Minimizing Risk in your raw material supply chain

John Hollenbach
Director of Sales and Marketing
Doe & Ingalls of North Carolina

December 6, 2007
Where are we vulnerable?

- Crude oil (or other basic source)
- Industrial chemical factory
- Chemical Manufacturer
- Supply chain partner or distributor
- Manufacturing by biotech company or CMO
- Global distribution
- Patients
A healthy supply chain is critical to success

- Saving or improving patient’s lives: everyone’s goal
- Financial impact
  - In one study, 33-40% of companies with a supply chain disruption had lower stock returns relative to benchmarks.
  - Cost of shutdown for even one day: immediate revenue loss
- Potential loss of market share
- Brand image problems: less trust in you from doctors and patients
How to mitigate the risks

• Business continuity planning (supply chain)
• Crisis management planning (supply chain)
• Designing reliable internal processes

→ Today, we will focus on upstream business continuity planning.
Agenda

• Developing a risk assessment program
• Assessing the level of risk for raw materials
• Handling immediate risks
• Proactively building a strong supply chain
• Engaging your suppliers as partners
Developing a risk assessment program
Developing a risk assessment program

1. Decide on scope.
   - Do you plan to analyze all materials? How do you rank materials based on critical nature to process?

2. Decide on tools for analysis – FMEA templates

3. Involve the appropriate people.
   - Purchasing, materials planning/management, process development, quality, manufacturing, company leadership

4. Determine goals and timeline.
Risk assessment process
Summary of the assessment process

- Prioritize materials for assessment
- Determine evaluation criteria – FMEA template
- Set goals for tolerable risk levels
- Assess types of risk
- Compare actual risk against targets
- Make recommendations to mitigate risk – develop action plan
- Re-assess risks after execution of recommendations
Prioritizing assessment

1. Map each material to its use & critical nature

2. Determine criticality of material to process

3. Rank materials by priority for assessment
   (very critical (1) to not critical (5))
Prioritizing assessment

<table>
<thead>
<tr>
<th>Criticality to process</th>
<th>Late stage, commercial applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Material use</td>
</tr>
<tr>
<td>High</td>
<td>R&amp;D</td>
</tr>
</tbody>
</table>

- Assess second
- Assess first
- Assess last
- Assess second
Determine evaluation criteria: what are the risk factors?

Chemical Manufacturer
Supply chain partner or distributor
Internal risk of biotech manufacturer
Manufacturer risk factors

- Production capacity
- Environmental risk
- Geo-political tensions
- Financial risk
- Audited quality systems
- Track record with FDA
- Lead time
- Sole sourced material
- Transparency into supply chain
- IT failure
- Disaster preparedness plan
- Historical supplier performance
- Management of Change Program
Distributor risk factors

- Environmental risk
- Geopolitical risk
- Audited quality system
- Space constraints
- Lead time
- Supply chain management
- IT failure
- Disaster preparedness plan
- cGMP storage & handling processes
- Management of change program
Internal risk factors

- Testing lead time
- Purchasing timeline
- Second source approved
- Second source available
- Storage capacity for material
- Communication between manufacturing planning and purchasing
- Management of change procedure
- Critical nature of process
- Difficulty in test methods
- Etc…
Evaluating the risk of each factor

• **Impact/Severity**
  – How serious is the effect?
  – 1=none, 10=highly hazardous

• **Risk likelihood**
  – How likely is the risk to occur? OR how likely is the criterion to fail?
  – 1=remote, 10=very high

• **Detection**
  – Likelihood of detecting the failure
  – 1=almost certain detection, 10=completely uncertain

• **Factors will be multiplied together to give composite score**

• **Will also be graphed to give pictorial view**
Set your risk tolerance levels

• Look at this on a composite and individual standpoint
  – Manage whole picture: composite allows trade offs between factors
  – Manage individual components: coordinates approach allows a max on an individual factor; when all pieces are not viewed as equal

• Example:
  – Could set a tolerance of 40 as a composite score
    • Scenario A: Severity 5, Likelihood 4, Detection 2
    • Scenario B: Severity 5, Likelihood 2, Detection 4
  – Or could set targets for risk components
    • Such as “Our severity score must always be 4 or less”
    • Scenario C: Severity 4, Likelihood 2, Detection 5

• Set high, medium and low risk levels:
  – Example:
    150+ = 
    100-149 = 
    <100 = 
Looking at a risk tolerance diagram
Assess risk using the framework

<table>
<thead>
<tr>
<th>Risk</th>
<th>Failure mode</th>
<th>Potential causes</th>
<th>Potential effects</th>
<th>Detection Method</th>
<th>Severity</th>
<th>Likelihood</th>
<th>Detection</th>
<th>Combined score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity of manuf.</td>
<td>Unable to meet product demand</td>
<td>Limited mixing tank resources, significant growth in other products</td>
<td>Unable to produce because other product demand high. Run out of material</td>
<td>Materials planner can identify issue</td>
<td>7</td>
<td>4</td>
<td>4</td>
<td>112</td>
</tr>
<tr>
<td>Dist. MOC program</td>
<td>Mgmt of change program fails</td>
<td>Manuf. does not notify distributor/DIQSM resigns or vacation</td>
<td>Customer uses unapproved product in process</td>
<td>Audit of MOC of supply chain</td>
<td>8</td>
<td>4</td>
<td>6</td>
<td>192</td>
</tr>
</tbody>
</table>
## Compare risk level to internal targets

<table>
<thead>
<tr>
<th>Risk</th>
<th>Assessed scores</th>
<th>Risk tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Severity</td>
<td>Likelihood</td>
</tr>
<tr>
<td>Capacity of manuf.</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Dist. MOC program</td>
<td>8</td>
<td>4</td>
</tr>
</tbody>
</table>

**Note:** Combined score could be lower, such as 80 to set indiv. and total max’s.
Plot materials in decision cube

- Risk likelihood
  - Medium priority mitigation
  - High priority mitigation
  - Medium priority mitigation
  - Medium priority mitigation
  - Medium priority mitigation
  - Medium priority mitigation

- Detection ability
  - Medium priority mitigation

- Severity
  - Low priority mitigation/no mitigation
  - Medium priority mitigation
  - Medium priority mitigation

Highest priority mitigation
High priority mitigation
Medium priority mitigation
Medium priority mitigation
Medium priority mitigation
Low priority mitigation/no mitigation
Mitigate risks

- Look at materials most egregiously out of range first
- Devise immediate actions to mitigate
  - Risk mitigation inventory
  - Approval of alternative source
- Consider long-term actions to mitigate
  - Capacity agreements
  - Supplier agreements
  - Regular audits
- Do a cost-benefit analysis
  - Cost to mitigate versus cost of failure
  - Many options; pick the one with greatest ratio of benefit over cost
- Re-evaluate risks
- Set up monitoring program
Re-evaluate risk measurement based on actions taken

<table>
<thead>
<tr>
<th>Risk of manuf.</th>
<th>Severity</th>
<th>Likelihood</th>
<th>Detection</th>
<th>Combined score</th>
<th>Action</th>
<th>Severity</th>
<th>Likelihood</th>
<th>Detection</th>
<th>Combined score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity of manuf.</td>
<td>7</td>
<td>4</td>
<td>4</td>
<td>112</td>
<td>Detail a control mechanism to alert of potential scheduling or resource conflicts</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>80</td>
</tr>
<tr>
<td>Dist. MOC program</td>
<td>8</td>
<td>4</td>
<td>6</td>
<td>192</td>
<td>Put MOC expectations in supply agreement</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>40</td>
</tr>
</tbody>
</table>
Monitoring programs protect your risk investment

- Periodic re-assessments ensure that materials are not drifting away from targets
- Also provides opportunity for further risk reduction
- Time, historical data or new information could motivate different mitigation decision: e.g. initial action was to hold 6 months of inventory, now it’s better to sign a supply agreement
- Gives you opportunity to apply lessons learned to any additional analysis
Lessons that we have learned

• Dual source products where possible: second supplier, second brand or alternate manufacturing site

• Smart sourcing
  – Consider risk factors during process development for smooth scale up
  – Capacity, quality and how custom materials will scale

• Partner with suppliers. Each should understand the other’s business.
  – Regular communication
  – Forecasting together: bullwhip effect magnifies distortions
  – Planning inventory together mitigates customer risk
  – Recognize the cost benefit analysis of this strategy
  – Long-term agreements should be considered
Questions?