MANAGING SUPPLIER PURCHASING CONTROL – GHTF GUIDANCE
SG3/N17:2008

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GMP ISO Experts specialize in helping organizations and suppliers with contract/consulting services listed below:

- **Retainer/Contractor/Consultant** – Provide services to customize your needs to manage Quality Systems to support CAPA, Nonconformance, Equipment and Process Validation, Risk Management, perform Gap Analysis of Quality Systems, and remediation to FDA/ISO Findings and Warning Letters

- **Quality Systems Enhancement** - Help to establish Quality Systems and enhancement from ISO 9001 to ISO 13485, 21CFR Parts 111, 211, 600, 820, and ICH Q7 to meet regulatory requirements

- **Global Supplier Performance Management** - Help to perform audits and manage global supplier performance using risk-based approach to meet regulatory requirements

- **Change Agent/Process Excellence** – Using Lean and DMAIC (Six Sigma) methodologies to streamline work processes to improve efficiencies and achieve desired results

- **Due Diligence Audit** – Support strategic mergers and acquisitions

- **Onsite Training** – Prepare site/s for regulatory audit and pre-approval regulatory inspection, ASQ Certifications, CAPA, Lean Six Sigma, Risk Management, GMP/ISO, and internal/external auditor training
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Agenda

- Increased scrutiny of suppliers
- Recent Issues with a Service Supplier
- Introduction to GHTF and Supplier Controls Guidance Document
- Comparison between GHTF and QS Regulation
- GHTF Supplier Controls General Principles
  - Planning
  - Selection of potential suppliers
  - Supplier evaluation and acceptance
  - Finalization of controls
  - Delivery, Measurement and Monitoring
  - Feedback and Communication
- Summary

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Reasons for Increased Scrutiny of Suppliers

- In an effort to reduce costs, many manufacturers began outsourcing to suppliers globally.
- An increase in failures of critical components led to global service outages, recalls and patient safety issues, catching the attention of customers, regulators and Congress.
- US acquisition of foreign companies and the purchasing of parts from companies with a different qualify system raises issues for safety and quality of the product.
FDA Warning Letter
Sept. 8, 2010 — CeraSys, Incorporated

“Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, and to maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants as required by 21 CFR 820.50(a) …”
Recent Issue with a Service Provider

- Research in Motion Canadian Telecom Giant (Blackberry)
- Issue – Nearly week-long global Blackberry outage during the week of October 10, 2011 in Europe, Africa, Asia and the Middle East
- RIM Says Global BlackBerry Outage Over, But Cause Remains Elusive

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Recent Issue with a Service Provider

- Co-CEO explained that the company was working with vendors to “correct the cause” of the switch failure.
- Let’s listen the conference call and try to catch key words.
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
Global Harmonization Task Force

- Representatives from regulatory agencies and regulated industries
- Comprised of five founding members – US, EU, Canada, Australia, and Japan
- Study Group 3 (SG3) – Quality System
  - Examines quality system requirements in countries having developed device regulatory systems and identifies areas suitable for harmonization
GHTF Guidance – Supplier Controls

- Title: Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers

Web link:

- Final Document posted on February 5, 2009
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Scope

- For the purpose of this 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.** This includes a supplier that may be part of the manufacturer’s organization but operating under a separate quality management system.
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.
Manufacturer’s Responsibility

- The manufacturer or entity that has the ultimate responsibility for its quality management system, can not 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 suppliers (internal or external) of products and services.
Suppliers That Are Already Regulated

- 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.**
Six Phases of Supplier Controls

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

- In establishing the controls, for product and services obtained from suppliers, it is expected that **planning initiates the process**.

- The output of this activity may be in the form of design and development plans, quality plans, purchasing plans etc., as defined in the manufacturer’s QMS.
Planning – Steps

**PHASES**

3.1 Planning

**ACTIVITIES**

1. Describe what is to be obtained
2. Identify technical and process information
3. Identify potential suppliers
4. Identify risk
5. Identify controls

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Planning, and the QS Regulations

- 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 …
Planning, and the QS Regulations cont’d

- 3.1.4, Identify risks associated with the product or service to be obtained
  [Objective Evidence: Risks identified]
- 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), Design validation shall include … risk analysis
- 820.30(g), and 820.50(a)/820.50(a)(2), (a) Establish and maintain the req’ts, including quality req’ts, that must be met by suppliers … (a)(2) Define the type and extent of control to be exercised

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Selection of Potential Suppliers

- 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 product and services.
Selection of Potential Suppliers

3.2 Selection of Potential Supplier(s)

Investigate business capability of supplier(s)

Investigate operational capability of supplier(s) (6)

Select potential supplier(s) (7)
Selection of Potential Suppliers

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

3.3 Supplier Evaluation and Acceptance

Select potential supplier(s) (7)

Planning for evaluation and selection criteria (8)

Communicate with potential supplier(s) (9)

Evaluate supplier(s) ability to fulfill specified requirements (10)

Single source and/or process improvement?

No

Supplier acceptable? (11)

Yes
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Supplier Evaluation and Acceptance, and the QS Regulation

- 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 req't's

- 820.50(b), Establish and maintain data that clearly describe or reference specified req't's...
Supplier Evaluation and Acceptance, and the QS Regulation cont’d.

- 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 req’ts …

- 820.50(a)(3), Establish and maintain records of acceptable suppliers
Finalization of Controls and Responsibilities

- Determining the extent and degree of controls, as well as defining clear lines of responsibilities, should be defined by the manufacturer. The controls need to be finalized as previously defined in the planning process. When risk dictates, defined controls around second and further-tier suppliers may be needed.
Finalization of Controls and Typical Considerations

- Changes to validated processes
- Complaint handling
- Root cause analysis
- Corrective action and preventive action
- Product risk management
- Design

- Labeling/traceability requirements
- Technical documentation (of the supply)
- Change control requirements
- Creation and retention of documents and records
- Supplier audits

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GHTF Phases, Activities, and Controls

**PHASES**
- Planning
- Selection of Potential Supplier(s)
- Supplier Evaluation and Acceptance
- Finalization of Controls
- Deliver, Measurement, and Monitoring
- Feedback & Communication

**ACTIVITIES**
- Describe what is to be obtained
- Identify technical and process information
- Identify controls
- Investigate business capability of supplier(s)
- Investigate operational capability of supplier(s)
- Sample sources and for process improvement?
- Communicate with potential supplier(s)
- Evaluate supplier(s) ability to fulfill specified requirements
- Supplier acceptable?
- Establish:
  - Purchasing Information
  - Controls (Acceptance Activities, Verifications, etc.)

**PRODUCT REALIZATION & RELATED PROCESSES**
- Receive product/service
- Carry out acceptance activities
- Conduct measurement and monitoring
- Analyze data
- Periodic re-evaluation of supplier

**CONTROLS**
- Supplier Assessment Form
- Quality Agreement
- Supplier Questionnaire
- Supplier Audit Report
- Supplier Scorecard
- Action Report (SCAR)
- Audit Closure Memo
- Contract Purchase Order
- Drawings
- Receiving Inspection
- Supplier Scorecard
- Supplier Corrective Action
- Re-evaluation

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

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Summary

- A robust system for supplier management helps to ensure
  - Consumer Safety
  - Compliance
  - Customer Satisfaction
  - Organizational Improvement

- The GHTF document provides guidance for medical device manufacturers on the control of products and services obtained from suppliers
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Thank you for your participation

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