

Risk-based Supplier Qualification

FDA on “Supplier Control Determined by Product Risk”

(Silver Sheet, May 2007)

“Control should be based on the risk associated with the device”

“How have you related this to the work you did in your design and ... risk analysis that you’re required to do?”

“Controls for low-risk devices are generally less stringent than for products that are considered high risk”

More resources need to be applied to the qualification/selection of suppliers of higher risk components and devices

“Have to balance the assurances that you didn’t get through purchasing on your incoming acceptance”

FDA expects a Supplier Control System with more scrutiny applied to higher risk devices/components

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A company needs to evaluate and select suppliers based on their ability to supply products and/or services in accordance with the company's requirements.

Criteria for selection and periodic evaluation should be defined.

Results of evaluations and follow-up actions should be recorded.

Purchasing documents contain information describing the product/service to be purchased.

Where appropriate, requirements for approval or assessment of products, services, procedures, processes, equipment, personnel and management system requirements should be included.

Selection is based on variety of factors: capability, cost, location, etc. It is good to have rating system to aid in selection process.

Risk-based process approach: The higher the risk, the greater the level of control exerted. On-site audit, mail-in, no audit, etc.

Risk-based Supplier Qualification

21 CFR Part 820 FDA Quality System Requirements

Subpart E Purchasing Controls

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

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:

(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.

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

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

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820.50 Purchasing Controls. Continued

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820.50 Purchasing Controls. Continued.

820.50(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. 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. Purchasing data shall be approved in accordance with [section] 820.40. (Document controls)

Risk-based Supplier Qualification

820.80 Receiving, In-Process, and Finished Device Acceptance

820.80(a) General. Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

820.80(b) Receiving acceptance activities. Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

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820.80 Receiving, In-Process, and Finished Device Acceptance

820.80(e) Acceptance records. Each manufacturer shall document acceptance activities required by this part. These records shall include: (1) The acceptance activities performed; (2) the dates acceptance activities are performed; (3) the results; (4) the signature of the individual(s) conducting the acceptance activities; and (5) where appropriate the equipment used. These records shall be part of the DHR.

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820.80 Receiving, In-Process, and Finished Device Acceptance. Continued

820.86 Acceptance status. Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

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Purchasing Controls

FDA's expectations are:

- These requirements apply to products as well as services, across all sites, including “sister” facilities.
- Company has flexibility in the degree and types of controls.
- ISO certification is not enough.
- Follow-up corrective actions will require a re-audit.
- Certificates of Analysis must be verified.

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§820.60 and §820.65, Identification and Traceability

FDA expectations are:

- The identity of all products must be clearly discernable. This links to the requirements of 820.86, Acceptance Status.
- The traceability of components should be based upon risk assessment.
- Components used in critical devices must be traceable to the original manufacturer by lot number.
- Use of specific lots of components must be traceable to specific lots of finished devices.

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§820.80 and §820.86, Acceptance Activities

FDA expectations are:

- “Acceptance activities” rather than “inspection and testing”.
- Use components in production before approval if traced.
- Finished devices cannot be shipped before approval.
- Acceptance status can be identified by any means that will achieve the objective.

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§820.100, Corrective and Preventive Action,

FDA expectations are:

- You must conduct complete investigations with the root causes determined.
- You must perform verification or validation of corrective actions.
- Repetitive supplier problems indicate that you are conducting ineffective CAPAs.
- Consistent disposition of non-conforming product as “Use as is” is a red flag.

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ISO 13485: 2003 Quality Systems – Medical Devices Particular Requirements for the Application of ISO 9001

7.4 Purchasing

7.4.1 Purchasing process. *The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.*

The type and extent of control applied to the supplier and the purchased product shall be dependent on the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

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7.4 Purchasing – continued

7.4.2 Purchasing information.

Purchasing information shall describe the product to be purchased, including where appropriate

- a) requirements for approval of product, procedures, processes and equipment.
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).

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7.4 Purchasing - continued

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Records of the verification shall be maintained (see 4.2.4).

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Ranking Suppliers

- **Categorize or classify based on level of risk.**
 - Highest risk = least control by purchaser
 - Least risk = greatest control and/or least inherent risk

Ranking

- OEM (original equipment manufacturer) – design control
- Contract manufacturer – process control
- Critical service provider – data control
- Critical material supplier – material control
- Catalog/off the shelf material supplier
- Routine or low risk service provider
- Distributors
- Sister plant – depends on impact of service or material

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Tools of Control

- Audits
- Contracts
- Quality standards
- Material specifications
- First Article Inspection
- Pilot Service
- Quality Metrics
- Communication
- Corrective Action Feedback
- Alternative Suppliers

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Audits

A company needs to evaluate suppliers based on their ability to supply products and/or services in accordance with the company's requirements.

What standard should you audit a supplier against? ISO, FDA?

Audit types

- On-site
- Mail-in
- Mid-term assessment
- Certificate review
- No audit

Audit frequency

- Commensurate with risk and performance.
- Annual, bi-annual, tri-annual, never
- Report and follow-up: 30 days

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Contracts

- What – material, service, process change
- When - delivery
- How – method, communication, e.g. purchase order
- Who – supplier as well as purchaser responsibilities

Quality Standards

- Expectations
- Standards (QSR, ISO, IEEE, ANSI, etc.)
- Communication

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Material Specifications

- Documented specifications – based on failure mode and effects or similar risk assessment
- Prints
- Drawings
- Document control

First Article Inspection- qualified through assessment ensuring supplier has capability to meet engineering specified requirements

- Verify process capability and process control
- Measurement correlation
- Certificate of Analysis
- Certificate of Conformance

Pilot Service

- Certificate of Compliance/Conformance

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Quality Metrics - capture the effectiveness of controls and drive improvements

How should I measure my supplier?

- Quality
- Service
- Delivery
- Cost
- Compliance

Management Review

- Dashboard – quality performance, delivery performance
- Scorecard – audit score, quality score, delivery score

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Supplier Performance Communication

- Supplier Corrective Action – quality performance issues and follow-up
- Quality Score
- Communicated by Supplier Quality – Compliance impact
- Communicated by Purchasing - \$ impact
- Communicated by Management – Escalation process

Supplier Recognition

- Based on quality and delivery performance
- Annual Awards
- Letter

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Supplier Process Change Notification

- Sixty days notification is typically required for: (i) any change in a supplier's processing or handling of product, the specifications, processing, composition, formulation, part or supplier of a raw material or component comprising or included in a product, or the manufacturing processes for or performance characteristics of any product or any part thereof (including labeling, etc.); (ii) use of any nonconforming materials in the manufacturing of the product; (iii) use of any temporary or permanent deviation that affects the production (including manufacturing process), handling or sterility of the product; or (iv) implementation of any corrective or preventative action that could affect the safety or efficacy of the product.
- Changes in facility locations typically require 12 month advanced notice. This is to allow adequate time for equipment qualification by the supplier and any necessary regulatory filings.

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Corrective Action Process

- Supplier Corrective Action Request
- 30 day time frame
- Follow-up
- Align with internal corrective action & preventive action system

Develop Alternative Suppliers

- Sole supplier – partnership
- Single source
- Dual source

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Reducing Inspection

- **Routine Inspection**
 - Appropriate to the inherent risk of the material
- **Sampling**
 - Multiple receipts of same supplier lot
- **Skip Lot Testing**
 - Every other lot, 5th, 10th, etc.
- **Source Inspection**
 - Inspection by purchaser
 - Inspection by supplier

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Reducing Inspection

- **Supplied Data** – qualified and approved supplier that has submitted an agreement and consistently meets all quality and delivery requirements.
 - Lot testing and/or inspection data submitted by the supplier
 - Monitor performance
 - Audit data
- **Dock to Stock**
 - Certificate of conformance and supplied data
- **Ship to Stock**
 - Material that is received and sent directly to stock.
 - Successfully passed first article inspection and multiple supplied data deliveries per agreement.
 - Supplier labels material according to requirements

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Benefits

- Consistent, multi-tiered risk assessment based on existing engineering analysis that focuses supplier control activities on vital materials or services
- Continuous improvement in patient safety
- Reduction in supplier-related field actions
- Optimized incoming acceptance activities (effectiveness and efficiency)
- Compliance with FDA requirements

Achieve target results for improved patient safety, optimized supplier control activities, reduced inspection costs, and FDA compliance.

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Questions and Answers

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