Minimizing Risk
in your raw material supply chain

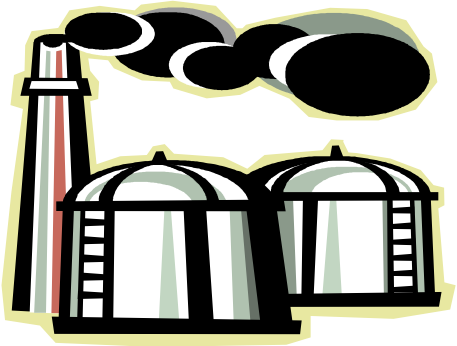
John Hollenbach
Director of Sales and Marketing
Doe & Ingalls of North Carolina

December 6, 2007

Where ~~are~~ aren't we vulnerable?

Crude oil (or other basic source)

Oil

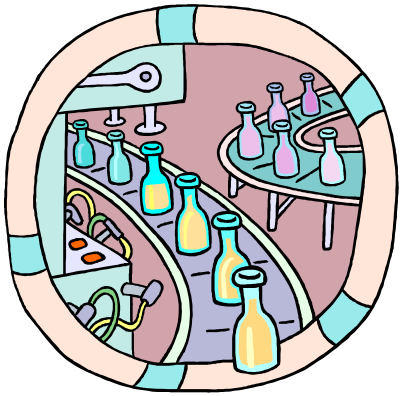


Industrial chemical factory

Basic chemicals

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

Doe & Ingalls

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.

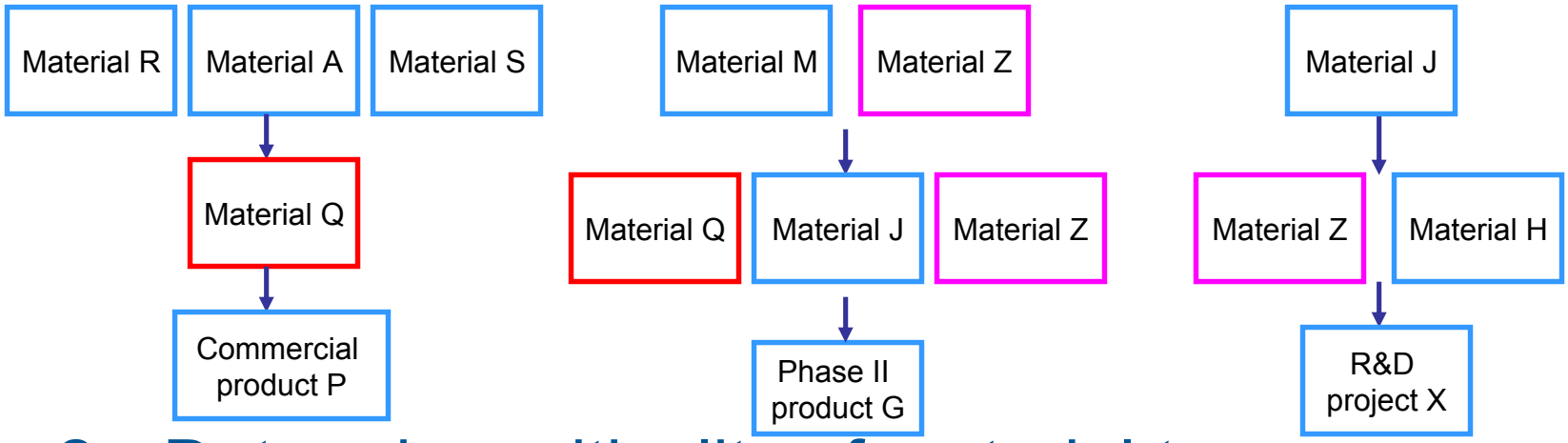
Risk assessment process

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

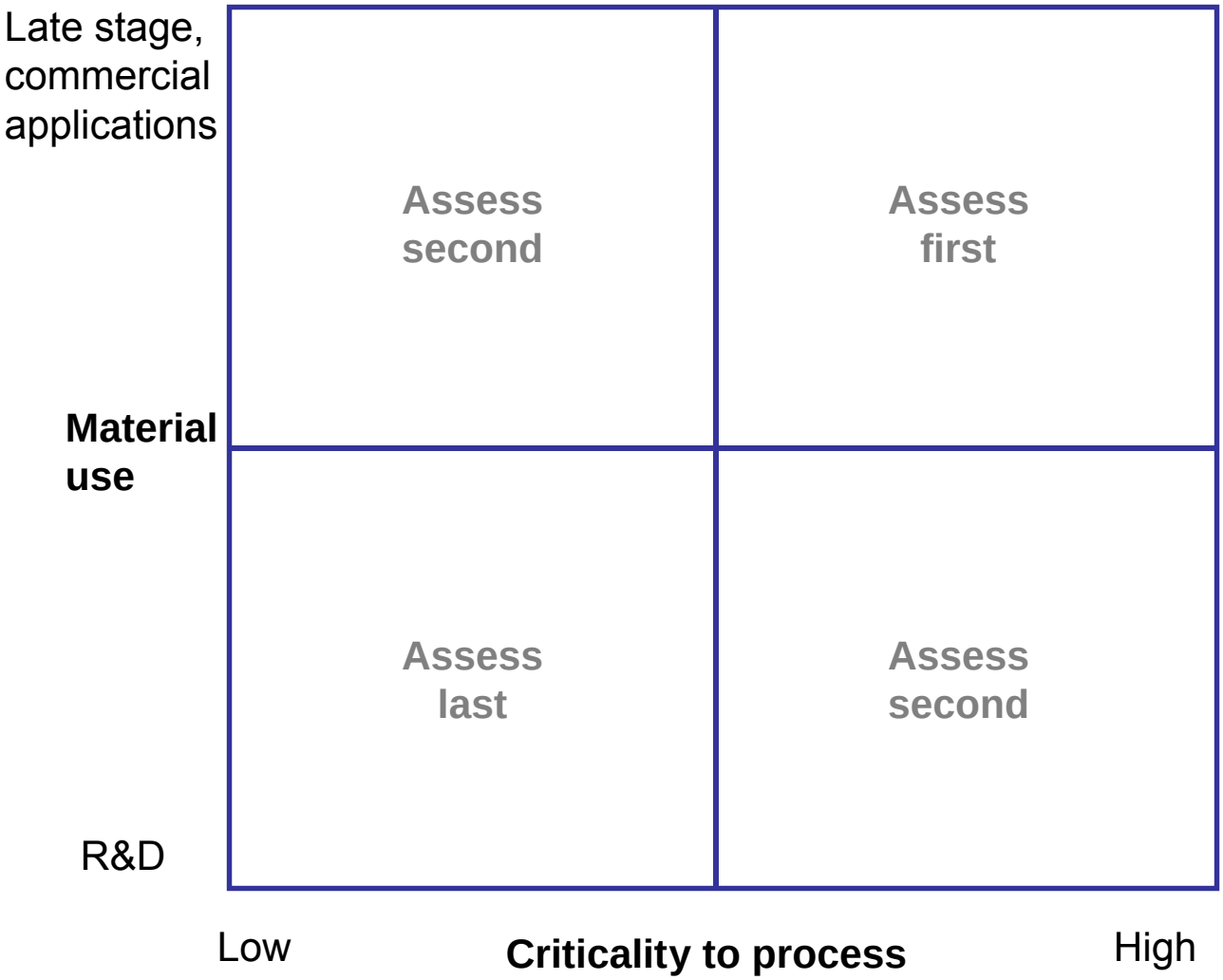
1. Map each material to its use & critical nature



2. Determine criticality of material to process
3. Rank materials by priority for assessment

   (very critical (1) to not critical (5))

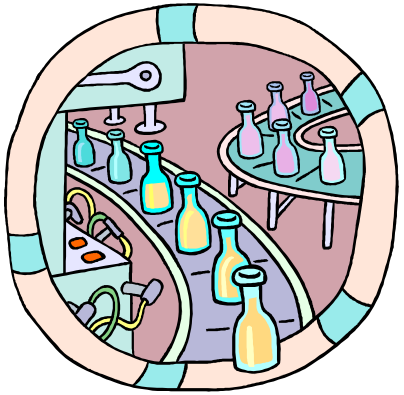
Prioritizing assessment



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

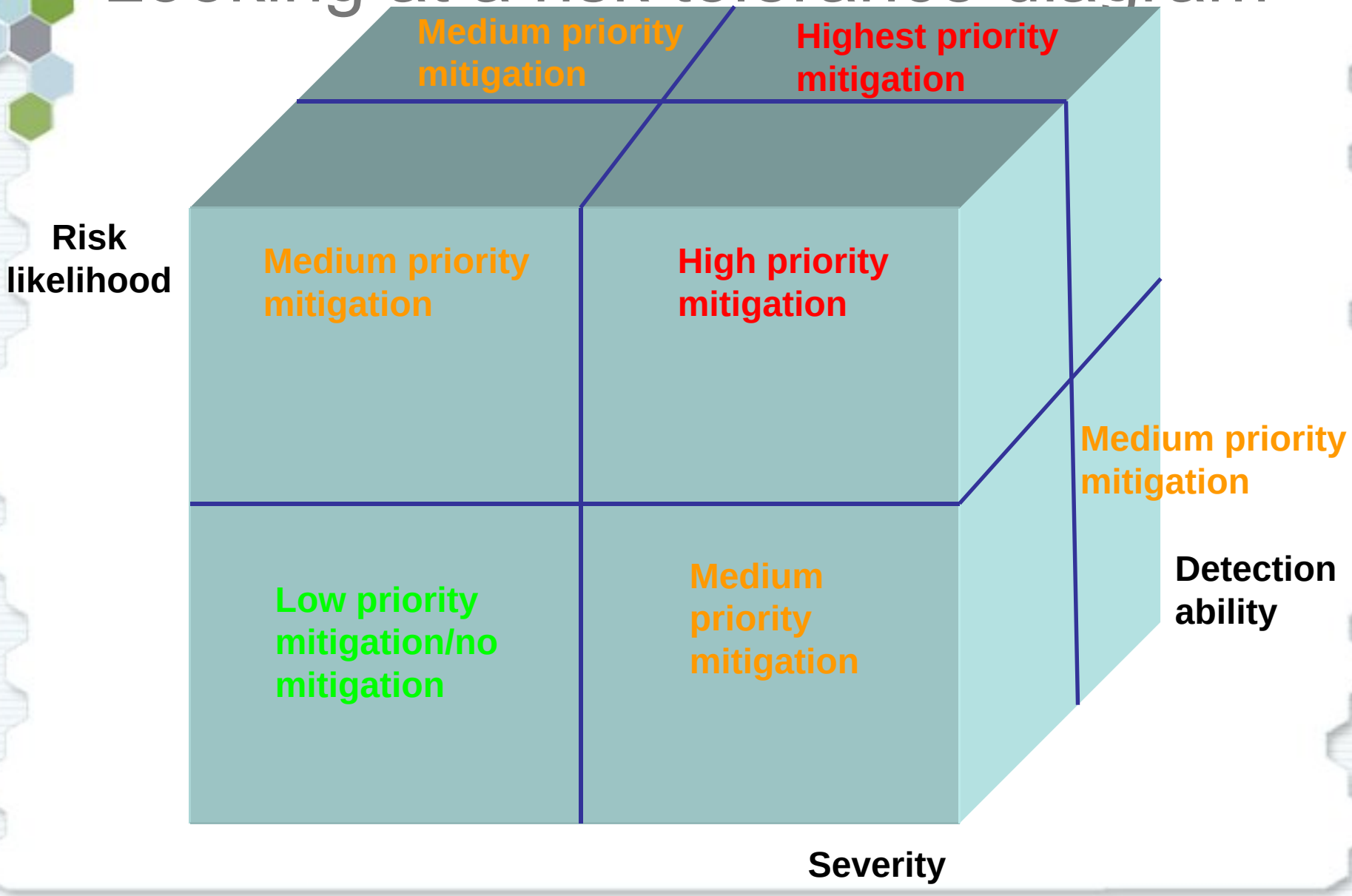
- Impact/Severity
  - How serious is the effect?
  - 1=none, 10=highly hazardous
- Risk likelihood
  - How likely is the risk to occur? OR how likely is the criterion to fail?
  - 1=remote, 10=very high
- Detection
  - Likelihood of detecting the failure
  - 1=almost certain detection, 10=completely 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



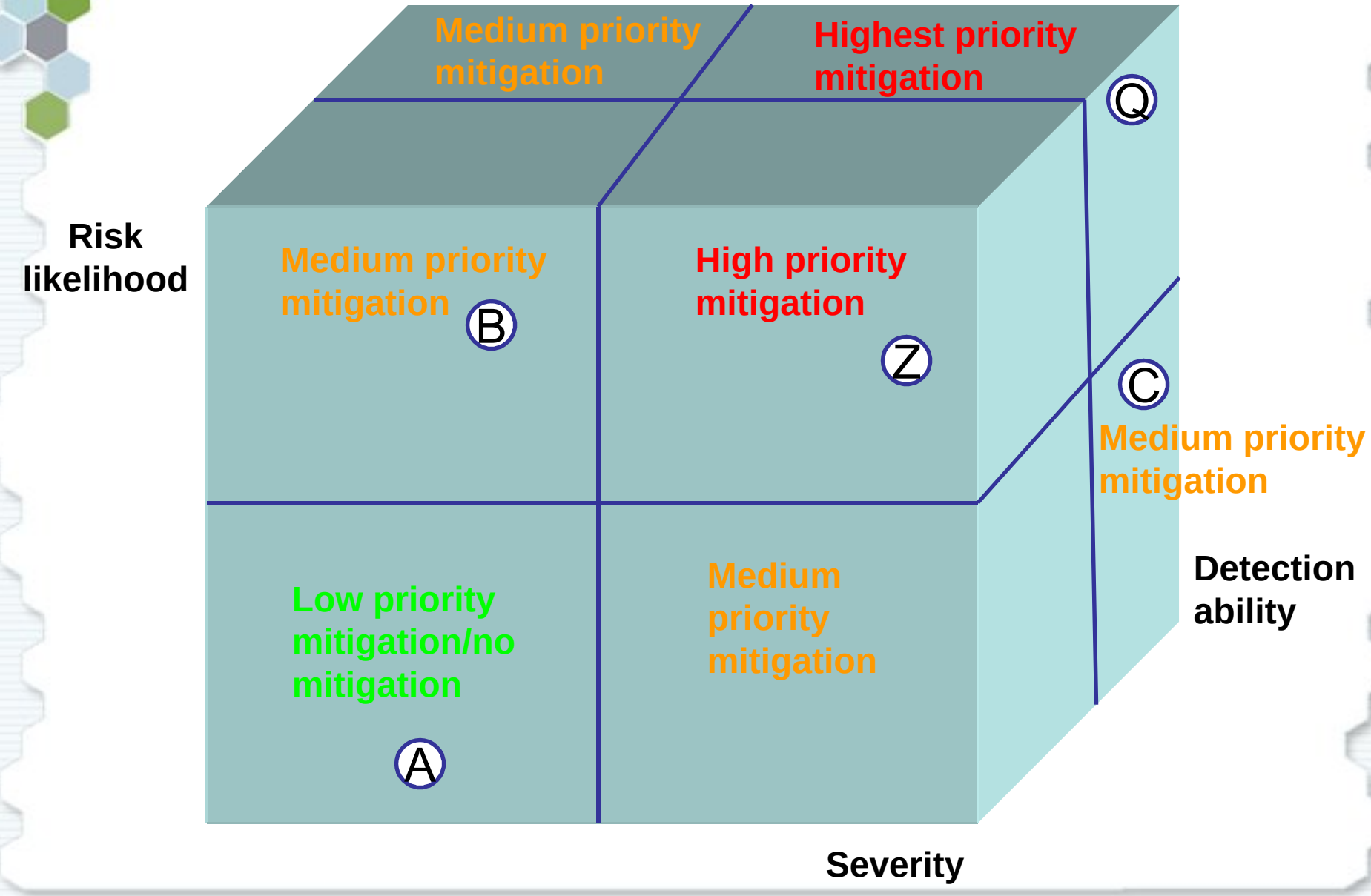
Assess risk using the framework

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

Compare risk level to internal targets

	Assessed scores				Risk tolerance			
Risk	Severity	Likelihood	Detection	Combined score	Severity	Likelihood	Detection	Combined score
Capacity of manuf.	7	4	4	112	5	5	4	100 **Note, combined score could be lower, such as 80 to set indiv. and total max's.
Dist. MOC program	8	4	6	192	5	5	4	100

Plot materials in decision cube



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

Risk	Severity	Likelihood	Detection	Combined score	Action	Severity	Likelihood	Detection	Combined score
Capacity of manuf.	7	4	4	112	Detail a control mechanism to alert of potential scheduling or resource conflicts	5	4	4	80
Dist. MOC program	8	4	6	192	Put MOC expectations in supply agreement	5	2	4	40

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?

Doe & Ingalls