



Managing risk to ensure quality, reliability and safety

Over the last few years we have seen the cold chain industry face significant new challenges — from a global pandemic and geopolitical tensions, to the emergence of advanced therapies with stricter temperature requirements and an expanding global market with new routes and new partners. These challenges not only place new demands on supply chains and all stakeholders, but they also add new risk on top of the existing threats and costs caused by delays, temperature excursions, and shipping and handling errors.

As a result, risk management has become an increasingly vital focus area. Here, we explore the different risk factors that need to be considered to ensure transportation that is highly dependable, as well as giving you a best-practice approach to risk management for our industry.

Mapping risk in the cold chain

Safe, effective storage and transportation of temperature-sensitive products is a complicated and demanding business involving a lot of moving parts. As a result, risk management for the cold chain covers a wide scope and the identification, assessment and mitigation of many potential risks including:

- **Temperature deviations.** Maintaining the right temperature range is one of the most critical areas for ensuring life-changing medicine gets to where it's needed.



- **Equipment failure.** The reliability of refrigeration and temperature-monitoring equipment needs to be assessed, including preventive maintenance measures to reduce the risk of breakdown and unplanned downtime.
- **Packaging failure.** Robust and quality-assured packaging is needed to minimize the risk of temperature deviations and product damage in transit.
- **Human error.** With people involved throughout multiple and critical stages including loading and unloading, temperature monitoring and documentation, there is a need for comprehensive training and adherence to standard operating procedures (SOPs) to reduce the potential for error.
- **Supply chain disruption.** The risk of transport delays, customs issues and other logistical challenges need to be considered. Along with contingency plans to include secondary and tertiary plans to handle these potential interruptions.
- **Unexpected events.** Extreme weather, natural disasters and geopolitical crises are frequently unforeseeable but the need for contingency plans and risk-mitigating measures are needed for when these instances occur.
- **Inaccurate information.** It is critical to ensure accurate product tracking and temperature monitoring data is available to stakeholders while also preventing against unauthorized access or data breaches.
- **Non-compliance.** Adherence to regulatory standards and industry guidelines is an essential part of risk management. Perhaps nowhere more so than in cold chain that brings two highly regulated industries together: pharma and aviation.
- **Market and demand changes.** Demand fluctuations and/or seasonal variations can be forecast to avoid excessive disruption to the supply chain and maintain efficiency.
- **Sustainability.** Choosing a total landed cost approach coupled with reusable equipment / containers to drive efficiencies in the supply chain by mitigating waste and supporting reliability.
- **Product expiration.** Delays in transportation and storage create the risk of exceeding product shelf life, a risk that can be minimized through effective inventory management and efficient processes.
- **Cross-border issues.** International shipments must successfully navigate different regulatory environments and address the challenge of customs procedures and compliance with international standards.

Taking a best-practice approach to risk management

When addressing the risk factors in these different areas, it is crucial to have a structured approach. Ad hoc problem-solving and/or isolated measures can lead to improvements but, without a consistent, shared framework for identifying, assessing and mitigating risk there is a danger that key details and opportunities to holistically improve are missed.



Here is a best-practice approach that can be applied for organizations, individuals and for the entire cold chain industry.

01

Characterize the process

Build a strong starting point and a common understanding with all stakeholders by clearly documenting and describing the distinctive structure and properties of each process. Define the origin, destination, Incoterms®, service providers and service levels such as IATA Special Handling Code Descriptions for temperature requirements. Establish the times, transfer points, geography and seasons of routes. And describe the type, size and supplier of the thermal shipping system and temperature monitoring.

03

Implement measures

Establish the standard operating procedures (SOPs) and/or quality-technical agreements (QTAs) for successful implementation.

SOPs, such as for Shipment Preparation, Shipment Transport and Shipment Receipt are day-to-day operational documents. While QTAs are generally higher-level documents agreed upon by cross-functional management representatives from the various organizations with process responsibility.

02

Assess the risk

Develop an end-to-end process flow to evaluate the steps — and associated risks. This should cover the time and temperature at every step from the shipping site to delivery.

04

Review Performance

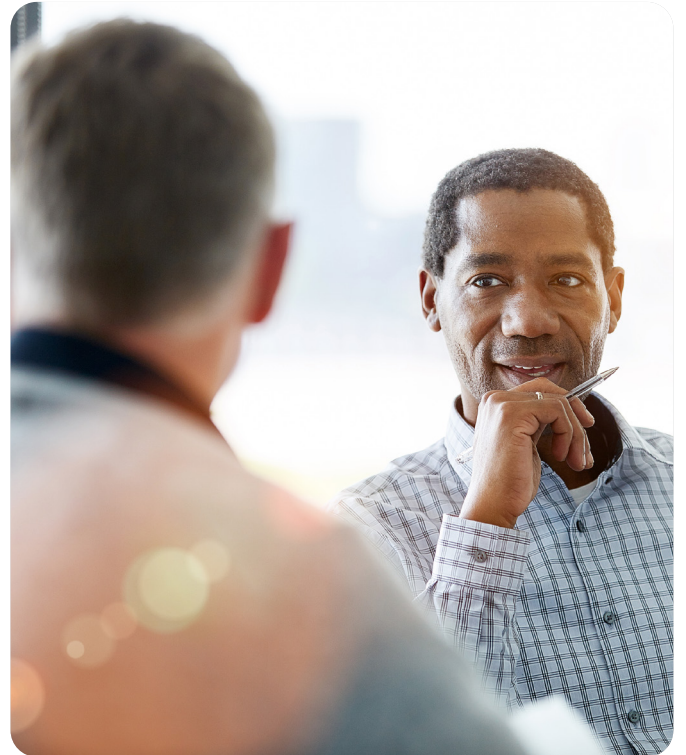
As part of a Quarterly Business Review or similar, meet regularly with stakeholders to review performance. This according to pre-defined KPIs such as temperature performance, exceptions, deviations, complaints, corrective actions and timely delivery. Also to register any changes to the process, equipment and conditions.

How can we help?

At Envirotainer, we know we play an integral part in helping manage and mitigate risk. We take responsibility as a leading supplier of solutions to maintain the desired temperature throughout a shipment's journey. We provide real-time monitoring and data logging to keep an eye on live status as well as provide valuable risk-mitigating insights including tradelane reliability reports. Working together with our customers and partners, we have consistently looked to identify and improve any weak points and vulnerabilities to minimize risk.

Importantly, through our Envirotainer Academy and Qualified Envirotainer Provide (QEP) program, we are also advocates for stakeholder training and operational quality, reliability and safety, driving standards and helping all personnel in the cold chain process to ensure the proper handling and transportation of pharmaceutical products.

We're here to help. Feel free to get in touch to discuss your risk management challenges and let us help you overcome them.



Resources

ISTA PCG-03 | Thermal Shipping System: Performance Qualification (PQ) and Performance Verification (PV) Best Practice Guideline

Contributors

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