Outsourcing Challenges and Strategies for Success - Managing Supplier Risk

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Content

- Outsourcing risks
- System to managing supplier risks enabling RFT – Zero defects
- Continuous improvement
In this presentation

• “Supplier” means:
  • Raw (Direct) Material Suppliers – Drug Substance / Product, Labeling, Packaging, Spare Parts (non-MRO), etc.
  • Service Providers – Calibration, Cleaning, Contract Labs, Warehousing, Shipping, Medical Device Design, Pest Control, etc.
What are the supplier related risks the Pharma Industry is facing by outsourcing materials and services?
Supplier related risks

• Quality Failures of Materials
  • Deviations at incoming control or in process

• Service Failures
  • Deviations in production / product release / distribution

• Supply Interruptions
  • Changes in planning and product stock out at patient level
What can be done to mitigate risks?

• Internal Measures
  • Understand materials (quality and quantity)
  • Understand criticality of services
  • Define type of supplier that fits through risk assessment

• External Measures
  • Select appropriate suppliers
  • Develop/integrate key suppliers into supply chain
Internal Measures

• Understand and communicate what is needed from the supplier

• Define material attributes and its function/risks to the (drug) product:
  • Critical/required attributes
  • “Defects” that are not deviations (TUPP)

• Clear understanding of services required
  • GMP vs non-GMP services
  • Desired benefit of the outsourced service
External measures - Managing supplier risk through a holistic approach

How can we get to Right First Time and Zero Defects by working with our suppliers?
Set common ground

• Explain how the materials/services are used
  • Which purpose do they serve in our products
  • Explain your own business
  • https://www.youtube.com/watch?v=q5KchW_QFxo

• Explain the Pharma regulatory environment
  • Requirements are more stringent than for non-pharma customers
  • Elevated quality levels
Supplier and category strategy

- Cross-functional teams define a material/service category strategy
- Supplier selection using pre-defined criteria
- Early development functions involved in strategy
- Set continuous improvement goals w suppliers to reduce Total Cost of Ownership (TCO)
- Negotiate Quality Agreement / Supply Specification
What do preferred suppliers have?

- Technical capability to deliver what we need
- Process / systems under control to ensure reliability
- Economic background to deliver quantity / service we need
- Code of Conduct to ensure sustainability
- Ability to develop a trustful relationship
How do we find these suppliers?

• Technical (”due diligence”) visit
• Supplier Qualification/Audit
  • Plant tour (ideally when production is running)
  • Intensive SOP and Document review
  • Findings corrected by suppliers
Other ways to find the right supplier

• Assess technical capability - shift audit focus from quality system to process capability and control
• Build relationship with people at suppliers - share common goals
• Build up understanding how suppliers contribute to product supply to patient
• Define win-win collaboration
Supplier capability assessment

• Identify critical process and control parameters at the supplier
• Review process risk assessment and identify gaps connected with the Critical Material Attributes (CMA)
• Audit production and control process - focus on (high) risk parameters and implementation of measures from process risk assessment
• Check SOPs and process documentation to understand level of control incl. statistical process controls (cp, cpk, etc.)
• Check the change control process to ensure relevant «Vendor Initiated Changes» are communicated prior to implementation
Formalized risk assessments

- Risk is composed of
  - Severity
  - Probability of Occurrence
  - Probability of Detection

of the harm

Risk = Severity * Probability of Occurrence * Probability of Detection
Risk contributors

• Severity relates to the material/service
• Probability of Occurrence relates to the supplier
  • correlation between supplier quality performance with probability of occurrence of future failures
• Probability of Detection depends on incoming control, testing at supplier, and internal controls
# Primary Risk Number (PRN)

## Severity * Probability of Occurrence

<table>
<thead>
<tr>
<th>Score</th>
<th>Quality/Regulatory Criteria</th>
<th>Patient Safety Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Effects may cause a Health Authority to suspend the Manufacturing/Marketing Authorization</td>
<td>Effects may cause serious adverse health consequences, permanent disability, or death</td>
</tr>
<tr>
<td>8</td>
<td>Effects may lead to serious/critical regulatory observations and/or lead to a product recall</td>
<td>Effects may cause a significant impact to patient health (e.g., temporary or medically reversible health problem or disability)</td>
</tr>
<tr>
<td>6</td>
<td>Effects may lead to major regulatory observations or nonconformance with internal quality standards, procedures or regulatory requirements leading to product quality impact</td>
<td>Effects are noticeable by user and may make product unusable; requires medical intervention</td>
</tr>
<tr>
<td>4</td>
<td>Effects may lead to only minor observations or recommendations in regulatory inspections; or minor nonconformance with internal quality standards, procedures or regulatory requirements and no product quality impact</td>
<td>Effect are noticeable by user and may make product difficult to use; does not require any medical intervention</td>
</tr>
<tr>
<td>2</td>
<td>Effects will not lead to nonconformance with internal quality standards, procedures or regulatory requirements</td>
<td>Effects will have negligible to no impact to patient health</td>
</tr>
</tbody>
</table>

## Score | Category | Criteria
---|----------|--------------------------|
10 | Very High | Certain to occur routinely |
8  | High      | Occurs frequently |
6  | Moderate  | Occurs occasionally |
4  | Low       | Has not occurred often |
2  | Remote    | Not expected to occur |

## PRN Matrix

<table>
<thead>
<tr>
<th>Severity</th>
<th>Probability of Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td><strong>catastrophic</strong></td>
<td>20</td>
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<tr>
<td><strong>critical</strong></td>
<td>16</td>
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<tr>
<td><strong>major</strong></td>
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<tr>
<td><strong>moderate</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>minor</strong></td>
<td>4</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Score Range</th>
<th>Description</th>
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<tbody>
<tr>
<td>40-100</td>
<td>High: Require Risk Control Action(s)</td>
</tr>
<tr>
<td>16-36</td>
<td>Medium: risk control actions must be investigated to determine if risk can be reduced</td>
</tr>
<tr>
<td>4-12</td>
<td>Low: no further risk control actions are required</td>
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</tbody>
</table>
## Risk Priority Number (RPN)

**PRN * Detectability Score**

<table>
<thead>
<tr>
<th>Score</th>
<th>Category</th>
<th>Criteria</th>
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</thead>
<tbody>
<tr>
<td>10</td>
<td>Remote</td>
<td>There is no established inspection, testing, or monitoring in place to detect the failure</td>
</tr>
<tr>
<td>8</td>
<td>Low</td>
<td>There is limited inspection, testing, or monitoring in place. Detection is delayed and multiple failures may go undetected between consecutive steps</td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
<td>Some inspection, testing, or monitoring is in place. Detection is delayed and single failure could go undetected between consecutive steps</td>
</tr>
<tr>
<td>4</td>
<td>High</td>
<td>Inspection, testing, or monitoring is in place. There is a high probability that the failure will be detected within the step</td>
</tr>
<tr>
<td>2</td>
<td>Very High</td>
<td>Consistent inspection, testing, or monitoring is in place to immediately and consistently detect the failure</td>
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### Probability of Detection

<table>
<thead>
<tr>
<th>Probability of Detection</th>
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<th>4</th>
<th>6</th>
<th>8</th>
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<td>256</td>
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<td>512</td>
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**Primary Risk Number (PRN)**

- **192–1000** High: Require Risk Control Action(s)
- **72–160** Medium: risk control actions must be investigated to determine if risk can be reduced
- **8–64** Low: no further risk control actions are required
FMEA outcome usage

• Severity drives initial supplier & material qualification requirements
  • More stringent requirements for High Risk Materials / Services

• PRN (Severity * Probability of Occurrence) drives reduced testing requirements
  • High Risk Materials/Services from High Risk Suppliers have more controls at incoming/point of use
FMEA outcome usage – cont’d

• RPN (PRN * Probability of Detection) drives supplier oversight model (e.g. audit frequency, supplier development initiatives, etc.)
  • High Risk Materials/Services from High Risk Suppliers with Low Probability of Detection have higher oversight level (e.g. tighter monitoring frequency)
Supplier Collaborations

• Dedicated group of (Master) Black Belts working with suppliers
• Specific issues are addressed
• Pro-active issue avoidance
• Reduction in number of discrepancies
• Generated savings of >1.5 m$ in 2018 by avoiding write-offs
Ongoing work to reach RFT/Zero Defects

• Define and develop requirements for materials/services with suppliers
• Using the data generated by the process to specify the right supplier to work with
• Focus on true supplier capability assessments
• Stop non-value adding activities
Doing now what patients need next
Synopsis

Managing supplier risks is a topic of very high importance for the Pharma Industry, given the implications of potential product stock outs, the involved costs, and reputation damage.

In this presentation a holistic approach to the reduction of material/service related deviations utilizing communication, supplier capability, and formal risk assessments is discussed.

This approach creates win-win situations for both suppliers and customers by fostering mutual understanding and collaboration.