Supplier Quality/Purchasing Controls Successful Practices

Topic:
Risk –Based Supplier Quality Management
Definition of Risk in a Supplier Quality Context

• Supplier quality risk is defined as the probability that the supplier will not be able to consistently provide products or services that meet specifications set by the manufacturer and/or end customer (e.g., patient). This risk shall consider quality and safety impact of the supplied material on the device, as well as business risks that may impact delivery and stability of the supplier’s business, manufacturing and service infrastructure, affecting supplier’s ability to provide product.

• The objective of supplier risk management is to implement proportional and balanced controls based on quality and business risks.

• The application of a Risk Management Framework across all aspects of Supplier Quality Management using risk management principles from ISO 14971

• Outputs from this process are used to define the activities for supplier controls

• Inputs to this process are triggers from the 6 aspects of supplier quality management (GHTF), and from related QMS elements (i.e., CAPA, Design Controls, P& PC)
Elements of Supplier Quality Risk

• The Basic Elements of Supplier Quality Risk are:
  • **Part Risk**: probability of part not meeting spec due to inadequately specified quality requirements, ineffective transfer of specifications, or quality defects in the supplier’s manufacturing, provision or delivery or products and services.
  • **Quality System and Regulatory Risks**: The risk of the supplier not meeting Quality system or other regulatory requirements due to inadequate implementation of required quality system elements, or inability to meet mandatory regulatory requirements.
  • **Business risks**: Risk not related to quality or regulatory that may affect procurement or sourcing of product or service from a supplier.
Framework for Supplier Quality Risk Management (ISO 14971 Approach)

The framework for product risk management for medical devices as defined in ISO 14971 can also be successfully applied to Supplier Quality Risk Management.

Supplier Quality Risk Management also draws from Risk Management in Procurement, R&D, Operations, and Finance.

The elements of ISO 14971 relate to product risk, which can be inputs to or outputs from the supplier risk management framework (see below):

• Risk Management Plan
• Risk Analysis
• Risk Evaluation
• Risk Control
• Evaluation of overall residual risk acceptability
• Risk Management Report
• Production and Post-Production Information
All Aspects of Supplier Quality Management are Risk-Based

Aspects of Supplier Quality Management (per GHTF N17):

- Planning
- Selection
- Evaluation
- Finalization of Controls
- Delivery and Monitoring
- Feedback and Communication
Elements of Risk Management In Supplier Quality

• Supplier quality risks need to be managed by applying controls that are commensurate with and proportionate to the elements of risk

• Suppliers are initially segmented on a “static” risk basis according to the type and complexity of the product/part/service provided, and its impact on the device’s patient safety and quality

• Suppliers are classified as being of High, Medium or Low risk based on both, the initial “static” segmentation, and the ongoing (dynamic) performance of the supplier as triggered/indicated by Supplier Oversight and Monitoring process
Basis of Supplier Segmentation and Risk Classification

• **“Static” Supplier Risk**: The risk attributed to a supplier due to the class of product or service provided by a supplier, and its impact on patient safety or device quality. This risk is often reflected in the “segmentation” of the supplier. This risk level determines the depth of initial supplier selection, qualification efforts and initially assigned frequency of audit and breadth/depth of controls.

• **“Dynamic” Quality Risk**: The risk attributed to a supplier due to supplier performance over time against defined quality characteristics and targets (e.g., right first time, dppm, field corrections due to supplier at fault, other). This risk is affected by the effectiveness of supplier performance relative to established quality measures and metrics. This risk can change over time depending on the supplier’s performance, and can be used to increase or decrease the assigned frequency of audits and breadth/depth of controls. Both safety and quality are considered in the determination of dynamic quality risk. Dynamic quality risk may be defined as “High”, “Medium” or “Low” risk, and this may be derived qualitatively or quantitatively (e.g., using risk prioritization number- RPN).
Basis of Supplier Segmentation and Risk Classification

• **Supplier Commercial/business risk**: Commercial or business risk considerations that impact a supplier’s risk profile (e.g., single or sole supplier, solvency or financial stability, geopolitical stability of supplier’s location, etc). Supplier commercial risk can change over time.

• **Supplier Status**: This refers to the degree of approval accorded to a supplier based on its ability to meet both, initial selection and qualification requirements, as well as ongoing quality performance requirements. For example, Supplier status on an Approved Supplier List may be “Qualified”, “Provisional”, “Probationary” or “Disqualified.”
Regulatory References


• Medical Devices – Application of Risk Management to Medical Devices (ISO 14971:2012).

• Planning of Product Realization (ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes), Sec 7.1)
Supplier Risk Management: 
Risk Classification and Characterization

• Suppliers are categorized or segmented based on the material or service they provide. Categories or segments are based on inherent potential risk to patient from the product, component or service provided by the supplier.

• Examples of such supplier segmentation are: Finished Medical Device Manufacturer of Class X device, Contract Manufacturer of Class Y device, Sterilization Service Provided, Calibration Service Provider, etc.
Supplier Risk Management: Risk Classification and Characterization

- Identify products/suppliers that are in and out of scope
  - In scope = parts and services that can impact finished device quality
  - Out of scope = parts and services that cannot impact finished device quality
- Quality Risk Factors for Static Quality Risk
  - Regulatory impact/device classification = GMP, Non-GMP (from Q&R assessment, e.g. Class I, II, or III device, Sterilization/calibration service provider
  - QMS Requirements for initial supplier selection and qualification
- Quality Risk Factors for Dynamic Risk
  - Supplier performance (meets, does not meet, or partially meets)
  - QMS Requirements met = meet or do not meet
- Business Risk Factors
  - Sourcing strategy: Sole, Single, Inter-Company, Dual
  - Review D&B

- The supplier category or segmentation determines the type of audit/assessment and initially assigned audit frequency. The types of assessment ranges from onsite audits, desktop audits to quality performance
- Approved Supplier List status examples; Approved, Conditional,
  - Probation & Disqualified.
Key Risk-Based Aspects for Managing Supplier Risk

• **Supplier Selection**
  - capability assessment; QMS, Technical, Supplier Business Risk
  - cultural assessment of supplier’s quality maturity

• **Supplier Segmentation (Static)**
  - Segmentation is established to define elements of supplier controls based on supplier type and product risk. For example:
    - OEM, CM, Specified component, critical process, other
    - Regulatory risk (e.g., based on product class, geography, regulatory requirements)

• **Risk-Based Supplier Performance Monitoring (Dynamic)**
  - Supplier’s performance should be used to modify the frequency and depth of supplier monitoring
  - Supplier performance Triggers
  - Supplier audits; Audit frequency
  - High, Medium, Low (Based on DPPM, SCAR, Complaints, CAPA, Recall, FCO, other)
Key Risk-Based Aspects for Managing Supplier Risk

Supplier Audits and Assessment
- on-site, 3rd party, desk
- capability assessments (QMS, Technical, Cultural)

Quality Agreements, their oversight and enforcement

Change notification and management

Inputs from Business/Procurement Risk
- Sole/single suppliers, financial considerations, business considerations
- Delivery, Other
Key Risk-Based Aspects for Managing Purchased Part Risk

• Advanced Part Quality Planning (APQP) and Purchased/Production Part Approval (PPAP)
  - risk-based Control Plans
  - identification of key/critical components and their CtQ characteristics
  - Application of dFMEA and pFMEA methods

• Process Audits of Critical Manufacturing/Service Processes
  - Deep dive technical process audits of quality-critical manufacturing and service commodities
  - Process validation and audits of suppliers process validation
  - Third party supplier accreditation and certifications (e.g., MedAccred)
Key Risk-Based Aspects for Managing Purchased Part Risk

• Ongoing Reliability Testing and Test to Fail Activities
• Sustainability considerations
• RoHS/REACH considerations
• Risk-Based Acceptance Activities
  - At supplier’s manufacturing facility
  - At OEM’s Receiving and in-Process
  - Application of Statistical methodologies for risk-based sampling

• Supplier Development
  - QMS, technical capability, & business capability development
# Example Elements of a Supplier Risk Management Plan

<table>
<thead>
<tr>
<th>Supplier Risk Classification</th>
<th>Audits (frequency Type)</th>
<th>Quality Reviews (frequency /Content)</th>
<th>Performance Reporting (from Supplier Oversight &amp; Monitoring)</th>
<th>Process Control Level</th>
<th>Quality Agreement Review (frequency of review, content and extent of)</th>
<th>Acceptance Activities (level of inspection)</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1-3 years Onsite (based on performance &amp; regulatory requirement)</td>
<td>Bi-Annual</td>
<td>Monthly</td>
<td>High</td>
<td>1-3 years</td>
<td>100% sampling or robust statistical method</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>4-5 years (based on performance, may be waived with justification) Onsite or desk (initial qualification)</td>
<td>Annual</td>
<td>Quarterly</td>
<td>Medium</td>
<td>4 years</td>
<td>CoA, CoC, statistical method</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>5-7 years/ Desk (onsite if for cause)</td>
<td>For Cause</td>
<td>Upon Request</td>
<td>As needed</td>
<td>As needed</td>
<td>Dock to Stock Or per sampling plan</td>
<td></td>
</tr>
</tbody>
</table>
Supplier Risk Management

- Supplier changes require notification and pre-approval prior to implementation.
- The example uses an A, B, C classification to categorize risk:
  - **Class A:** Simple change with **no impact to company.** No further analysis required.
  - **Class B:** Change with **potential impact to company,** but does **not impact** form, fit or function of finished good or component. Supplier engineering to determine data collection and analysis plan to show pre and post change acceptance.
  - **Class C:** **Significant change** which may include potential to **impact form, fit or function** of component/finished good, manufacturing processes or design of component/finished good. Supplier engineering to initiate analysis activity.

- Measurement and Monitoring method examples:
  - Scorecards
  - Audits
  - Business Reviews
Elements of Managing Part & Process Risk

• **Inputs from Design Controls**
  
  – Part Risk Planning
    • Part type and key characteristics from Design Outputs
    • Critical to Safety/Quality/Reliability/Other Characteristics
    • Options for Risk Controls
  
  – Design Release
    • Early engagement (of supplier and SQE)
    • Identification and Control of Critical to Quality Product Characteristics
    • Product CtQ’s (DfMEA
    • Control and variability of Product CtQ’s

  – Design Transfer
    • Flow down of CtQ from OEM to Suppliers (first-tier and sub-tier)

• **Process Risk Controls**
  
  – Identification and Control of Critical to Quality Process Characteristics
  
  – Process Capability
Elements of Managing Part & Process Risk

• Part Qualification
  – Control Plans
  – Supplier Process validation
  – Purchased Part Approvals
  – Target defect rates (Yield, CpK, PpK)
  – CoA, CoC

• Life Cycle Risk Management
  – Product performance post-release, throughout its life cycle (to sunset)
  – Change management and update of control plans

• Acceptance Activities

• Quality Agreements and Purchasing Contracts
Supplier Risk Management
Risk Classification and Characterization

- Ensure that specifications provided to supplier are measurable and unambiguous
- Establish a mechanism to cascade Critical To Quality (CTQ) characteristics to supplier (for part and process)
  - Criticality based on risk: Feature criticality – Part Criticality – Supplier Criticality
  - Part criticality is obtained from design outputs
  - This flow diagram demonstrates the cascade of requirements
Material qualification is required to demonstrate the capability of supplier/material to meet requirements. This example applies risk to establish supplier capability requirements.

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Product Quality Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Serious/Moderate Quality Characteristic</strong> (Risk Assessment Severity ≥ 3)</td>
</tr>
<tr>
<td></td>
<td><strong>Minor Quality Characteristic</strong> (Risk Assessment Severity &lt; 3)</td>
</tr>
<tr>
<td><strong>Product Evaluation</strong></td>
<td>Product Testing</td>
</tr>
<tr>
<td></td>
<td>First Article Inspection</td>
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<tr>
<td><strong>Supplier Process Evaluation</strong></td>
<td>Process Validation or Capability Study</td>
</tr>
<tr>
<td></td>
<td>MSA/Gage R&amp;R</td>
</tr>
<tr>
<td><strong>Supplier Process Controls</strong></td>
<td>Control Plan or process monitoring</td>
</tr>
<tr>
<td></td>
<td>Inspection</td>
</tr>
</tbody>
</table>
Supplier Risk Management

- This is a high level overview of the Material Qualification process that demonstrates how risk is implemented.

- **Design Document** defines the “Critical to Control” feature for the component (CTC).

- **FMEA** CTC Patient Safety risk evaluation; sets subsequent capability requirements.

- **Critical to Control Requirements:** defined, documented, linked to acceptance criteria, reviewed and approved before release.

- **Acceptance Activities** establishes continuous production monitors per CTC valid product.

- **Component Qualification** validates CTC production capability; locks processes.

- "Receiving Acceptance Activities. Each manufacturer shall establish and maintain procedures for acceptance of incoming product.”
Supplier Risk Management

- Acceptance methods examples:
  - Receiving inspection
  - Certificate of Analysis
  - Certificate of Conformance
  - Certified Part
  - Supplier Self-Inspection

- Sampling plans should be risk based
- Materials and Suppliers with a high level of risk should require inspection and those with a low level of risk do not require inspection
- For example, the table shows an approach to risk-based acceptance activities

<table>
<thead>
<tr>
<th>Acceptance Methods / Risk Types</th>
<th>100% Inspection</th>
<th>Sampling</th>
<th>CofA Only</th>
<th>CofC Only</th>
<th>Dock to Stock</th>
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</thead>
<tbody>
<tr>
<td>Group 1 Risk Index</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>N/A, 0</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td>X*</td>
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<tr>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td>X*</td>
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<td>2</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td>X*</td>
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<tr>
<td>3</td>
<td>X</td>
<td></td>
<td>X*</td>
<td>X*</td>
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<tr>
<td>Group 2 Custom</td>
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<tr>
<td>Essential</td>
<td>X</td>
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<tr>
<td>Non-Ess</td>
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<tr>
<td>Catalog</td>
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<tr>
<td>Essential</td>
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<tr>
<td>Non-Ess</td>
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<tr>
<td>Supply Items</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

- $X =$ optional acceptance methods
- $X^* =$ additional restrictions apply, see Certificate of Compliance/Certificate of Analysis section