Integrated Risk Management from Design to Delivery
Disclaimer

This presentation is intended for educational purposes only and does not replace independent professional judgement.

Statements of fact and opinions expressed are those of the presenter and, unless expressly stated to the contrary, are not the opinion or position of MSD.
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 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**.

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
- Help identification of risks that are not visible
Leveraging ICH Q9 Principles to Build a Successful IRM Program

**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

---

G. Haddad, PhD
**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.**
IRM will drive consistency in how all supply risks are viewed across the organization.

IRM will promote consistent risk language, including the definition...
Understanding

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

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability</td>
<td>Time-Supply Chain Disruption</td>
</tr>
<tr>
<td>Very High</td>
<td>&gt;75%</td>
</tr>
<tr>
<td>High</td>
<td>60.1-75%</td>
</tr>
<tr>
<td>Medium</td>
<td>41-60%</td>
</tr>
<tr>
<td>Low</td>
<td>25-40%</td>
</tr>
<tr>
<td>Very Low</td>
<td>&lt;25%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Risk Acceptability Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>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.</td>
</tr>
<tr>
<td>Medium</td>
<td>Further risk reduction should be considered. Plans must be developed to take actions on risks should they be realized.</td>
</tr>
<tr>
<td>Low</td>
<td>Risk is acceptable. No further action is required.</td>
</tr>
</tbody>
</table>
Sharing

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

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

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.

Executive Leadership
Accountable for company strategy and the associated risks

Global Leadership
Accountable for viewing risk and decision making at a Global level

Product Leads
Accountable for product supply disruption risk unless escalation is needed; Product level decision making

Site Leadership
Accountable for site level risk mitigation and escalation of product supply disruption risk
**QRM vs. IRM**

**IRM** focuses on any risks that could impact a product's continuity of supply.

**QRM** specifically focuses on product quality and patient safety risks.

**QRM risks that could impact a product's continuity of supply**

---

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

**Risk 1:** Risk Score & Reduction Action

---

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

**Risk 2:** Risk Score & Reduction Action

---

**Risk:** product quality impact = YES; supply reliability impact = YES

**Risk 3:** Risk Score & Reduction Action

---

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 based on lessons learned from risks of current products
- **Portfolio, budget, and strategy aligned** and based on a shared process
Questions