Case for Quality

Internal Suppliers
- ‘Definition’ of Internal Supplier – when does an Internal Supplier exist?
- A Risk Based Approach to Internal Supplier Management
- The Role of Supplier Quality in Internal Supplier Management
Case for Quality – Internal Suppliers

Internal Suppliers – ‘Definition’ / Expectations

GHTF

GHTF/SG3/N17R9:2008 (Sec 1.0 Scope)

- For the purposes of this document, a product or service is one which is purchased or otherwise obtained by the manufacturer. In addition, 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 operates under a separate quality management system. For example, if the supplier is not a part of the manufacturer’s internal 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. Therefore, one division or group can be an internal supplier to another division or group within the same corporation/company.
- Internal suppliers are to be controlled in a similar way as external suppliers are controlled.

FDA

21 CFR 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.

FDA Preamble #100

- 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.

FDA Quality System Regulation 21 CFR 820 Basic Introduction Presentation

Case for Quality – Internal Suppliers

Considerations for interpretation of FDA ‘definition’ of Internal Supplier

1. Part of the Manufacturers Organisation
   - Is affiliated to the same corporation/corporate governance as the manufacturer.
   - Is a part of the same division or group within a corporation/company as the manufacturer.
   - Is not an ‘External Supplier’ (i.e. has no affiliation to manufacturer).

2. Operates under a Separate Quality Management System
   - Has a separate Quality Manual
   - Does not use the same QMS Standard Operating Procedures (SOPs) as the manufacturer.
   - Is not included in the same Quality Management Review (QMR) as the manufacturer.
   - QMR is not conducted with the same management representatives as the manufacturer.

3. Not part of the manufacturers Internal Audit Scope (Quality Audit)
   - Is not included in the manufacturers Internal Audit schedule/scope

**Internal Audits:**
FDA 21 CFR § 820.22 Quality audit. Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a re audit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and re audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and re audits shall be documented.

FDA Preamble #53. The requirements under § 820.22 Quality audit are for an internal audit and review of the quality system to verify compliance with the quality system regulation. The review and evaluations under § 820.22 are very focused. During the internal quality audit, the manufacturer should review all procedures to ensure adequacy and compliance with the regulation, and determine whether the procedures are being effectively implemented at all times.

FDA Preamble #160. Internal audits are valuable and necessary tools for the manufacturer to evaluate the quality system. The audit reports should be used to analyze the entire quality system and provide feedback into the system to close the feedback loop, so that corrective or preventive actions can be taken where necessary.

Additional useful references for Internal Audit requirements/expectations:
ISO13485, Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO19011, Guidelines for auditing management systems

FDA 21CFR § 820.3 Definitions:
Quality System means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
Quality Audit means a systematic, independent examination of a manufacturer’s quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
ISO 9000 Terms and Definitions:
Organization: Group of people and facilities with an arrangement of responsibilities, authorities and relationships.
Quality Management System: Management system to direct and control an organization with regard to quality.
When does an Internal supplier relationship exist and when not?

An ‘Internal Supplier’ Relationship exists where Establishments have separate QMS, QMR and Internal Audit programs. The supply relationship is in scope of Purchasing Controls regulatory requirements.

Where a shared QMS, QMR and shared audit program exists between Establishments then, No ‘Supplier’ Relationship exists - supply relationship is not in scope of Purchasing Controls regulatory requirements.

**Key Consideration**

Establishments that receive Products/Services from ‘sister’ establishments need to:

- Determine whether an Internal Supplier relationships exist and document the rationales for decision.
- Determine how Product Acceptance Activities will be managed for Products received from all ‘sister’ establishments. (required whether an Internal Supplier relationship exists or not).
- Controls and Assurances around Controls is core regardless of who and how the relationship is managed i.e. through Purchasing controls (§ 820.50 ) or Product Acceptance (§ 820.80).
- Controls should be scalable with Risk.

“Establishment” means a place of business under one management at one general physical location. 
*Source: FDA 21CFR207.3(7)*
Where an Internal Supplier Relationships exists, and Purchasing and supplier controls are required use a Risk Based Approach to Internal Supplier Management

**Supplier Management**

- Define Selection Decision (i.e. based on Internal Supplier’s ability to provide core technology/business strategy)
- Establishment of an Internal Approved Supplier Listing
- Define relationship via Agreement document detailing operating mechanism/interface
- Define Performance Management approach (if required and frequency) or as per defined shared Business review process. Consider and document approach to:
  - Metrics
  - QBR’s (if required and frequency)
  - Audits
  - SCAR or CAPA processes

**Part / Component Risks and Controls**

- Define expectations and requirements
- Manufacturers qualification (IQ/OQ/PQ) and control requirements
- Defined Acceptance Activities: E.g. Dock to stock, COC/COA, or physical incoming inspection
- Logistics – PO process, material movement controls
- Change management communications and controls

Management expectations, assurances and controls defined based on risk in an *Internal Supplier Quality Agreement Document.*

*At min. Quality Agreement approval requirements: To be signed by the Internal Establishment Quality Directors.*

Ref slide 6 Managing Internal Suppliers – Activity Ownership Matrix - Example
### Case for Quality – Internal Suppliers

**Managing Internal Suppliers – Activity Ownership Matrix - Example**

<table>
<thead>
<tr>
<th>INTERNAL SUPPLIER MANAGEMENT</th>
<th>SUPPLIER QUALITY</th>
<th>OPERATIONS QUALITY</th>
<th>OPERATIONS</th>
<th>SOURCING</th>
<th>R&amp;D/NPD/DESIGN QUALITY</th>
<th>COMPLIANCE/AUDIT FUNCTION</th>
<th>POST MARKET QUALITY</th>
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<td>Ranking of Part Criticality</td>
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Where does Supplier Quality function ‘fit’ in the management of Internal Suppliers?

What are the value add activities SQ can provide?