - ISO 13485:2003
  - ISO 14971:2007

Referenced Documents

- List the documents by number, revision, and name to completely identify them.
- In the text you can use “shorthand” to refer to them
- Possible documents include:
  - 21 CFR Part 820 Quality System Regulation
  - GHTF/SG3/N15R8 Implementation of risk management principles and activities within a Quality Management System
  - GHTF/SG3/N17:2008 Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
  - ISO 9001:2008 Quality Management Systems – Requirements
  - ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes
  - ISO 14971:2007 Medical devices – Application of risk management to medical devices

Products & Services

- List the products and services covered by the agreement
  - You could have more than one agreement with the same supplier
  - Don’t define the specifications here or even list the revision of documents
    - There are better places to do this
    - You could create a maintenance problem, forgetting to update some impacted documents

Sites Involved

- List the Suppliers and Customers site where work is performed
  - If the supplier makes the same product in multiple locations, you will want to know this
  - QMS registrations, such as 9001 and 13485, are site specific
  - Don’t forget separate distribution centers
- This list will be very important if foreign locations are involved

QMS Requirements

- The obvious choices are:
  - QSR
  - ISO 13485
  - ISO 9001

- Don't forget "QMS-like" standards
  - ISO 14971
  - Include the GHTF guidance (GHTF/SG3/N15R8) on integration risk into a QMS

Use of Third Parties

- We distinguish two kinds of third-party
  - Directed Procurement
    - The Customer directs the Supplier to use a certain supplier for a particular product or service
    - Examples:
      - The Customer has safety approval (UL, CSA, *etc*.) on a major electrical component that the Supplier will incorporate
      - The Customer has validated a sterilization processes that the Supplier will utilize
  - Supplier Selected
    - The Supplier has selected the Third Party
    - Examples:
      - The Supplier provides a power supply with an OEM line voltage transformer
      - The Supplier provides a sterile pack (using a contract sterilizer) the Customer incorporates in the final product

Third Party – Directed Procurement

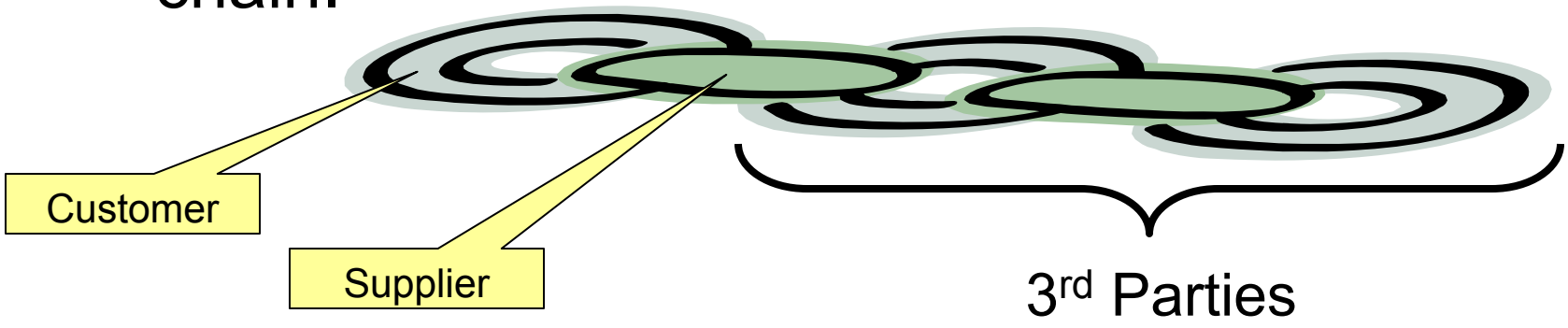
- The Customer has direct responsibility for the Third Party evaluation, selection, and performance.
  - The Customer may never write a PO to the Third Party
  - The Customer still needs to monitor and measure the Third Party Supplier's performance

Third Party – Supplier Selected

- The Supplier has direct responsibility for the Third Party evaluation, selection, and performance.
  - If the Third Party Supplier provides an important product or service the Customer should know the Supplier's identity and qualifications
  - Knowing the identity of Third Party Suppliers outside the US can be critical.

Third Party – The Generic View

- Take a broad view of Third Party
  - A Third Party Supplier is somebody in the supply chain who is neither the Customer nor the Supplier.
  - A Third Party Supplier could be in the fourth tier (starting with the customer) of the supply chain.



Terms and Assignment

- These are typical clauses
  - Terms explain the length of the agreement and the provisions for renewal and termination
  - Assignment explains that neither party can assign its rights or obligations without approval of the other party

Compliance

Specifications
Specification Changes
Activity by Regulators, Notified Bodies, or Certification Bodies
Third Party Quality Agreements

Specifications

- The Customer defines the specifications for the Supplier.
- The Supplier undertakes to fulfill them
- The Actual Specifications
  - We don't define them here
  - We don't want to create a problem with excessive change control in this document
  - As part of evaluation of the Supplier you should have offered the specifications and gained agreement

Specification Changes

- Both parties will agree to specifications changes before they go into effect
- Agreeing on the change is important
- Agreeing on the effectivity date can be critical!
  - Remember that the Apollo 13 accident was caused by failure to coordinate a change implementation from a 28 volt to a 65 volt power supply.

Regulators

- Activity by Regulatory Authorities
  - In the US regulators could include the FDA, EPA, and OSHA (and corresponding state authorities)
  - Foreign suppliers have similar regulatory authorities
  - You want to be informed if your Supplier receives a formal visit

- Activity by Notified Bodies or Certification Bodies
  - Know when the surveillance activity is scheduled
  - Obtain copies of the reports and your Supplier's response.

Third Party Quality Agreements

- The Supplier should have a Quality Agreement with the Third Party Suppliers
  - The Customer should have a Quality Agreement with Directed Procurement suppliers.

- The Customer should be able to get a copy from the Supplier on request.
  - If you get one, read it. Don't just file it for "paperwork compliance"

Manufacturing, Packaging, and Labeling

Environmental Control
Equipment
Inspection, measuring, and test equipment
Process Validation
Packaging Operations
Personnel
Automated Processes
Labeling Operations

Manufacturing, Packaging, and Labeling

- This section follows QSR
- The Template rephrases and simplifies, but leaves the essentials in place
- Not every clause in the template will apply to all cases, so this is an area to expect a lot of tailoring

Environmental Control

- Based on 820.70(c)
- Determine if environmental controls are important to the product
- Implement them and keep them effective (good working order)
- Keep records of decisions, periodic maintenance, and performance checks

Personnel

- Based on 820.70(d)
- Determine if contact between people and product could cause a problem
- If necessary, implement requirements for health, cleanliness, personnel practices, and clothing.
- Keep records of decisions, periodic maintenance, and performance checks

Equipment

- Based on 820.70(g)
- Ensure manufacturing equipment is appropriately designed, constructed, placed, and installed.
- Establish maintenance, cleaning, and adjustment schedules
- Keep records of all these checks

Automated Processes

- Based on 820.70(i) but doesn't include the requirement for quality system validation
  - Written more like ISO 13485:2003
- Validation requires a protocol and a report
- Software change also requires a protocol and a report
- Keep records of all these activities

IM&TE

- Based on 820.72
- IM&TE must be suitable where suitability includes specification for accuracy and precision
- Establish schedules for calibration, adjustment, cleaning, and other maintenance
- Calibration standards used for IM&TE shall be traceable to national or international standards
- Keep records of all these activities

Process Validation

- Based on 820.75 with two clarifications
  - Requires process validation when the process output is not fully verified by inspection or test
  - Defines “high degree of assurance” as Cpk ≥ 1.33
- Validation requires a protocol and a report
- Process change also requires a protocol and a report
- Shipments from validated processes include process documentation:
  - The date the process was operated
  - The name of the operator
  - The identity of major equipment used
  - The identity and calibration recall date of the IM&TE used in the process
  - The setting of each input process parameter

Labeling

- Based on 820.120
- Control all labeling and packaging operations to prevent labeling mix-ups
- Keep records of the activities

Packaging

- Based on 820.120
- Pack and package the product
  - using the agreed methods or best practices
  - to protect the product from deterioration or damage during processing, storage, handling, and shipment.
- Keep records of the activities

Labeling & Packaging

- Don’t forget the special labeling requirements in 21 CFR Part 801
  - For contract sterilizers, 21 CFR §801.150(e), requires a written agreement when the non-sterile device is labeled sterile and entered into interstate commerce

Documentation and Records

Device History Record

Record Retention

Device History Record

- In some cases, the DHR obligations may be split between the parties
- This section has a table that lists all the categories of records required by 820.184
- Complete the table to show the applicable records, the responsibility, and the specific records.

Record Retention

- Define the record retention period
  - Make the record retention period the longest of all applicable rules
  - For example, the FDA regulation may say 2 years, but Sarbanes-Oxley (because these records may also be financial transactions) may require 7 years.

Storage and Shipment

Storage

Shipment

Storage

- Store product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects

- Retrieve product from stock using First In, First Out (FIFO) methodology.

Shipping

- Ship products using agreed shipping methods to prevent the damage or deterioration of the product
- The Quality Agreement includes a table with the column headings:
  - Product
  - Packaging
  - Handling
  - Carrier
  - Reusable Container
- Reusable containers are an effective method for both parties to cut costs
  - Be sure you define:
  - The party that purchases the initial stock of reusable containers
  - The party that replaces missing or damaged reusable containers
  - The party who owns the reusable containers at the end of the agreement

Change Control

Change Requests

Deviations

Other Changes

Change Requests

- Change requests are “permanent” changes
  - They will change the revision of the document, drawing, specification *etc*. to which they apply
- Change requests include:
  - the specific change
  - the reason for the change
  - the benefit derived from approving the request
  - the loss incurred from disapproving the request
  - the anticipated lead time before the change is reflected in the product
- The Customer must make a decision quickly and provide the rationale for rejection

Deviations

- Deviations are “temporary” changes
  - They do not change the revision of the document, drawing, specification *etc*. to which they apply
  - They expire after a certain time, number of parts, *etc*.

Other Changes

- This implements part of 820.50(b)
- Promptly notify the Customer of changes in the product or service so the Customer may determine whether the changes may affect the quality of a finished device

Non-Conformance, CAPA, and Complaints

Disposition of Non-conforming Material
Corrective Action
Complaints
Medical Device Reports
Corrections and Removals

Disposition of Non-conforming Material

- The Supplier segregates, investigates, and dispositions nonconforming material

- Dispositions
  - The Supplier can make rework and scrap dispositions
  - The Supplier needs Customer concurrence for a repair or concession disposition

- Nonconforming material dispositions are also used to update the Risk Management file

Supplier Initiated Corrective Action

- The Supplier takes Corrective Action on Nonconforming Material, regardless of disposition

- Corrective Action includes the following steps:
  - Determining the cause(s) of nonconformity
  - Evaluate the need for action to ensure the nonconformity doesn't recur
  - Determine the action needed to prevent recurrence
  - Implement the action needed to prevent recurrence
  - Review the effectiveness of the corrective action

Customer Initiated Corrective Action

- The Customer may initiate corrective action for the Supplier when the Customer identifies a nonconformity after receipt of the Supplier's product.

- Corrective Action includes the following steps:
  - Determining the cause(s) of nonconformity
  - Evaluate the need for action to ensure the nonconformity doesn't recur
  - Determine the action needed to prevent recurrence
  - Implement the action needed to prevent recurrence
  - Review the effectiveness of the corrective action

- Include timing for response in the agreement

Supplier Received Complaints

- If the Supplier receives a complaint related to the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.

- The Customer enters the information into the complaint management system and makes an investigation decision

Customer Received Complaints

- If the Customer receives a complaint it is entered into the Customer's Complaint Management System.
- The Customer reviews and evaluates the complaint to determine whether an investigation is necessary.
- If the Supplier's product is involved in the investigation, the Customer initiates a Corrective Action Request

Medical Device Reports

- If the Supplier files a Medical Device Report for the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.

- The Supplier and Customer agree to exchange information.

Corrections and Removals

- If the Supplier files a Corrections or Removals for the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the customer.

- The Supplier and Customer agree to exchange information.

Audits

Customer Audits of Supplier Facilities

Customer Audit Findings

Auditing Third Party Suppliers

Customer Audits of Supplier Facilities

- The Supplier allows the Customer (or authorized representative) to perform audits at the Supplier's facilities.
- Audits are conducted at mutually agreed dates and times.
- The Supplier and Customer agree to protect intellectual property

Customer Audit Findings

- Customer audit findings are issued quickly (five working days)
- The Supplier prepares a plan for correction, cause, and corrective action quickly (thirty working days)

Auditing Third Party Suppliers

- The Supplier allows the Customer (or authorized representative) to perform audits at Third Party facilities.
- Audits are conducted at mutually agreed dates and times.
- The Supplier, Third Party Supplier, and Customer agree to protect intellectual property

Summary & Conclusions

Summary

- Develop a Quality Agreement with major suppliers
- The Quality Agreement should start in the requirements determination phase.
- It will be tailored in the evaluation and selection phase.
- The Quality Agreement is part of the Supplier/Product control system

Summary

- A major element in the agreement is the Quality Management System (QMS).
- Select from QSR, ISO 13485, or ISO 9001
- Include Risk Management from ISO 14971
- Use GHTF guidance documents to create a comprehensive program

Conclusions

- Define your agreements with suppliers.
- Do not leave anything to “assumptions”
- The formal agreements are important, but do not let them override communication and collaboration.

QUESTIONS