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Second Sourcing: A Strategy to Mitigate Supply Chain Risk

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Second Sourcing: A Strategy to Mitigate Supply Chain Risk

Agenda

- General framework for risk assessment and management
- Major risks in pharma supply chain
- Quantifying risk exposure and mitigation costs
- Practical considerations for second sourcing arrangements
- Conclusions and recommendations

General framework

Enterprise Risk Management

- ONLY 18% OF BUSINESS RISK IS INSURABLE
- Enterprise risk management (ERM) is the process of planning, organizing, and controlling the activities of an organization in order to minimize the effects of risk on an organization's capital and earnings
- Enterprise risk management expands the process to include not just risks associated with accidental losses, but also financial, strategic, operational, and other risks

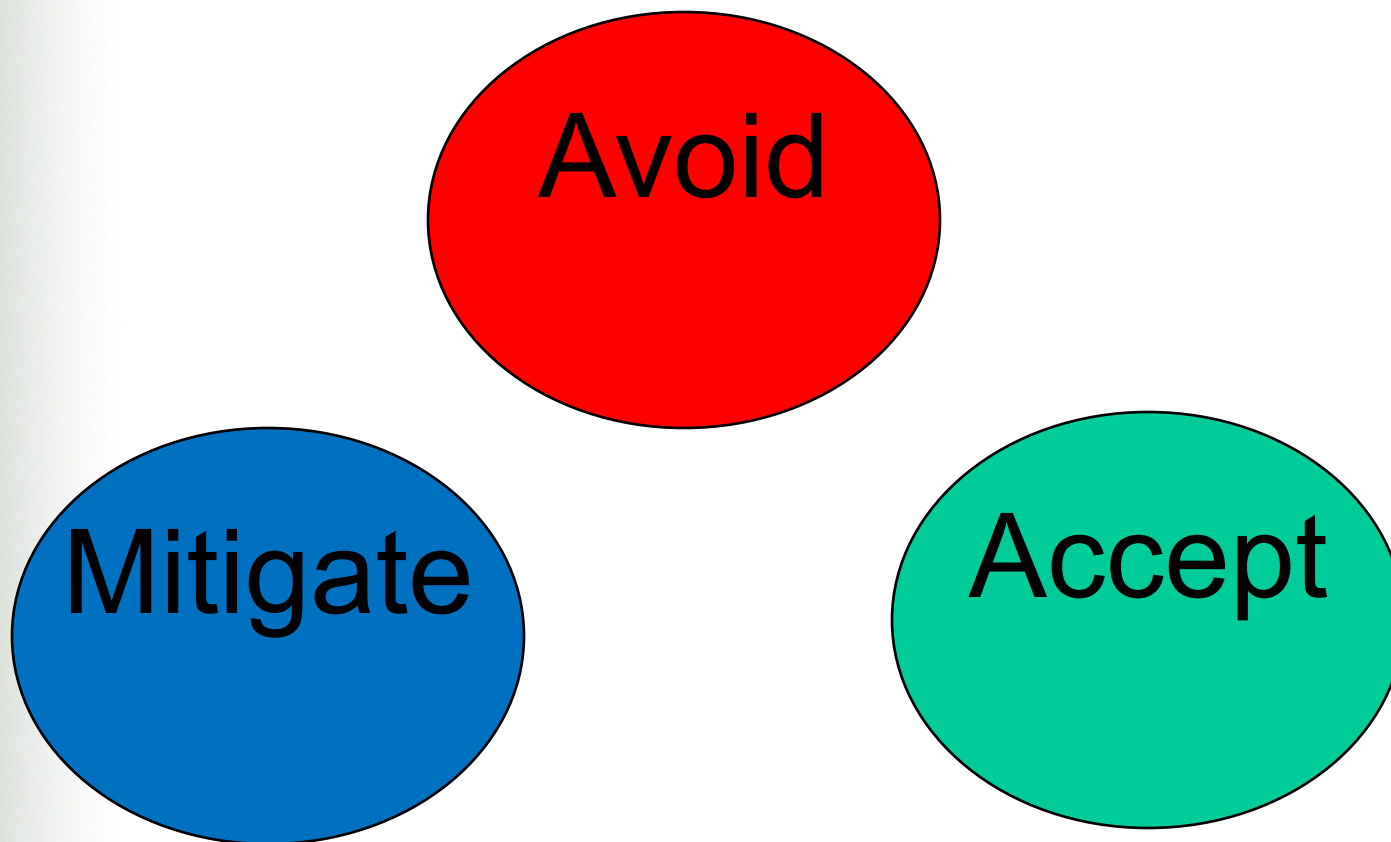
General framework

Risk management process

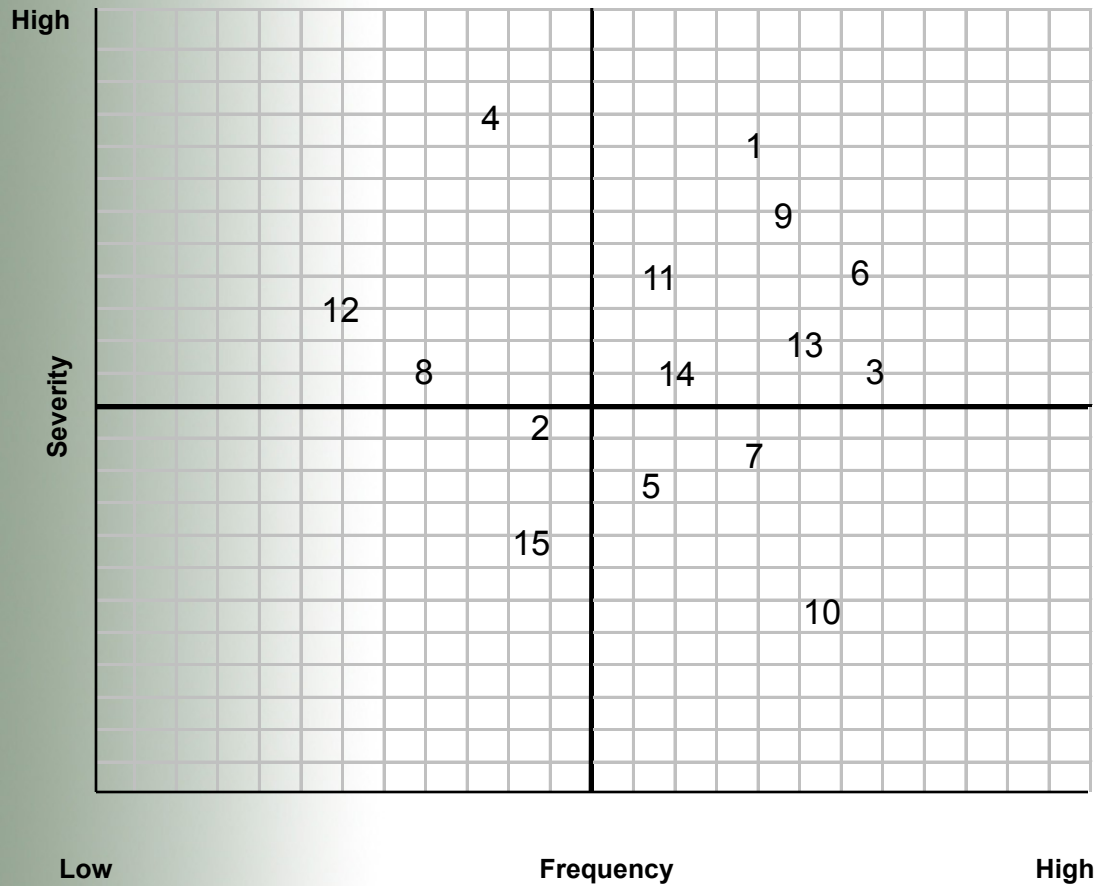


General framework

Risk mitigation strategies



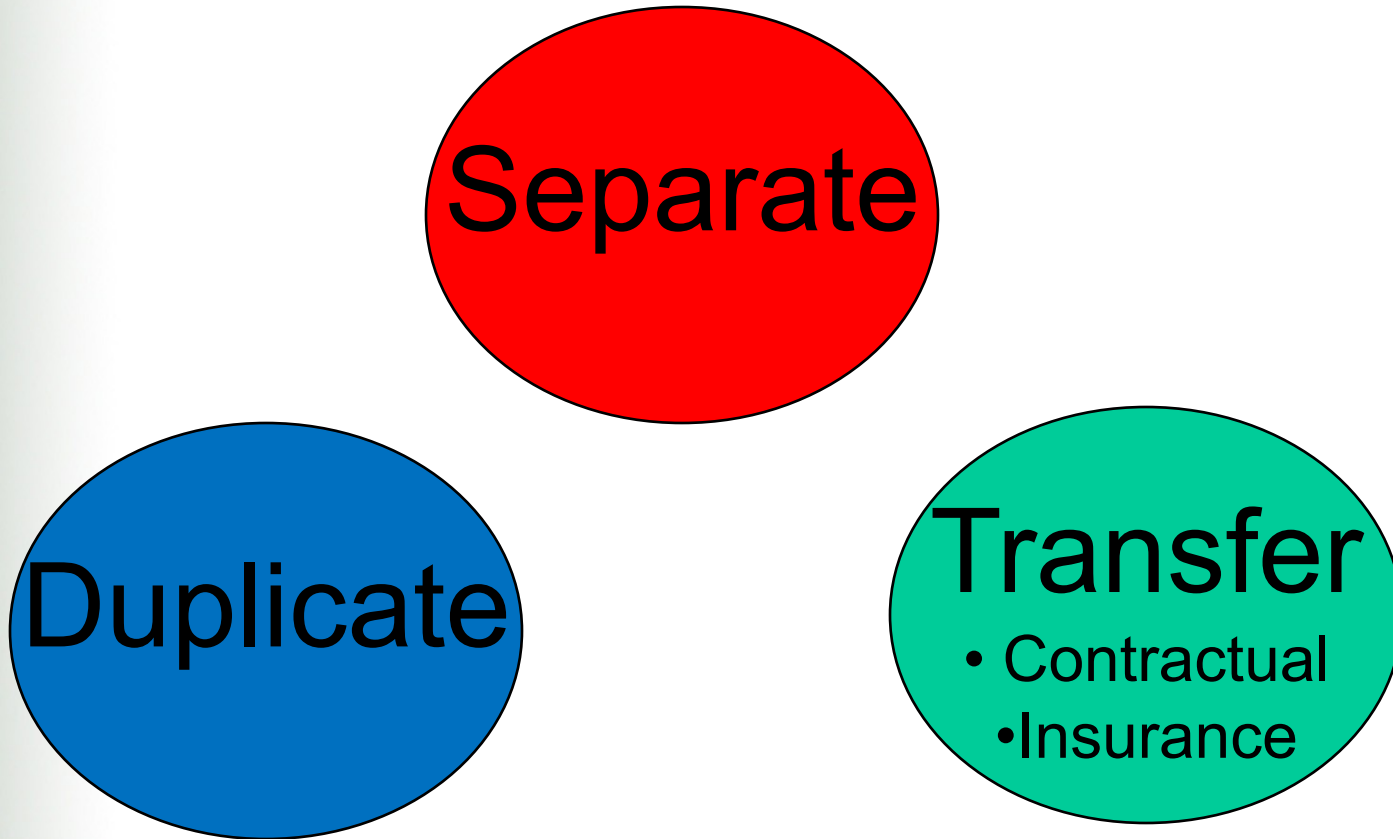
Pharma Risk Map



- 1 Pipeline Sustainability/Delivery
- 2 Product Exclusivity
- 3 Manufacturing Quality
- 4 Product Liability
- 5 FDA/ Government Regulation
- 6 Strategic Alliances/Outsourcing
- 7 Clinical Trials
- 8 Counterfeiting/Drug Reimportation
- 9 Product Recall
- 10 Government Controls/Pricing
- 11 Late Stage Product Delivery
- 12 Sales and Marketing Practices
- 13 Product Safety
- 14 Compliance Infrastructure
- 15 M & A

General framework

Risk mitigation techniques



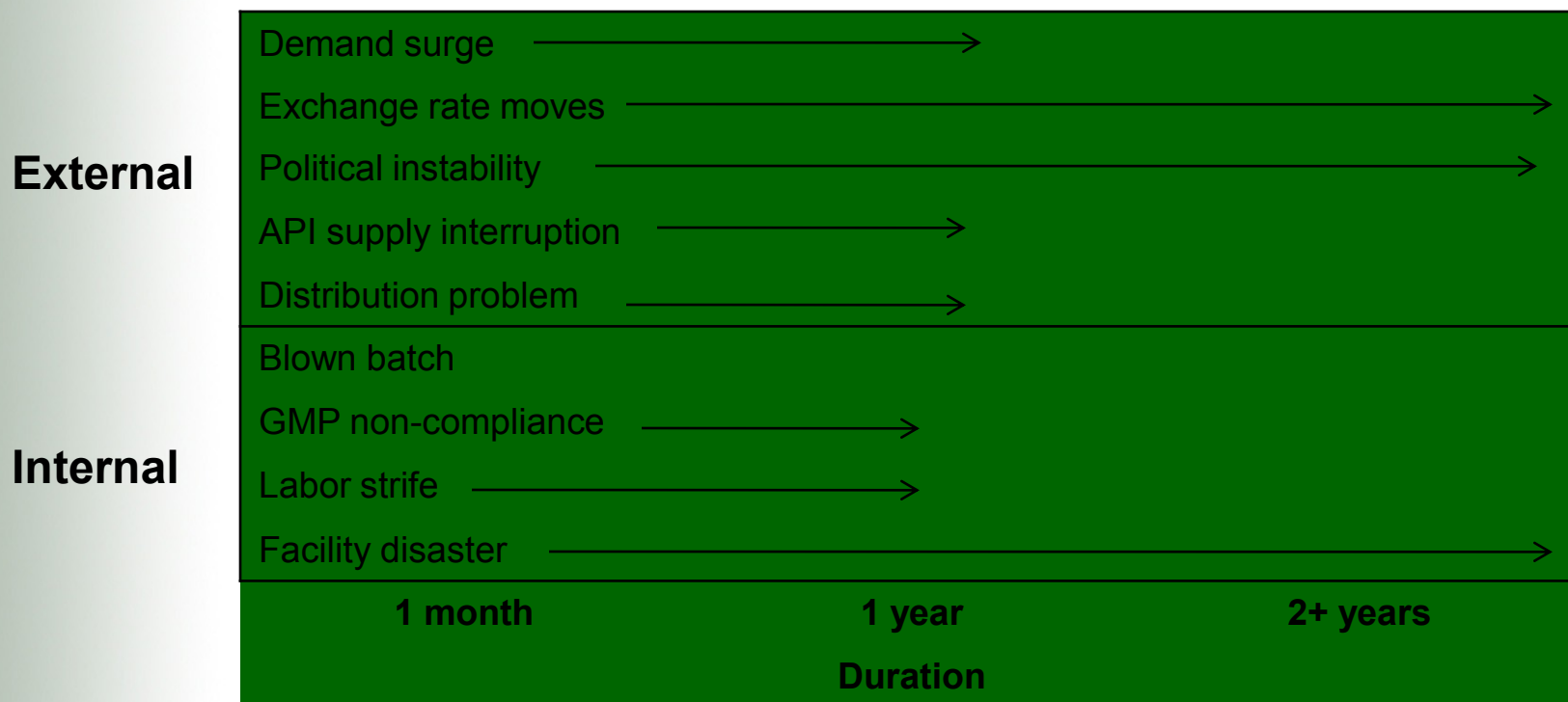
General framework

Level of risk management awareness

Risk Maturity Level	Risk Processes	Attitude	Behaviour	Skills & Knowledge
Risk Skepticism	No formal processes	Risk avoidance	Fear of blame culture	Unconscious incompetence
Awareness	Patchy use of standalone processes	Suspended belief	Reactive, fire-fighting	Conscious incompetence
Understanding & Application	Tick box approach	Passive acceptance	Compliance, reliance on registers	Conscious competence
Embedding & Integration	Risk embedded in key business processes	Active engagement	Risk-based decision making	Unconscious competence
Robust risk management	Regular review & improvement	Evangelical	Innovation, confident risk taking	Expert

Major supply chain risks

Sources of supply chain risk



Major supply chain risks

Preventing/remediating supply chain risk

	Event	Loss	Mitigation
External	Demand surge	Sales + share	Second source
	Exchange rate moves	Gross margin	Second source, hedge
	Political instability	Sales + share Manufacturing assets	Second source Insurance
	API supply interruption	Sales + share	Second source
	Distribution problem	Sales + share Cost of goods	Split shipments Insurance
Internal	Blown batch	API and materials	Training, audits
	GMP non-compliance	Gross margin Sales + share	Training, audits, QA Second source
	Labor strife	Sales + share	Labor relations Second source
	Facility disaster	Sales + share Replacement cost	Engineering Second source

Quantifying risks and costs

Expected loss from supply interruption

Annual sales	\$500 m
Market share	25%
Cost of goods	20%
Batches per year	50

Event	Blown batch	Supply disruption	Facility disaster
Duration	1 week	3 months	1 year
Initial lost revenues	0	\$125 M	\$ 500 M
Lost market share	0	25%>20%	25%>10
Total lost revenues (5 years)	0	\$590 M	\$ 1.7 B
Total lost margin	\$ 2 M	\$472 M	\$ 1.36 B

Quantifying risks and costs

Total cost of second source arrangement

Annual sales	\$500 m
Market share	25%
Dose cost of goods	10%
Batches per year	50

Costs	One-Time	Annual
Vendor search & contract	\$ 0.3 m	
Tech transfer & validation	2.0 m	
Incremental unit cost		2.0 m
Extra inventory		0.1 m
Contractor oversight		0.2 m
Total cost	\$ 2.3 m	\$ 2.3 m

Quantifying risks and costs

Benefit/cost assessment for second sourcing

	Blown batch	Supply disruption	Facility disaster
Lost contribution	\$ 2 M	\$472 M	\$ 1.44 B
Cost of second sourcing	\$ 13.8 M	\$ 13.8 M	\$ 13.8 M
Cost/Loss ratio	690%	3%	1%

Decision criteria

- What is combined probability of all possible risk scenarios?
- How risk averse are you?

Practical considerations

Attributes of a second source provider?

- Everything you would want in a primary source
 - Quality, financial stability

- Ability to respond quickly to changes in requirements

Practical considerations

How much volume to second source?

- Initially, enough to ensure manufacturer gains and maintains experience in making the product
 - 20% is typical starting point
 - Expect push back from primary source
- Likely to grow over time
 - Performance
 - Regional market growth
 - Exchange rates

Practical considerations

Where should second source be located?

- Physical separation is important
 - Second line in same facility is not second source
- Should not compound risk
 - Stable government and economy
 - Good trade links in and out
- Additional benefits
 - Open new markets/better serve existing ones
 - Exchange rate hedge

Practical considerations

When to engage second source?

- A balancing act
 - Don't want to make expenditure until approval and market acceptance demonstrated
 - But can take 1-2 years to identify/contract/validate
- Identify providers during initial CMO search
 - Could be second choice in the selection process

Practical considerations

Special regulatory considerations?

- Product compatibility
 - Is it the same product?
- How competency is being maintained
- How component inventory is managed
 - Is it being turned over regularly?

Concluding thoughts

- Supply chain risks are growing
 - Less inventory slack
 - Longer supply lines
 - Greater exposure to global political and financial events

- Second sourcing central to managing risk of supply interruption
 - Should be incorporated into supply chain planning from the beginning