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Integrated Risk Management from Design to Delivery

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Integrated Risk Management

Integrated risk management (IRM) is a set of practices and processes supported by a risk-aware culture and enabling technologies, that improves decision making and performance through an integrated view of how well an organization manages its unique set of risks.*

IRM is *often* ***expanded out from QRM*** *to meet business needs beyond product quality and* ***allows the pharmaceutical sector*** *to identify and manage end-to-end products risks to ensure a reliable, compliant supply to patients.*

Leveraging the concepts of Quality Risk Management per ICH Q9, establishing an IRM program enables the:

One, standardized ***process*** for the aggregation, tracking, and management all supply continuity risks across the company

- IRM will provide ***visibility and prioritization*** of supply continuity risks

Simple, effective ***tool /technology*** to enable direct visibility and faster understanding of a company's s end-to-end supply continuity risks

- IRM will provide tools and methods to manage the lifecycle of a risk, such as how it is ***identified, assessed, communicated and escalated to Senior Leadership***

Effective ***governance*** to coordinate risk management, escalation, and response execution by sites and functions

- IRM will provide processes for how risk control recommendations are incorporated into ***business strategies, portfolio management, and in decision making principles.***

*https://www.gartner.com/en/information-technology/glossary/integrated-risk-management-irm#:~:text=Integrated%20risk%20management%20(IRM)%20is,its%20unique%20set%20of%20risks.

IRM Drives Consistency, Understanding, and Sharing of Supply Risks

1 **Pharmaceutical companies need *Consistency* in how they view and discuss risk across the value chain**

2 **Pharmaceutical companies need to *Understand* their risks, causes of risks, and the detail behind risk responses**

3 **Pharmaceutical companies need to *Share* and leverage risk information effectively across their network**

Continuous improvement managing known risks

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Help identification of risks that are not visible

Leveraging ICH Q9 Principles to Build a Successful IRM Program

Risk Communication
Timely tracking and communicating risks to decision makers and stakeholders

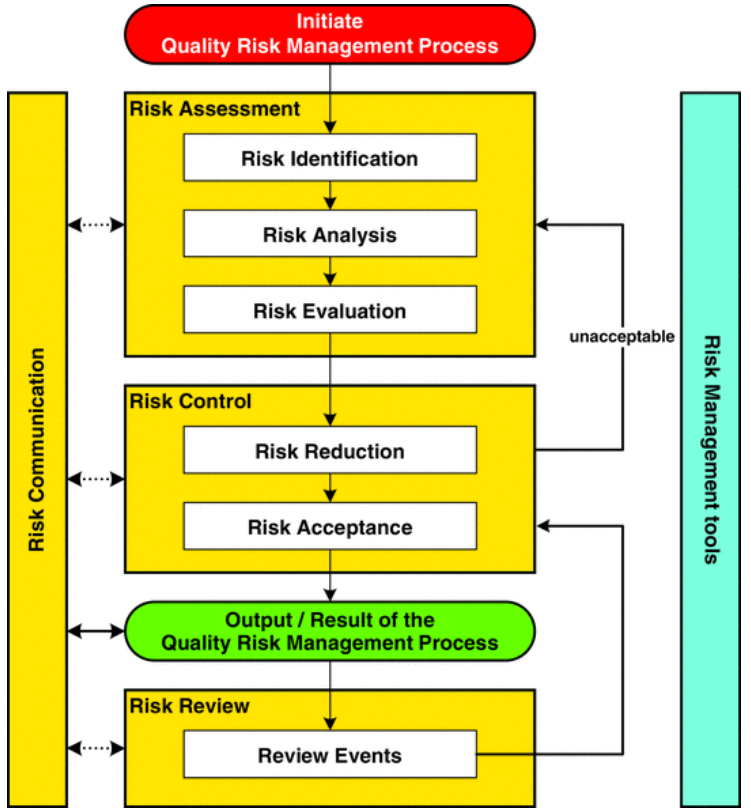
Initiation and Strategy
Developing, deploying, and implementing a framework for continuous improvement through effective governance and ownership of risks

Risk Assessment
Identification, analysis, evaluation and prioritization of risks

Risk Control
Identification of existing controls and implementation of additional controls to manage potential risks

Risk Review
Monitoring the effectiveness of controls, tracking risk ownership and accountability in decision making

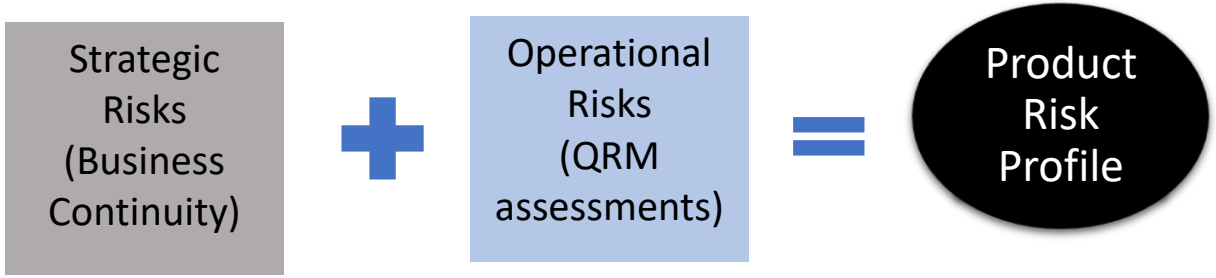
Technology
Designing and implementing a digital solution to allow consistency in risk reporting



IRM Risk Question

Question 1: What events could result in potential supply continuity risks to the patient, from both a Strategic and Operational Level?

Question 2: What is the product strategy to ensure continuity of supply?



Key Process Indicators and key business objectives should be aligned to measure product availability to the patients

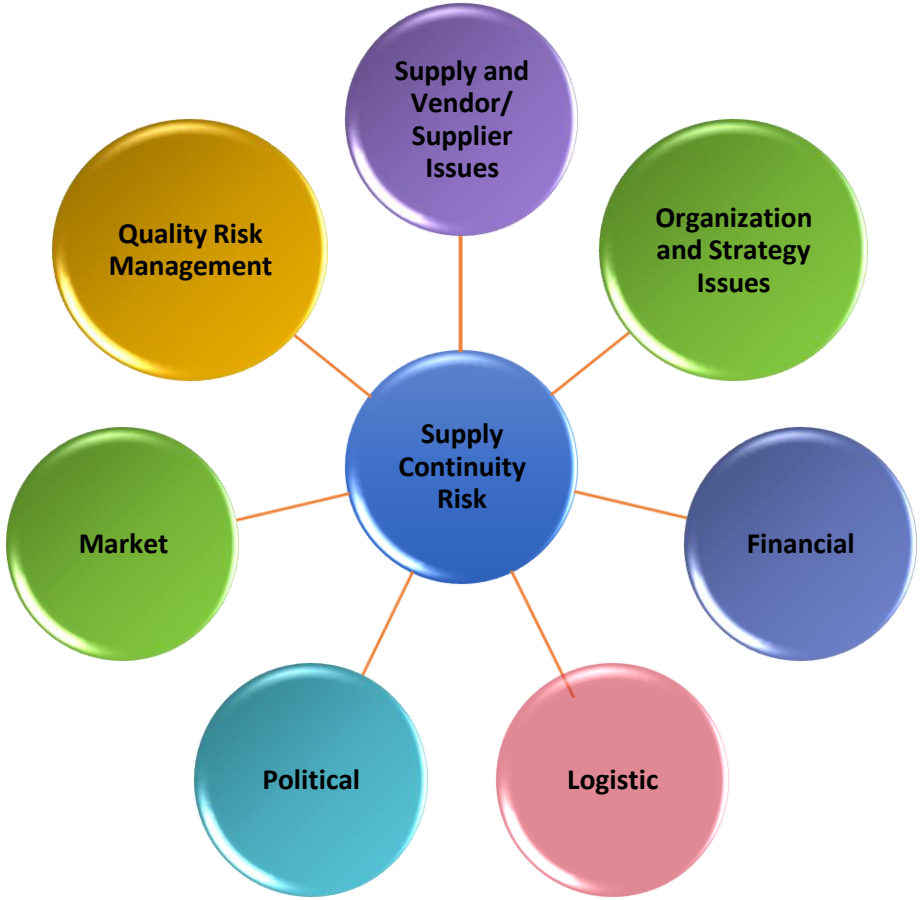
Understand Existing Landscape- How Do we Bring All Together

Various sources of risk, tool usage, scoring methodology, and gaps in communication requires assessing existing Risk Management Programs.

THERE IS NO ONE SIZE FITS ALL TOOL

And

Engaging Leadership in Strategic Risk Management activity;
Without sponsorship from Leaders an IRM program will not be successful.



Consistency

IRM will drive consistency in how all supply risks are viewed across the organization

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IRM will promote consistent risk language, including the definition

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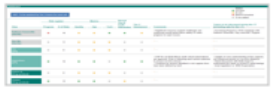
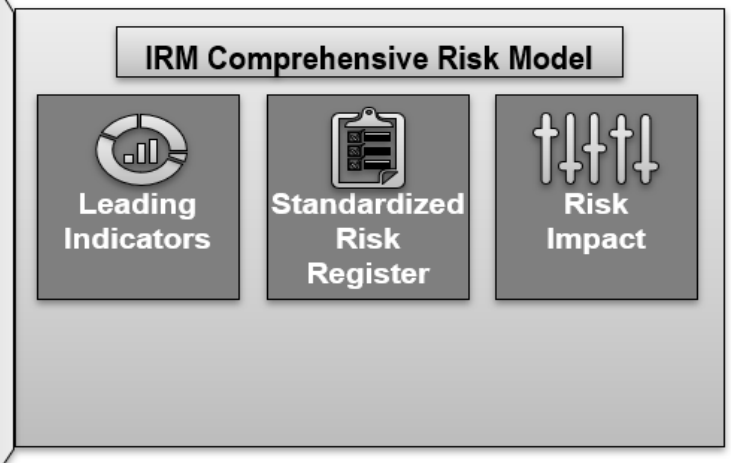
Risk Program	Tool	Scoring System
EH&S Risks		Risk Priority Level High – Med – Low
Device Risk Management		Impact & Probability Scoring 2 – 4 – 6 – 8 – 10
Technology Transfer Risk Assessment		Impact & Probability scoring 1 – 3 – 7 – 9
Project Risk Assessments		Risk Elements 1 – 3 – 6 – 9
Loss Prevention Risk Assessment		Risk Priority Level 1 – 2 – 3
QRM		Quality/Regulatory impact 2 – 4 – 6 – 8 – 10
Analytical I Risk Assessment		Impact & Probability scoring 1 – 3 – 7 – 9



G. Haddad, PhD

Understanding

1 Pharmaceutical companies need *Consistency* in how they view and discuss risk across the value chain

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Continuous improvement managing known risks

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Help identification of risks that are not visible

IRM technology will give all levels of the Company one, unified view of *all company supply continuity risks* to enable understanding and action

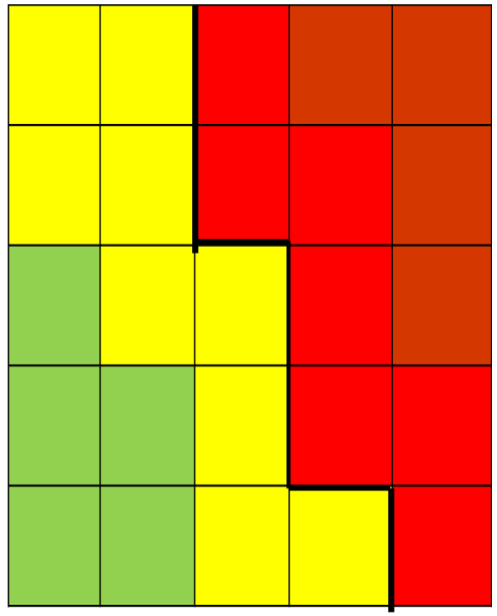
- Risks are updated and maintained in a single register, either for the Product or the Site
- Risk review frequency must be established in the charter. Risks must be updated for a healthy program

Standard Scoring and Risk Tolerance Matrices

	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

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

Must develop one definition for product supply disruption to patient



Risk Decision Matrix

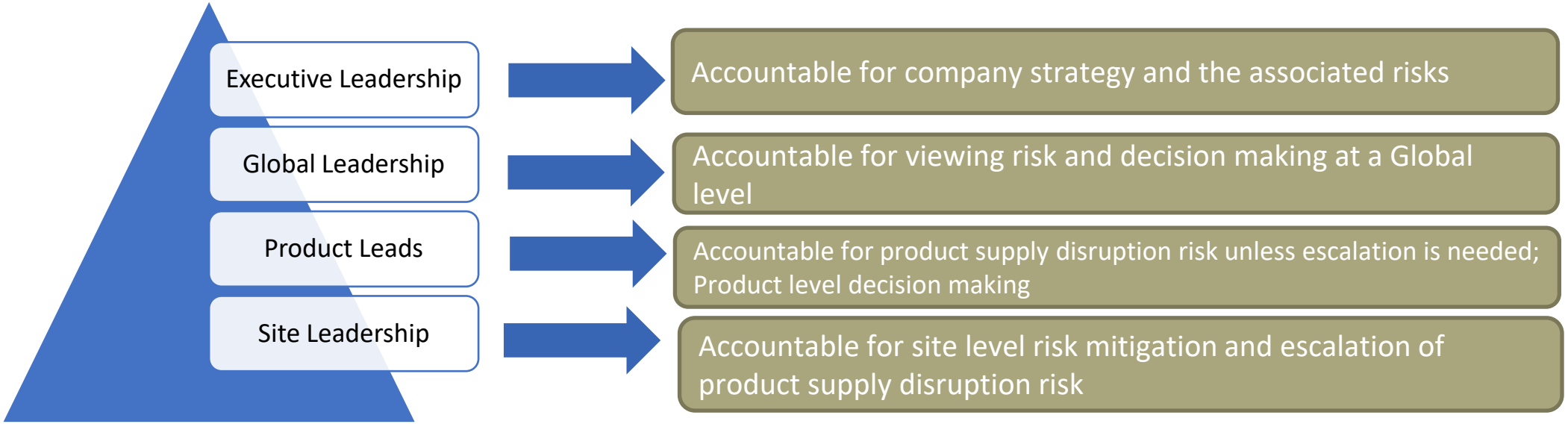
Risk Category	Risk Acceptability Decision
High	Risk reduction/control actions are required. Recommended risk control actions must be integrated into the project portfolio process. If risk is accepted this must be documented and approved by leadership and plans must be developed to take actions on risks 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.

Slide courtesy of Lori Richter, Ultragenix

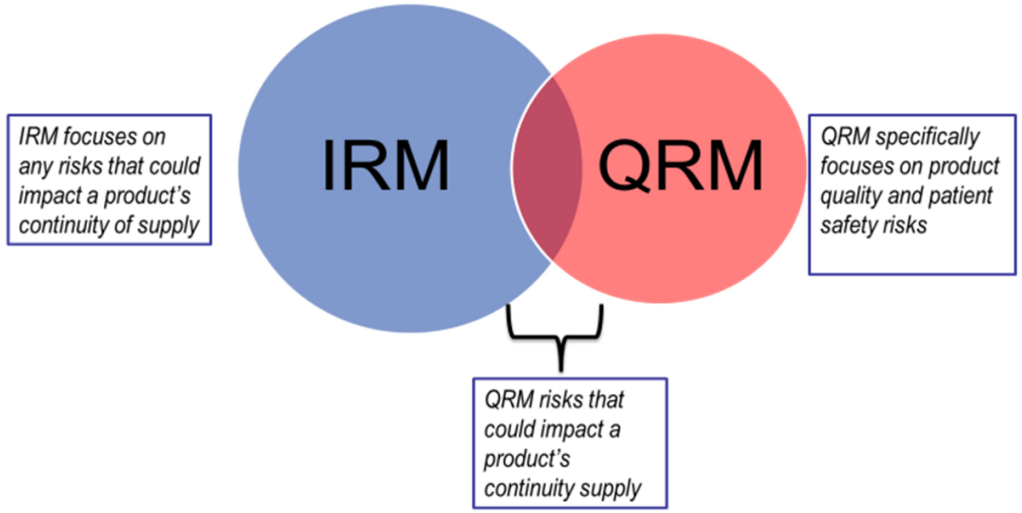
Sharing

Risk Communication
Timely tracking and communicating risks to decision makers and stakeholders

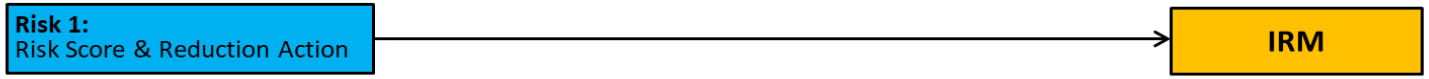
Defined governance and business processes will help identify, manage, and communicate risks as well as drive accountability



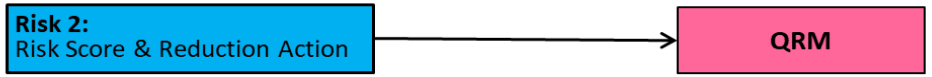
QRM vs. IRM



Risk: product quality impact = NO; supply reliability impact = YES



Risk: product quality impact = YES; supply reliability impact = NO



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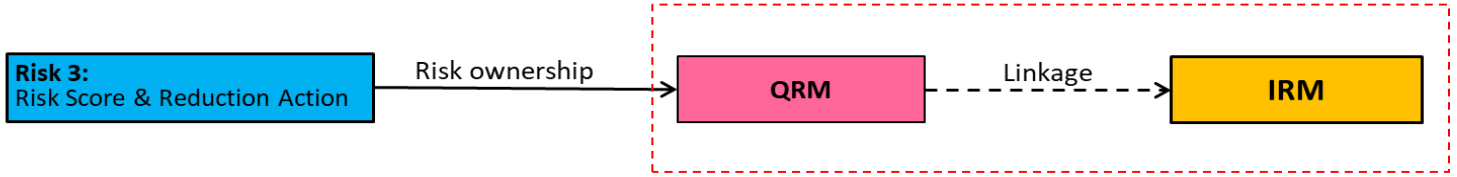

IRM evaluation could **increase** prioritization of risk reduction action beyond QRM prioritization
IRM could **not** decrease QRM prioritization of product quality driven actions

Benefits of IRM

- Real-time product knowledge
- Faster decision making based on data
- Protecting your ***reputation and integrity***
- Improving product pipeline and development of the future products bases on lessons learned from risks of current products
- ***Portfolio, budget, and strategy aligned*** and based on a shared process

Questions

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