Integration of Risk Management into Product Strategy and Portfolio

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Focus for Today

• Leveraging ICH Q9 risk management concepts to identify risks beyond the scope of QRM that have the potential to impact the availability of products to patients and strategic direction

• Tools and methods to manage the lifecycle of a risk, such as how it is identified, assessed, communicated and escalated to Senior Leadership

• Processes for how the risk control recommendations are incorporated into business strategies, portfolio management, and in decision making principles.
Imagine...FabMAb Supply Chain

Source of Graphic: Global Supply Chain Risk Increasing, MH&L Staff, Mar 18, 2016
What it Will and Will Not Do

Will not:
• prevent ALL bad things from happening
• make decisions for you
• will not be a one time exercise
• manage itself or keep information relevant
• execute its own risk control recommendations

Will:
• provide you with a process to reduce supply continuity risk
• provide response plans to ensure continuity of supply to patients.
• reduce cost associated with response to supply continuity issues and impact to reputation
• improve product lifecycle decisions and go/no go project execution decisions
• increase confidence of customers and regulators
• make shareholders happy!
Product Portfolio and Level of Rigor

- Define product with respect to availability of alternatives and the therapeutic use
  - Profile of end user/patient base

- Determine where a product is in its lifecycle
  - Defines the level of rigor applied

*TR-66 Risk Based Approach for Preventing and Managing Drug Shortages*
Define the Risk Question: What events could result in a supply continuity risk to the patient, from both a Strategic and Operational Level?

Top Down from Senior Leadership

Bottom Up from Site Level

Product Risk Profile

KPIs and key business objectives should be aligned to measure product availability to the patients.

What is the product strategy to ensure continuity of supply?
Example Strategic and Operational Scope

What is the product strategy to ensure continuity of supply?

**Internal Services: Quality, EH&S, Engineering, Facilities, IT**

*Raw Materials* → *Process Development* → *Manufacturing & Testing* → *Packaging* → *Warehouse & Distribution* → *Customer / End User*

**External Services:** CMO, testing, artwork, packaging, warehouse and distribution, equipment maintenance

*Raw materials include starting materials, excipients, intermediates, packaging materials etc.

**A Guide to Supply Chain Risk Management for the Pharmaceutical and Medical Device Industries and their Suppliers – 2010 The Chartered Quality Institute**
Understand Existing Landscape

1. Assess existing Risk Management Programs
   • QRM Program per ICH Q9
   • EH&S Risk Programs
   • Asset Management
   • Project Risk Management
   • Others?

2. Gap Assessment

3. Develop Risk Checklist(s)

4. Engage Leadership in Strategic Risk Management activity
Internal Risk Landscape

- **Leadership**
  - Decision making and accountability
  - Project funding/investments

- **Supply Continuity Risk**
  - Financial
  - Political
  - Logistic
  - Market
  - Environmental Control
  - Quality Risk Management

- **Supply and Vendor/Supplier Issues**

- **Organization and Strategy Issues**

- **Quality, delivery, and manufacturing**

- **Production and Warehouse capacity requirements**

- **Asset Management**

- **Regulations**
  - Quality and Compliance

- **Leadership**
  - Decision making and accountability
  - Project funding/investments

Includes risk beyond the QRM scope
External Risk Landscape

- Multiple Health Authority Requirements
- Local EH&S Laws
- Environment/Nature
- Suppliers and Vendors
- Market Demand/Competition
- New Technology
- Market
- Quality Risk Management
- Supply and Vendor/Supplier Issues
- Organization and Strategy Issues
- Financial
- Political
- Supply Continuity Risk
- Fraud/Counterfeit
- Includes risk beyond the QRM scope
Example Risk Gap Checklist - QRM

- What areas have been assessed?
- Do they represent current state?
- Are they living in the Quality System?
- What areas have not been assessed?
- Are they on a schedule, statuses reported to leadership, resources allocated?
Existing Risk Programs

Various sources of risk, tool usage, scoring methodology, and gaps in communication

How do we bring this together?
Risk Aggregation

Strategic Risks and Operational Risks are aggregated to determine risks associated with continuity of supply to patients.
Analyze and Evaluate

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability</td>
<td>Time-Supply Chain Disruption</td>
</tr>
</tbody>
</table>

Very High    | >75%     | >8 weeks  |
High          | 60.1-75% | 4-8 weeks |
Medium        | 41-60%   | 2-4 weeks |
Low           | 25-40%   | 1-2 weeks |
Very Low      | <25%     | <1 week   |

Must develop one definition for product supply disruption to patient

Impact should be right sized to fit the specific product strategy (demand, patient base, future markets, clinical trials)
# Product Risk Profile

- Single repository for Medium/High risks with mitigations and accepted high risks.
- Data can be evaluated depending on decisions being evaluated
  - Site
  - Product
  - Common product platforms
  - Process Step
- Imagine the decision making power in seeing risk in one repository!

<table>
<thead>
<tr>
<th>Product</th>
<th>Risk Description</th>
<th>Risk Score</th>
<th>Proposed Mitigations</th>
<th>Risk Acceptance Statement</th>
<th>Accountable</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product X</td>
<td>Trucking company labor dispute may result in 4-8 weeks in shipping disruptions in South American countries</td>
<td>![Risk Score Icon]</td>
<td>Secure contract with secondary backup shipping company</td>
<td>N/A; Risk is not acceptable</td>
<td>Bob Davis</td>
<td>Q2 2017</td>
</tr>
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</table>

**Example Product Risk Scorecard**
# Risk Decision Matrix

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Risk Acceptability Decision</th>
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<tr>
<td><strong>High</strong></td>
<td>Risk reduction/control actions are required. Recommended risk control actions must be integrated into the project portfolio process. If risk is accepted this must be documented and approved by leadership and plans must be developed to take actions on risks should they be realized.</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Further risk reduction should be considered. Plans must be developed to take actions on risks should they be realized.</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Risk is acceptable. No further action is required.</td>
</tr>
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*Response plans to strengthen strategy for product supply to patients*
Integration of Risk Management into Strategy and Portfolio

KPIs and key business objectives should be aligned to measure product availability to the patients.

Example Product Risk Scorecard:

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There must be risk communication between the phases of the lifecycle to maintain knowledge management:

- Products
- Product families
- Similar technology platform

Risk Communication

Product Development

Product Discontinuation

Commercial Manufacturing

Technology Transfer
Governance

Executive Leadership

Division Leadership

Product Teams

Site Leadership

- Accountable for corporate strategy and the associated risks
- Accountable for viewing risk and decision making at a division level
- Division level decision making
- Accountable for product supply disruption risk unless escalation is needed
- Product level decision making
- ICH Q10 across the lifecycle
- Supply Chain
- Accountable for site level risk mitigation and escalation of product supply disruption risk

Risk review frequency must be established in the charter. Risks must be updated for a healthy program
Decision Making Benefits

• You know your product and it’s **at your fingertips** (inside and out)!

• Protecting your **reputation and integrity**
  • Patients receiving quality therapies without interruption =
  • Happy Regulators =
  • Happy Shareholders

• **Cross – lifecycle communication** enables a stronger pipeline; risks of current products are being leveraged to improve product pipeline and development of the future

• **Portfolio, budget, and strategy aligned** and based on a shared process

• Stronger **supplier and CMO selection** process (You know what you need and it can be inserted right into the selection process)

• **Technology transfers** can be improved by evaluating past similar platform transfers and enhancing checklists with risk profile information.
Failure will be imminent if....

• Lack of Senior Leadership accountability
  • Driving decisions from the risk profile process
  • Developing ad hoc lists of risks
  • Allowing an “opt out” culture
  • In engaging and identifying risk
• Decisions are made outside of the Product Risk Profile
• One time program installation but not waiting for realization
  • Timeframe too short to properly install
• Deprioritized because of fire fighting
• Lack of program maintenance with dedicated resources
• Not investing in a strong IT tool with appropriate capabilities
Revisit...FabMAb Supply Chain

Source of Graphic: Global Supply Chain Risk Increasing, MH&L Staff, Mar 18, 2016
Thank You!