

Integration of Risk Management into Product Strategy and Portfolio

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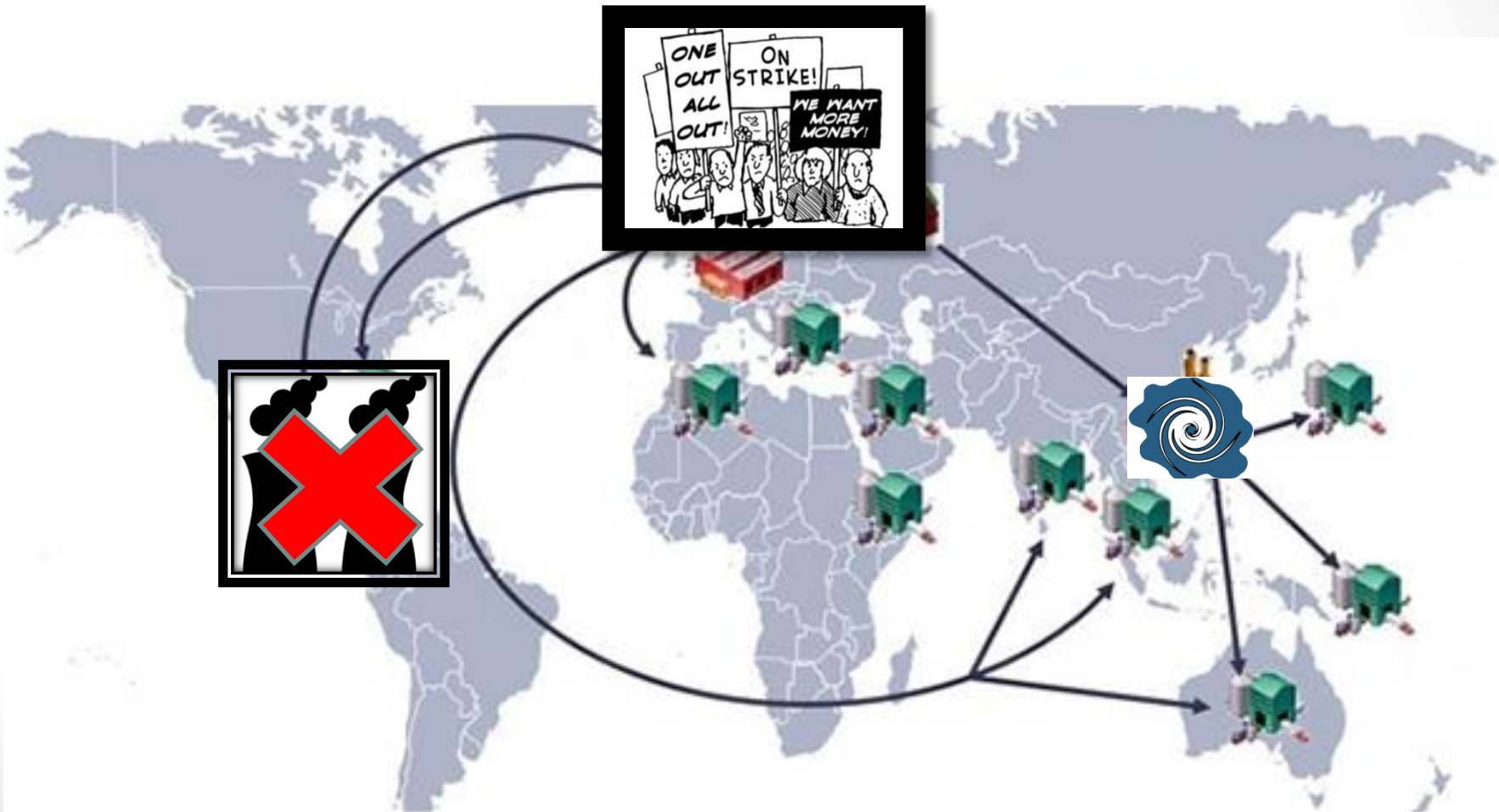


Focus for Today

- 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:

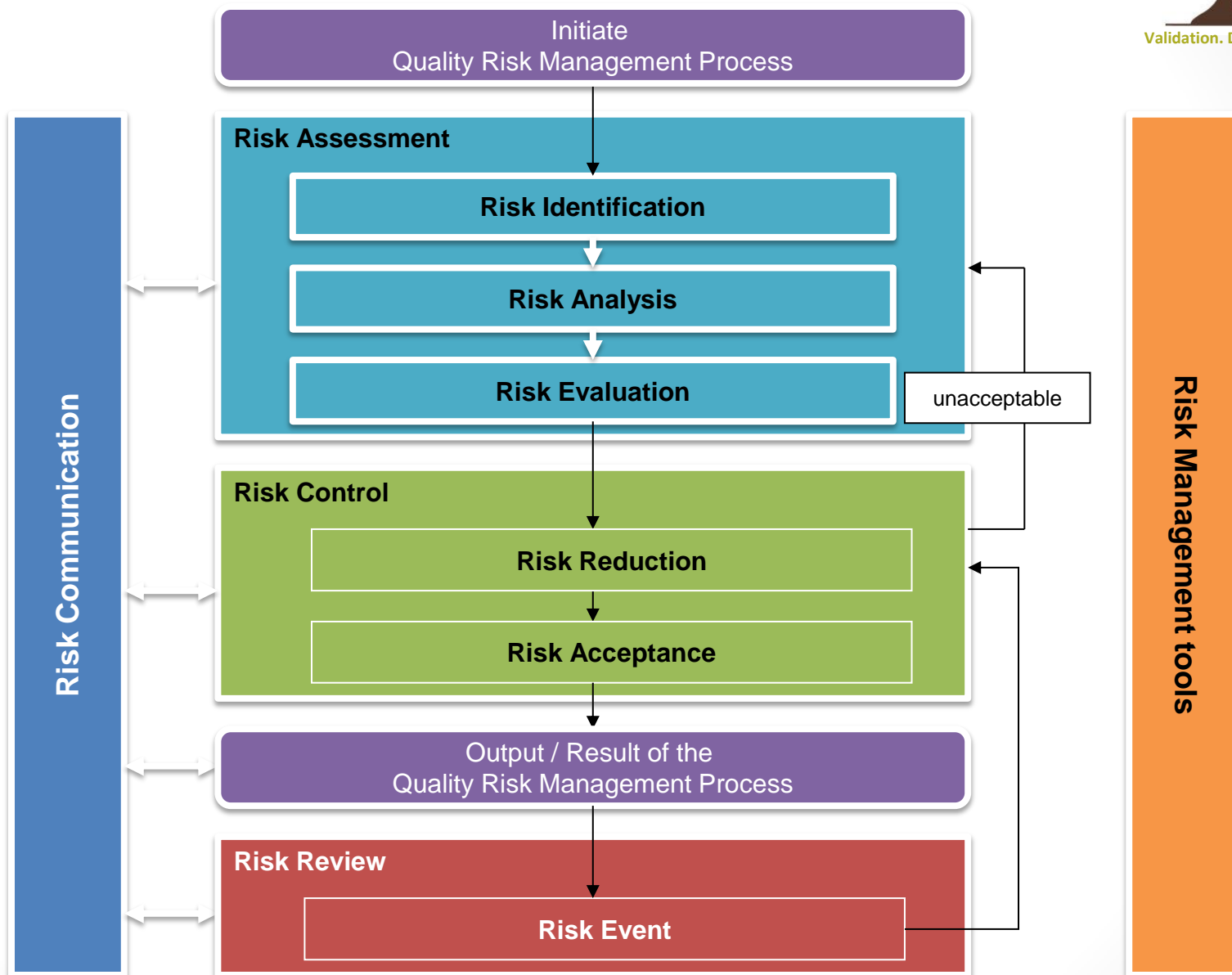
- prevent ALL bad things from happening
- make decisions for you
- will not be a one time exercise
- manage itself or keep information relevant
- execute its own risk control recommendations

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!***



Risk Management Process



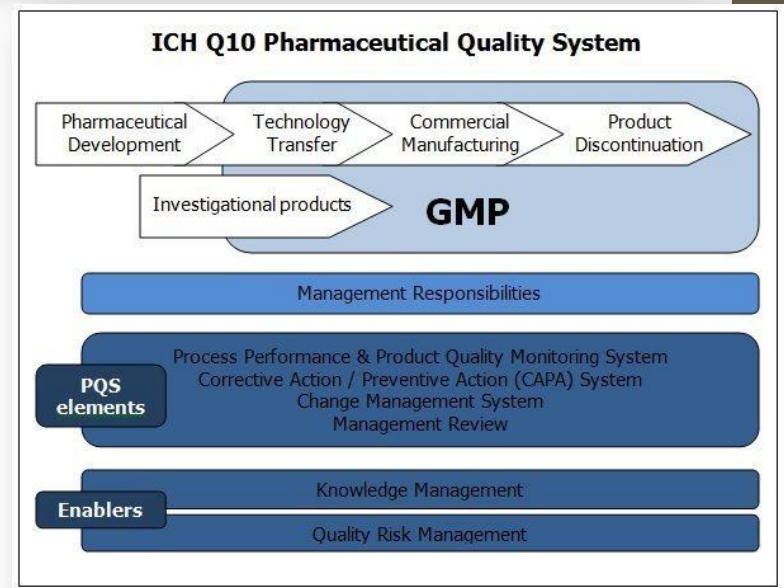
Product Portfolio and Level of Rigor



Validation. Delivered.

- 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

Define Impact to Patient			Availability of Alternatives		
			No Alternatives Available	Alternative Products Available: Similar Therapy	Exact Product Available but in Other Presentations
Therapeutic Use & Consequence if product not available	Medically Necessary Product, Life Supporting or Life Sustaining	Fatal or severe irreversible harm if the patient is not treated with the product	Risk Level A	Risk Level A	Risk Level B
	Acute Short Term or Chronic Long Term	Severe harm but reversible if patient is not treated with the product	Risk Level A	Risk Level B	Risk Level C
	Other Indications	Inconvenience if patient is not treated with the product	Risk Level B	Risk Level C	Risk Level C



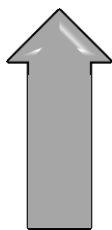
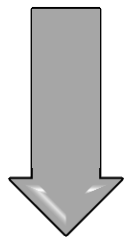
*TR-66 Risk Based Approach for Preventing and Managing Drug Shortages”

Define the Risk Question



Define the Risk Question: What events could result in a supply continuity risk to the patient, from both a Strategic and Operational Level?

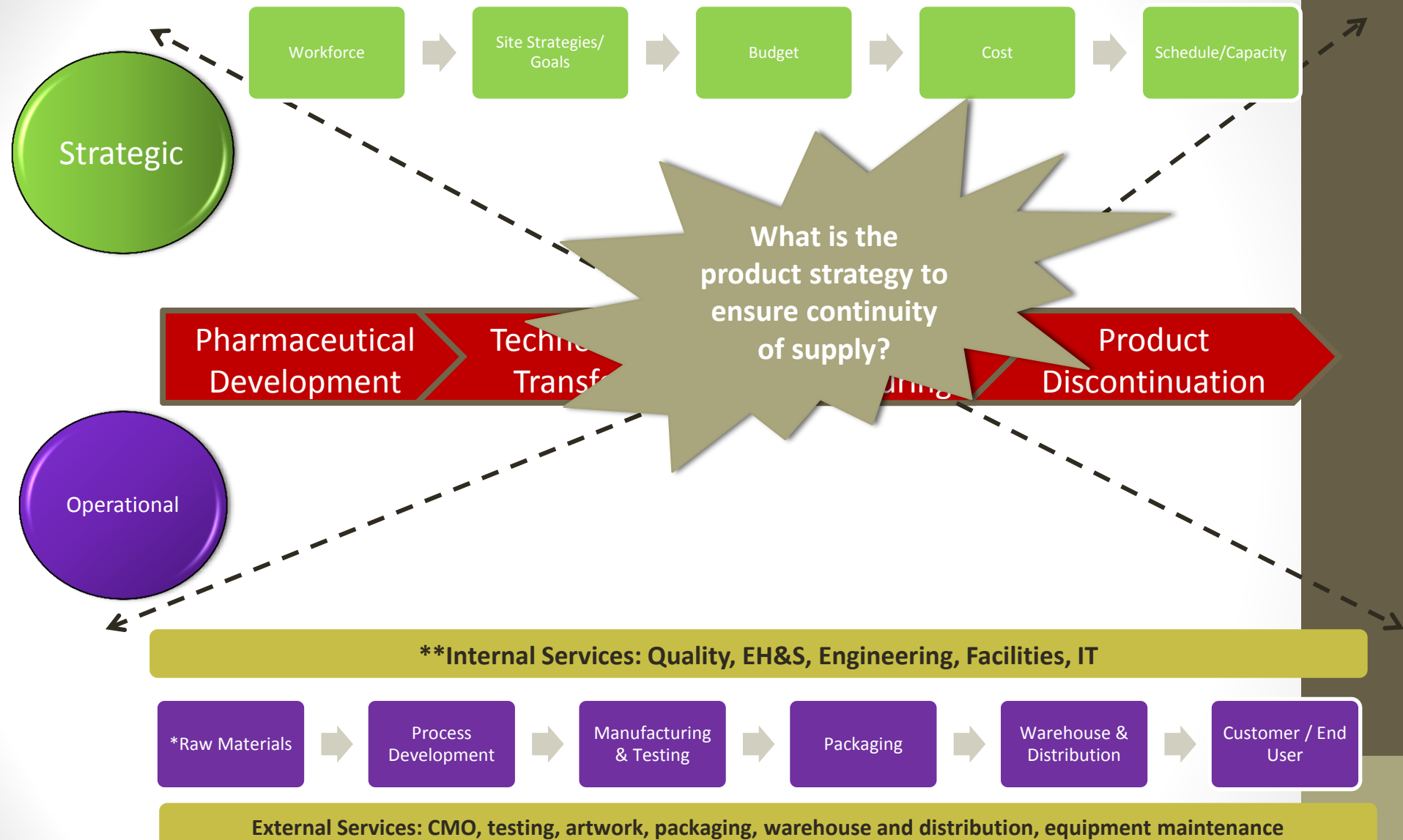
Top Down from
Senior Leadership



Bottom Up from Site
Level

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

Example Strategic and Operational Scope



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

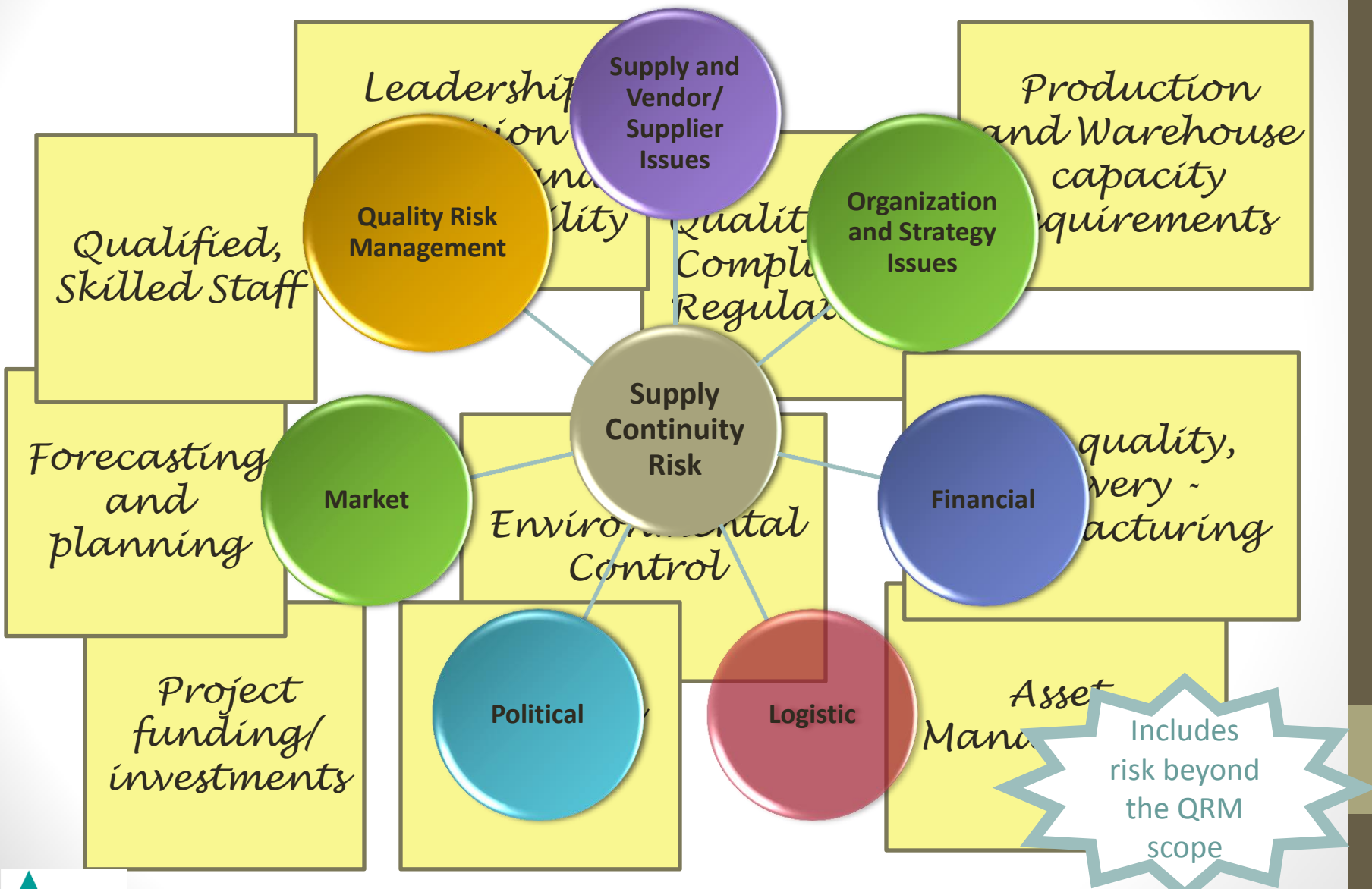
**A Guide to Supply Chain Risk Management for the Pharmaceutical and Medical Device Industries and their Suppliers – 2010 The Chartered Quality Institute

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



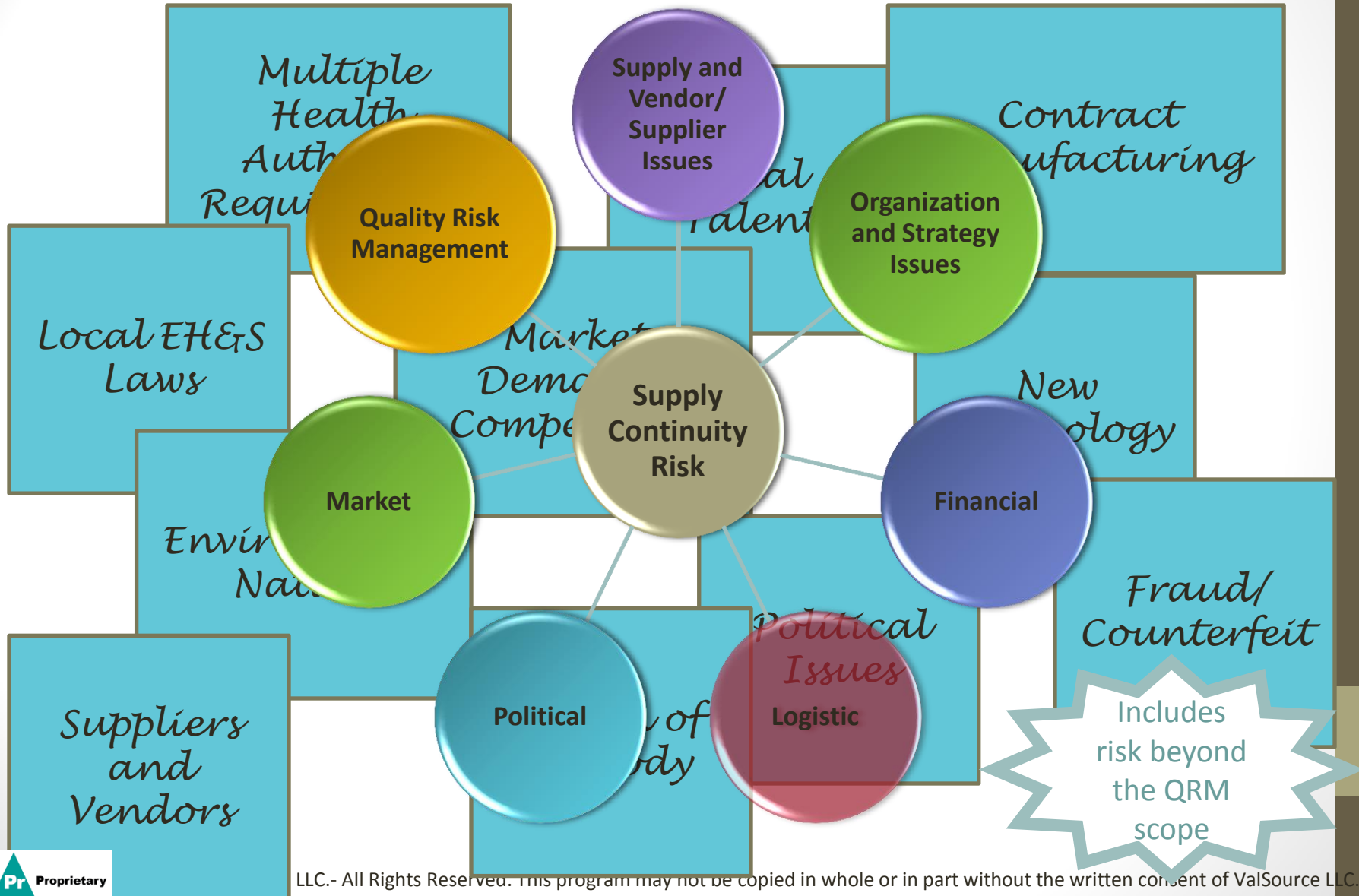
Internal Risk Landscape



External Risk Landscape

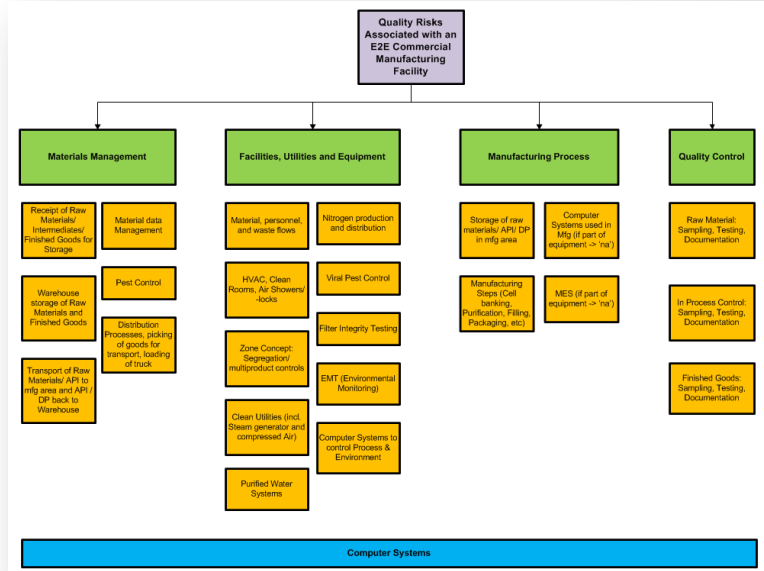


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Example Risk Gap Checklist - QRM

- 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?

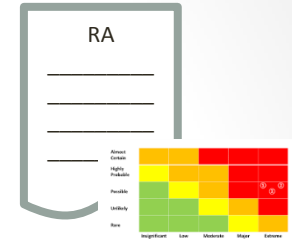
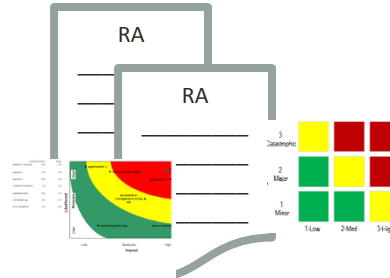
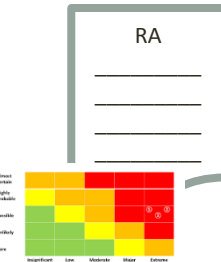
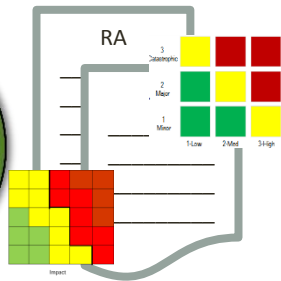
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Existing Risk Programs



Validation. Delivered.

Strategic



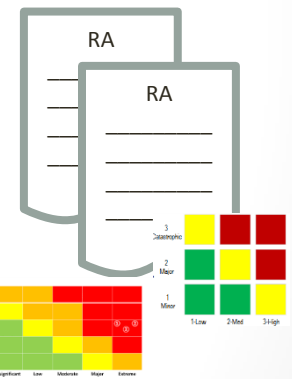
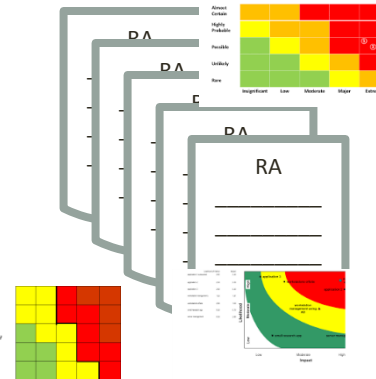
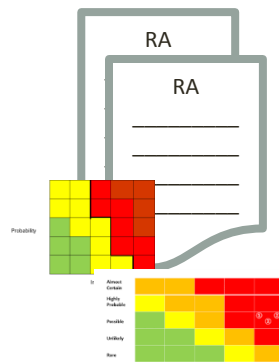
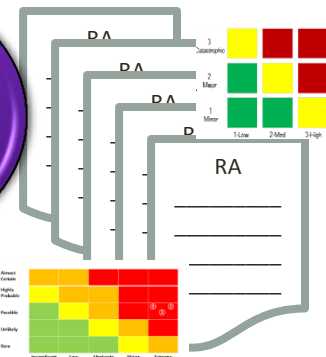
Pharmaceutical Development

Technology Transfer

Commercial Manufacturing

Product Discontinuation

Operational



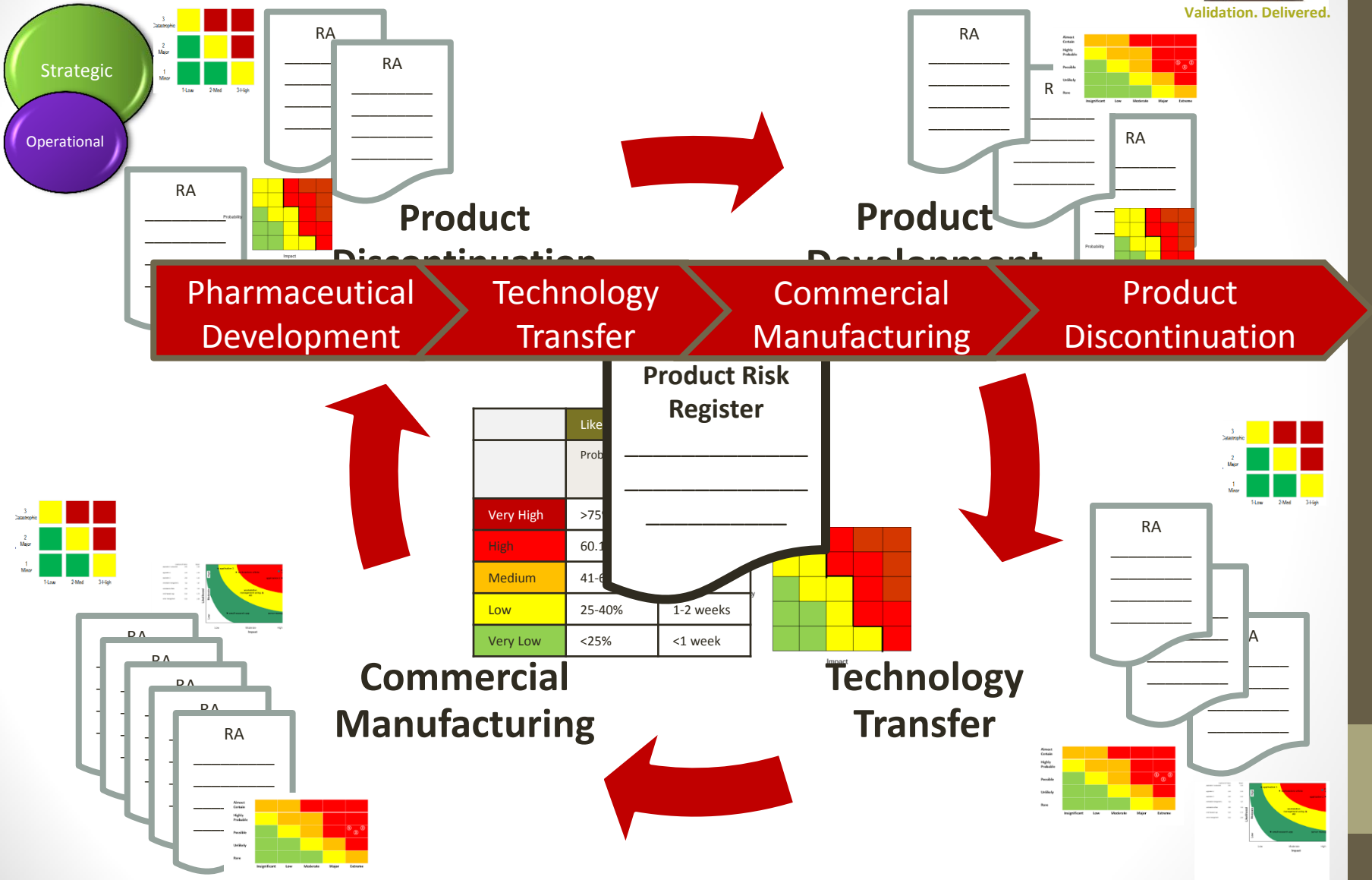
Various sources of risk, tool usage, scoring methodology, and gaps in communication

How do we bring this together?

Remove the Silos



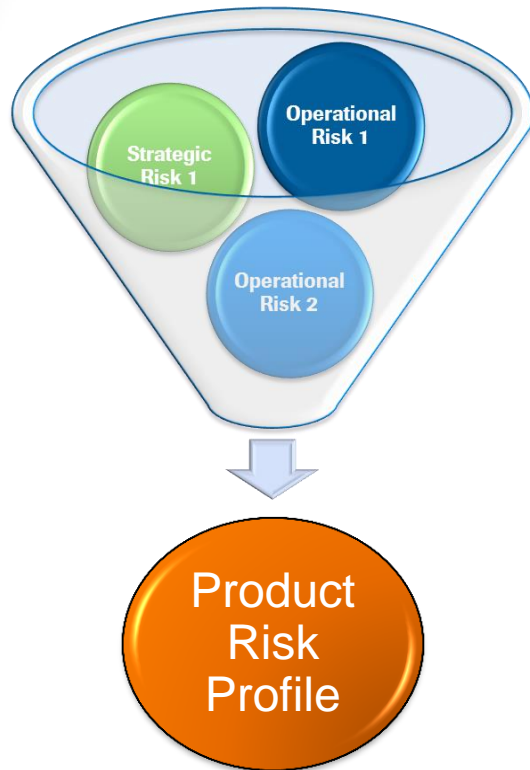
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Risk Aggregation



Validation. Delivered.



Strategy	Product	Risk Description	Risk Score	Proposed Mitigations	Risk Acceptance Statement	Accountable	Due Date
Strategy A	Product X	Delivery performance measurement may be at risk due to sole sourced trucking and shipping company		Secure contract with secondary backup shipping company	N/A; Risk is not acceptable	Bob Davis	Q2 2017

Strategic Risks

Example

Process Step	Product	Risk Description	Risk Score	Proposed Mitigations	Risk Acceptance Statement	Accountable	Due Date
Step A	Product X	Process step may not reach specification and batch will be rejected.		Perform studies to reduce variability in process step	N/A; Risk is not acceptable	Sanjay Johl	Q1 2017

Operational Risks

Example

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

Analyze and Evaluate



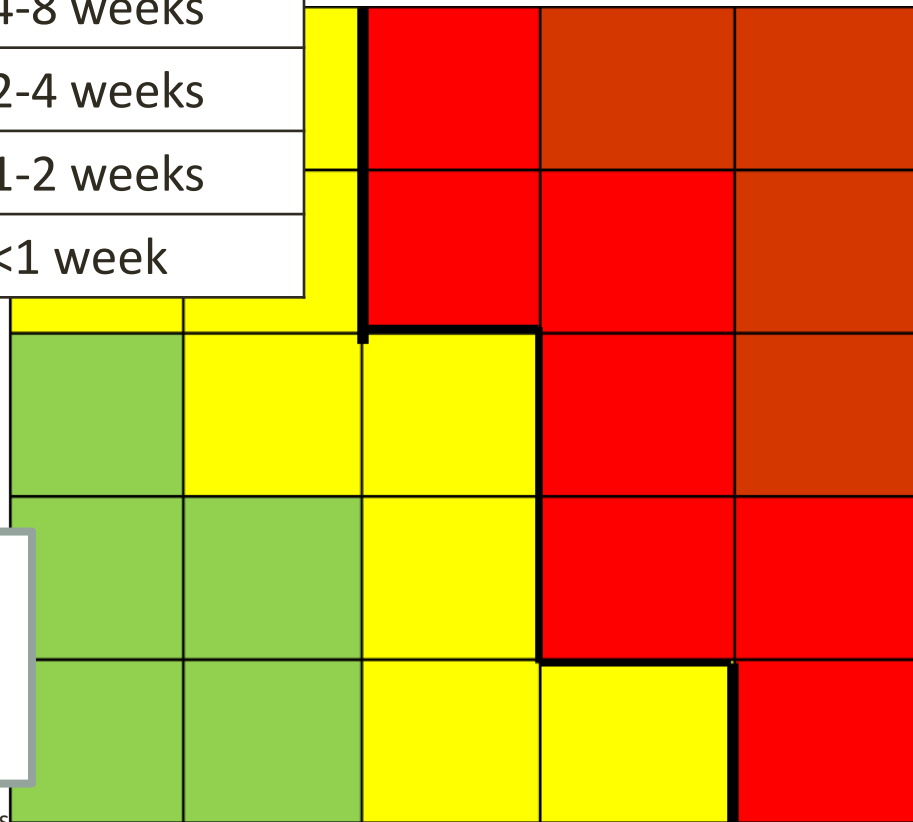
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	Likelihood	Impact
	Probability	Time-Supply Chain Disruption
Very High	>75%	>8 weeks
High	60.1-75%	4-8 weeks
Medium	41-60%	2-4 weeks
Low	25-40%	1-2 weeks
Very Low	<25%	<1 week

Must develop one definition for product supply disruption to patient

Probability

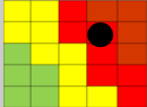
Impact should be right sized to fit the specific product strategy (demand, patient base, future markets, clinical trials)



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!

Product	Risk Description	Risk Score	Proposed Mitigations	Risk Acceptance Statement	Accountable	Due Date
Product X	Trucking company labor dispute may result in 4-8 weeks in shipping disruptions in South American countries		Secure contract with secondary backup shipping company	N/A; Risk is not acceptable	Bob Davis	Q2 2017

**Example Product Risk
Scorecard**

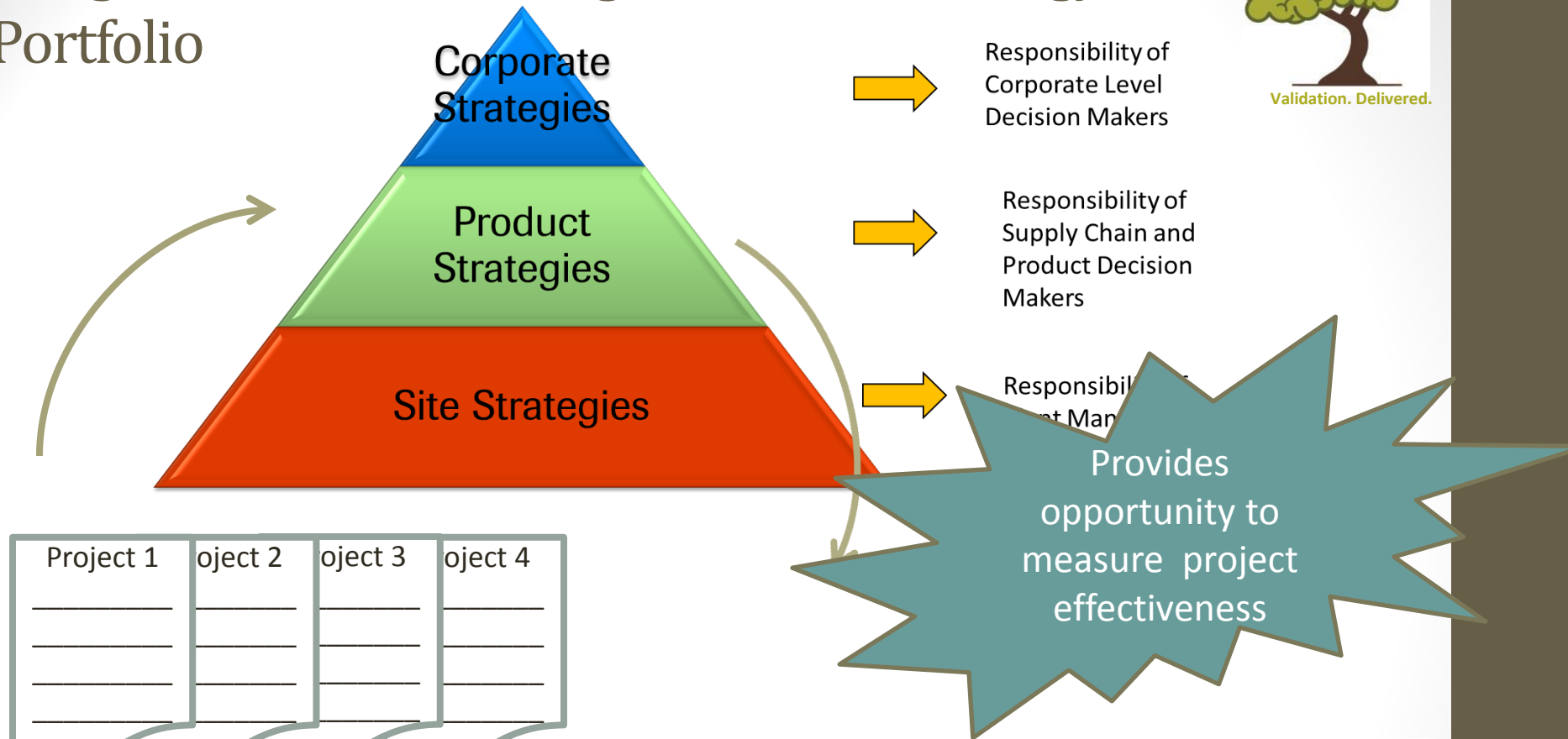
Risk Decision Matrix



Risk Category	Risk Acceptability Decision
High	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.
Medium	Further risk reduction should be considered. Plans must be developed to take actions on risks should they be realized.
Low	Risk is acceptable. No further action is required.

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

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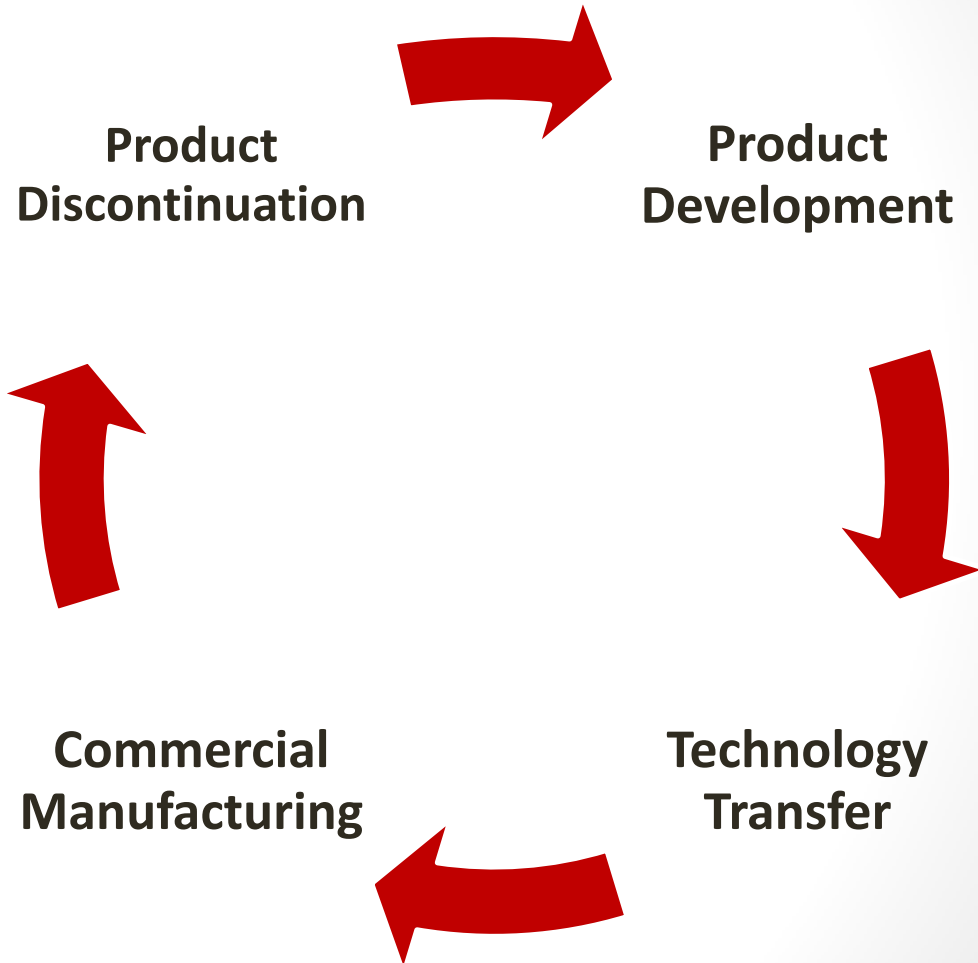
Example Product Risk Scorecard

Risk Communication

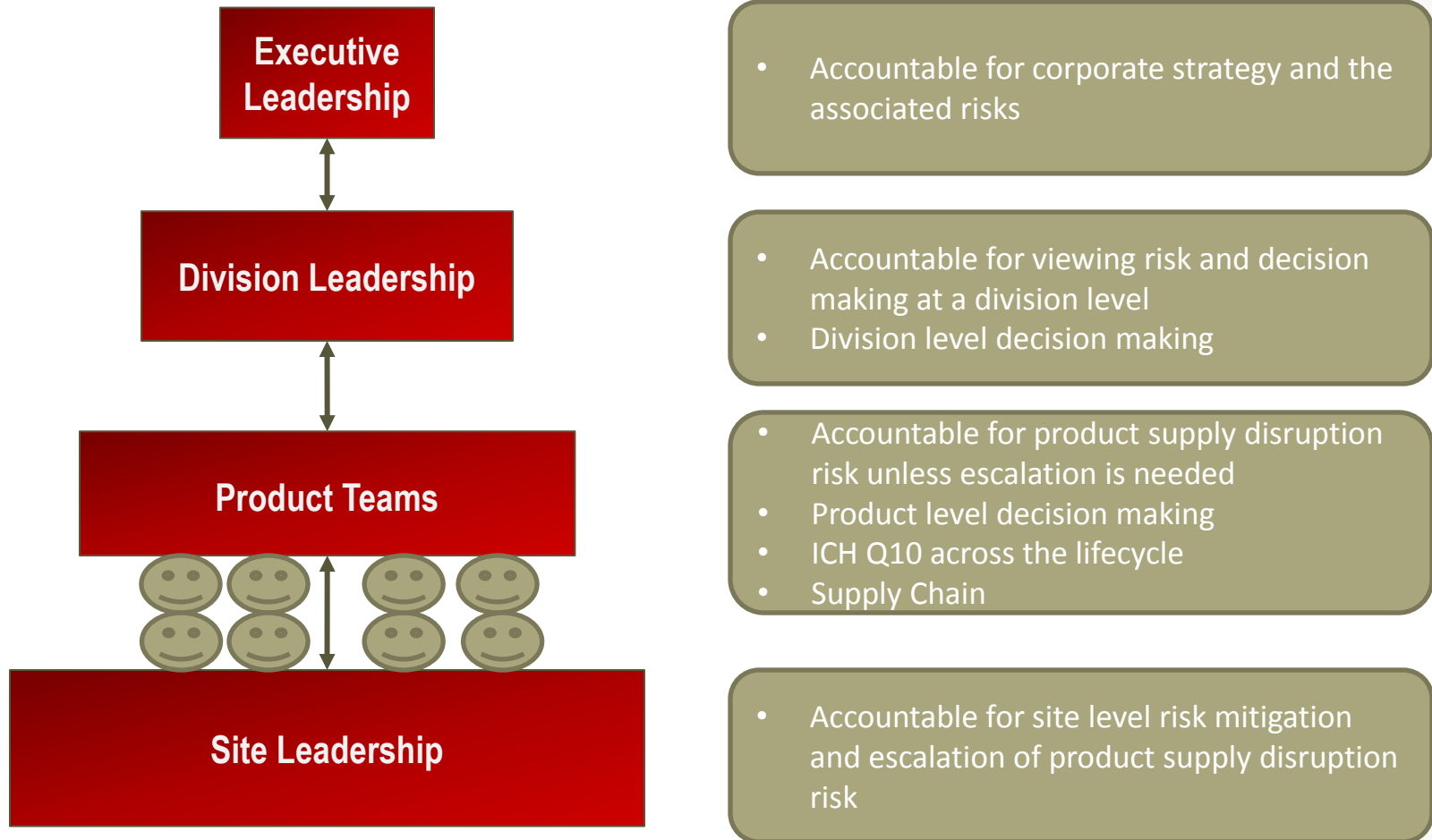


There must be risk communication between the phases of the lifecycle to maintain knowledge management:

- Products
- Product families
- Similar technology platform



Governance



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.



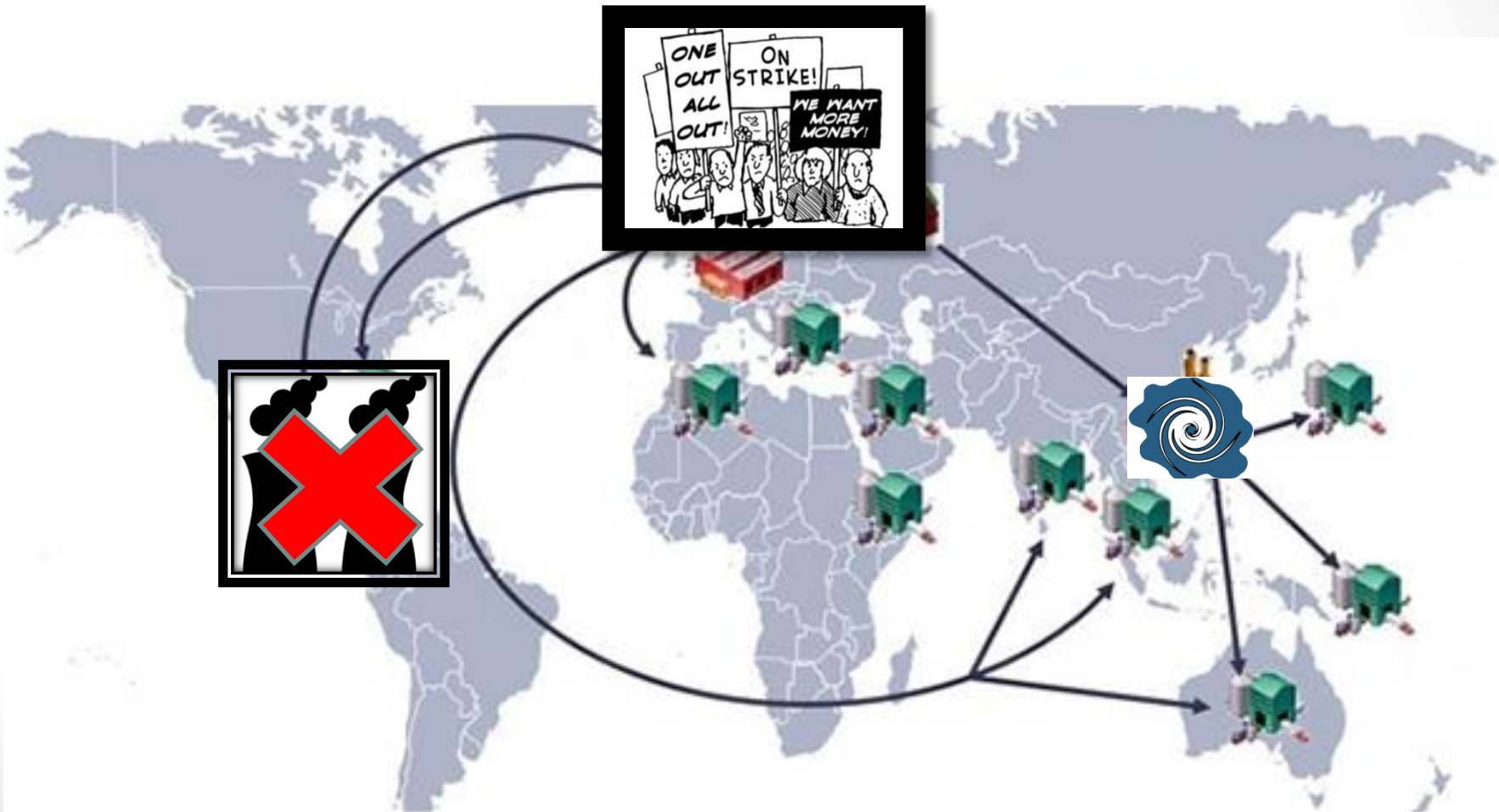
Failure will be imminent if....



- 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!