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Use the Gartner Five-Step Framework to Build a Cold Chain Distribution Strategy

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Initiatives: [Logistics Strategy and Operations](#)

More cold chain products are being launched with temperature-sensitive storage and transportation requirements, increasing complexity. Logistics leaders in life science companies need a cold chain distribution strategy to build efficient networks, minimize costs and ensure regulatory compliance.

Overview

Key Challenges

- Less than 10% of life science companies interviewed in a recent Gartner survey have a well-defined cold chain distribution strategy or have developed the necessary in-house expertise to optimize processes and minimize costs.
- Logistics leaders are faced with spiraling costs in cold chain transportation as specialized product portfolios expand and products are increasingly launched to market with specific cold temperature storage and transportation requirements.
- Changes to temperature-sensitive transportation regulations place significant new demands on manufacturers due to additional qualification and validation protocols.

Recommendations

Logistic leaders in life science companies:

- Use the Gartner five-step framework to define specific protocols to build a robust cold chain distribution strategy. Develop in-house expertise specifically in cold chain distribution.
- Collaborate with a broader set of stakeholders internally and externally to find cost-effective solutions for an expanding cold chain portfolio.
- Ensure cross-functional teams are aligned to the most recent regulatory guidelines on temperature-sensitive distribution. Don't hesitate to involve the local regulatory authority for expert advice on how to interpret regulatory guidelines.

Introduction

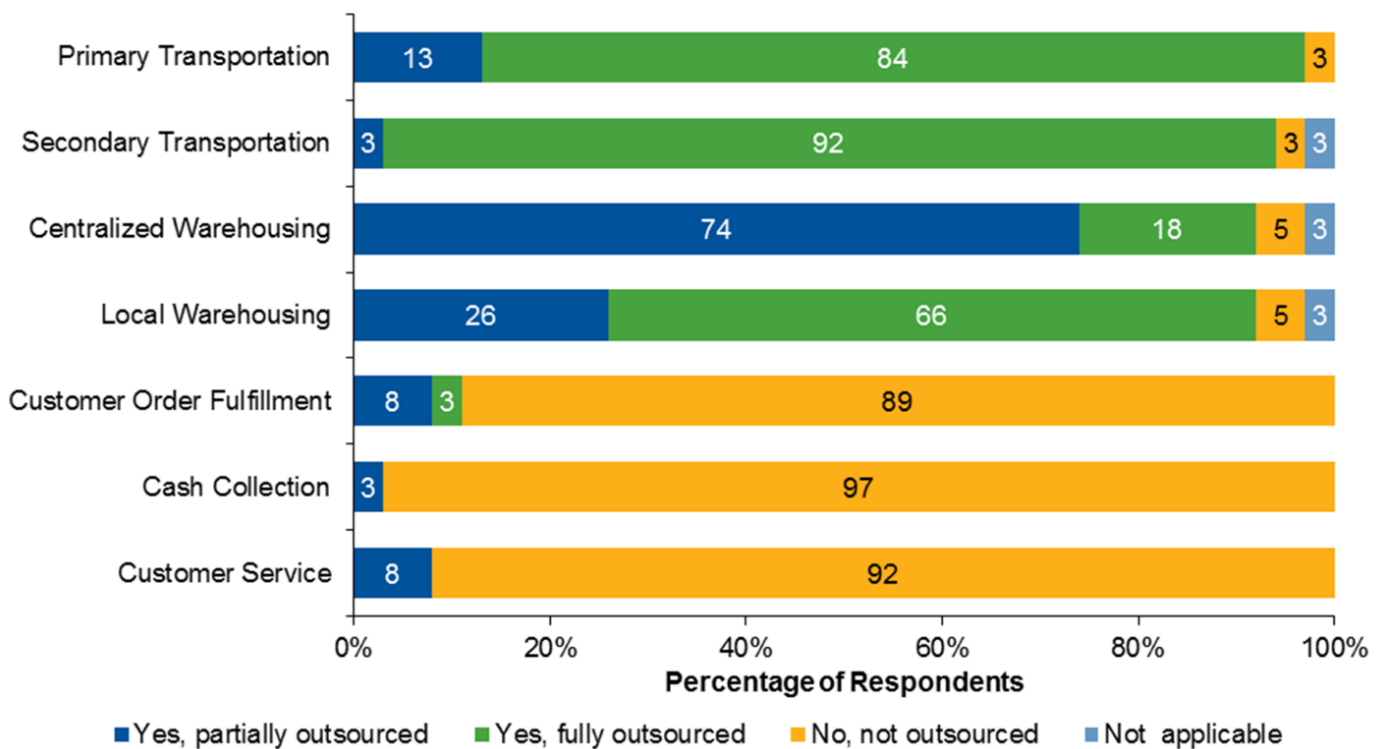
This research, based on a recent Gartner survey of 38 life science companies, helps logistics leaders overcome the obstacles related to the design of a robust cold chain strategy. ¹ It will help leaders realize the benefits of placing a focus on cold chain distribution by creating the right governance structure and designing protocols that build capability and secure the cold chain distribution network.

The growth of specialty drugs and biologics that are more susceptible to changes in environmental conditions is predicted to fuel approximately 60% in cold chain logistics spending, which is estimated to reach \$13.4 billion by 2020. ² Layer on top of this the surge in complexity due to growth in emerging markets and the increased pressure to reduce costs, and we can start to appreciate the logistic challenges for life science companies.

A recent scandal in China has highlighted the devastating effects of failures to adhere to temperature instructions. A massive illegal vaccine operation was uncovered in Shandong Province, where \$88 million worth of vaccines were not adequately refrigerated or transported in approved conditions and were dispensed into the general population. The full extent of the risk to patients is yet to be determined; however, this scandal emphasizes the responsibility of manufacturers and authorities to collaborate to safeguard patients and ensure product integrity throughout the supply chain. ³

Cold chain logistics are complicated by the fact that they are hugely dependent on that most unpredictable of factors — the human being. A recent Georgia Institute of Technology study highlighted that 90% of failures in the cold chain are attributed to human error, with the vast majority of these errors happening during handling. ⁴ Life science companies are also heavily dependent on third-party logistic (3PL) providers for their cold chain distribution needs. As found in the recent life science distribution survey, more than 84% of cold chain primary distribution is outsourced, increasing to 92% for secondary and last-mile distribution (see Figure 1).

Figure 1. Please State the Extent to Which Cold Chain Logistics Is Outsourced by Your Organization to a 3PL Provider



n = 38

Source: Gartner (April 2016)

Despite the obvious challenges, few life science companies have a fully integrated logistics network that incorporates the design, qualification and deployment of cold chain strategies. Similarly lacking is the interconnectivity of the qualitative and quantitative data, which results in a fragmented view of shipping temperature profiles. Logistics leaders are missing the opportunity to optimize processes, take out cost and mitigate risk with enhanced visibility through a well-defined cold chain strategy.

Analysis

Use the Gartner Five-Step Framework to Define the Specific Protocols to Build a Robust Cold Chain Distribution Strategy

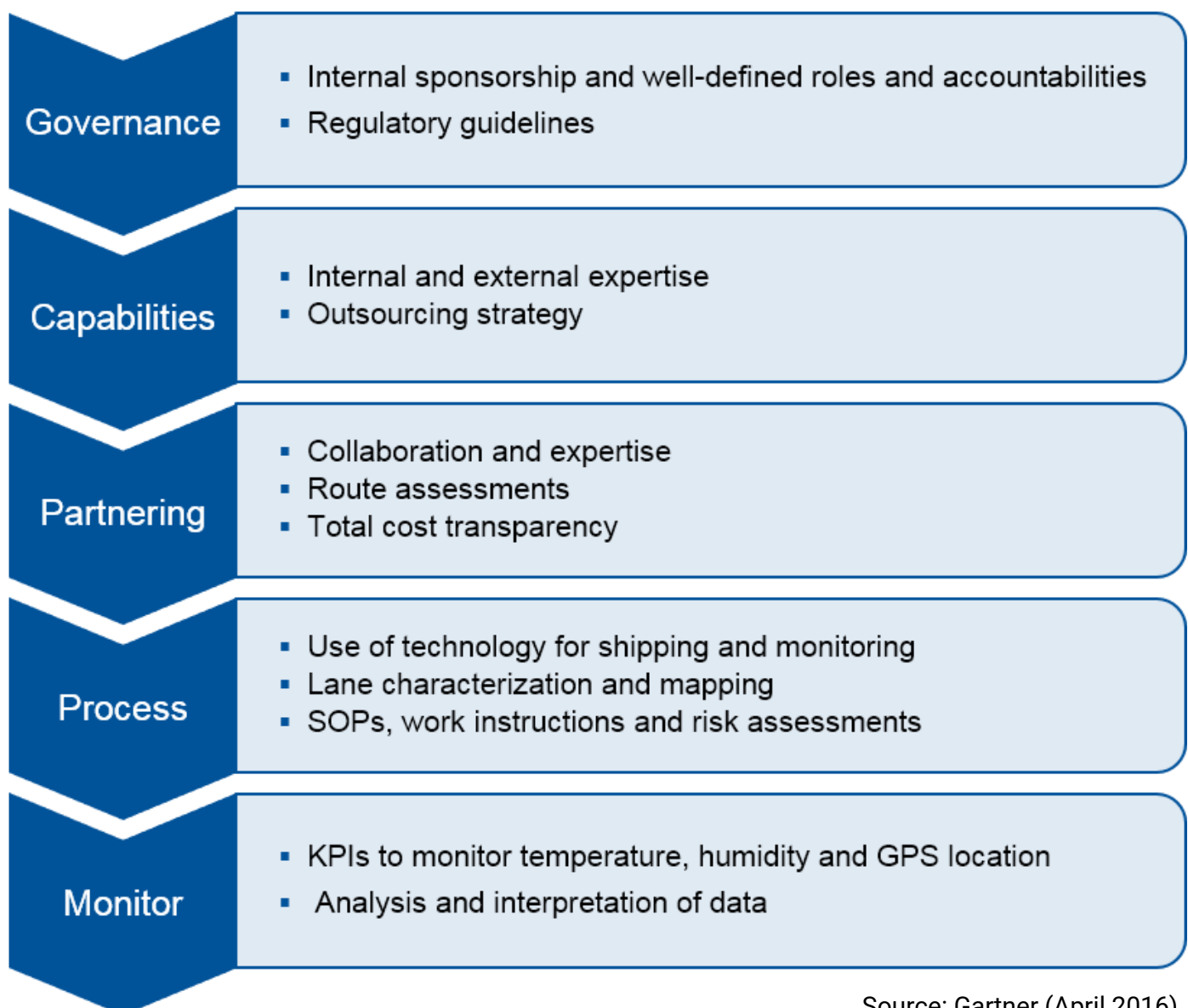
Before embarking on the task of creating a robust cold chain distribution strategy, logistics leaders should ensure that they are aligned with the strategic direction of the organization and importantly the role of supply chain. A cold chain strategy should fit seamlessly into the overall supply chain strategy so that resources can be leveraged and synergies exploited. Life science companies in the early stages of maturity typically take a decentralized approach to cold chain network design, allowing each country affiliate to "do their own thing" often resulting in fragmented methods and inconsistencies in regulatory compliance. In fact at this level of maturity, most organizations do not differentiate cold chain as a key process that necessitates its own strategy.

More mature companies develop center-led approaches where the cold chain network is designed often at a regional level and capability requirements are considered based on the specific requirements of each geographical cluster. Executional accountability, however, still resides at a local level and some of the inconsistencies and risks still remain.

At the highest levels of maturity, cold chain strategy is defined at a global level. The organization designs a standard framework that then applies to all regions across the globe. Of course in terms of cold chain, the requirements of each geographical zone will vary along with local regulations; however, there is a defined set of guiding principles that help local logistics managers evaluate risk and align processes to a global set of protocols. For more information on logistics maturity, see ["Apply the Five-Stage Maturity Model to Drive Logistics Excellence Within the Supply Chain."](#)

Gartner has developed a framework setting out the five key protocols that logistics leaders should focus on when building their cold chain distribution strategy (see Figure 2).

Figure 2. Strategy Framework for Cold Chain Distribution



Source: Gartner (April 2016)

SOPs = standard operating procedures; KPI = key performance indicator

Governance

Logistics leaders should aim to establish a centralized governance organization with a clear remit as a decision-making forum. Ensure roles and responsibilities are well-defined and reporting lines are clear, so improvements are effective, sustainable and shared across the entire organization. Supply chain leaders should:

- Engage the expertise of the regulatory and quality teams as key stakeholders in developing a cold chain distribution strategy.
- See that the key stakeholders are determined by each individual company, as organizational structures differ from one company to the next.

Capabilities

Cold chain products require a specialized set of skills to ensure products are properly stored and handled, from the moment of preparation to the last mile and handover at the point of delivery. Most life science companies choose to outsource the execution of these processes to a 3PL service provider; however, as the marketing authorization (MA) holder, it is essential to have the necessary expertise in-house to establish standards and to monitor quality and regulatory compliance. In the case of cold chain, the choice of packaging and transport modes depends very much on the product specification and stability data. This expertise sits with the manufacturer, and ultimately it is the manufacturer who is accountable to the patient. Logistics leaders should focus on the following key capabilities and develop the necessary expertise in-house:

- **Shipment preparation** – This is the assessment of product characteristics, destination and temperature recording.
- **Modal choice** – Route assessment (exterior temperature), size, weight and distance are important factors to consider.
- **Global trade** – If the shipment crosses international borders, customs procedures can become very important. Delays at customs are often identified as the most significant risk factor in establishing reliable international cold chains.
- **Last mile** – Logistics leaders are in agreement that this part of the journey is the highest risk zone for maintaining temperature. Collaboration with the customer to align timing of the delivery with available cold storage space will ensure the product can be put away upon delivery and minimize the potential for a breach in temperature. Other actions shippers can take to reduce the risk at the handover point include accuracy of paperwork, real-time delivery notifications and dedicated customer service support staff.
- **Quality and compliance** – The manufacturer must be able to demonstrate that temperature has been maintained throughout the entire journey of the product to the delivery handover point.

Temperature deviations must be recorded and appropriate action taken in the event of a discrepancy.

For more information on temperature regulations, see ["Assess Regulatory Guidelines for Transporting Temperature-Sensitive Pharmaceutical Products."](#)

Partnering

Ninety-two percent of cold chain consignments are outsourced to logistics service providers (LSPs). This illustrates the importance of the LSP as a partner for life science companies. Manufacturers need to work with LSPs who have the global infrastructure to scale capacity and capabilities, meeting the rising demand for cold chain services. Some of the largest players in the market – such as DHL, FedEx, Kuehne + Nagel and UPS – have made sizeable investments in dedicated warehouses, specialized aviation and ground transport equipment to develop global logistics networks for temperature-sensitive storage and transportation. There are also the smaller providers that provide specialist services on a more local level. This infrastructure is interconnected through advanced software management systems controlled by operators with specialized training in the distinctive nature of temperature-sensitive cargo.

Process

Regulatory agencies globally expect that manufacturers can confirm drug product quality and the potential effects of transport on the purity, efficacy and potency of the drug after transport. Many companies rely heavily on packaging qualification to validate the transport process. However, this alone is not sufficient. Logistics leaders should consider the following key processes as the core building blocks for a robust cold chain distribution strategy:

- **Thermal packaging qualification** – This should include qualification of the packaging component (for example, gel packs for passive systems). Other critical factors to evaluate are temperature ranges, allowable exposures and duration of qualification.
- **Lane characterization/mapping** – This should include a definition of the qualification testing specifications and acceptance criteria. It is important to recognize that this is not an exact science, as factors such as unforeseen delays and extreme weather conditions can impact the shipment. These factors should be considered when designing test protocols, and temperature ranges should be widened to anticipate extreme events.
- **Written procedures (SOPs)/risk assessments/change control/work instructions** – These documents are essential to ensure a good understanding by the operators handling temperature-sensitive products. Additionally, it is a regulatory requirement to ensure proper documentation, which needs to be presented to the authorities during an audit.

Monitor

For temperature-sensitive products, it is important to have a complete detailed history of the products as they travel through the supply chain. Typically, monitoring devices or systems will collate data on temperature, humidity and GPS location. The continuous monitoring enabled by the technology available today for large fleets and distribution networks potentially generates huge sets of data. It is important to collect this data, and essential that the data is analyzed and interpreted correctly. It needs to be presented in a way that assures companies that their products are meeting regulatory standards and, ultimately, are safe to use. This data also facilitates real-time capability to re-evaluate shipping lanes that logistics leaders can use to prequalify shipping routes, and potentially remove cost, due to expensive packaging solutions. Supply chain leaders should detail how the cold chain processes will be measured monitored, analyzed and interpreted as part of the overall cold chain strategy.

Collaborate With a Broader Set of Stakeholders Internally and Externally to Find Cost-Effective Solutions for an Expanding Cold Chain Portfolio

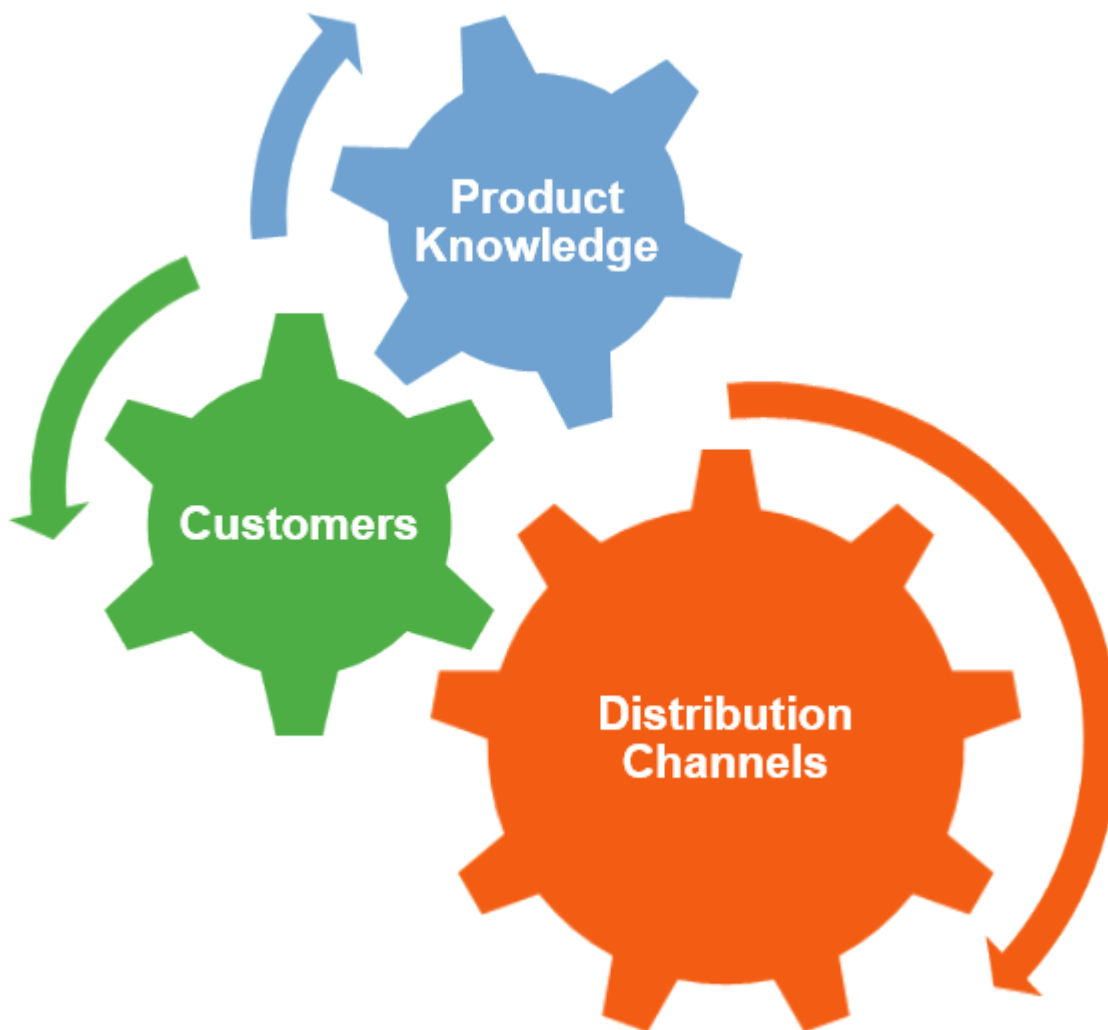
Life science manufacturers are increasingly trying to find the right balance between the costs of cold chain logistics in an ever-more stringent regulatory environment. A well-defined cold chain strategy should link stakeholders along the end-to-end supply chain, creating transparency of costs in each step of the chain. Logistics leaders should build standardized cost structures to understand landed cost drivers as a foundation for cost containment opportunities in cold chain distribution (see "[Use Cost to Serve to Optimize Logistics Costs](#)").

As the rate of temperature-sensitive products launched to market increases, supply chain leaders must look at opportunities to contain costs over the longer term. An often-overlooked opportunity is to link temperature-sensitive logistics and product development, and to create those interdependencies in the early stages of development. Many leading companies are exploring the proper and effective use of stability data to mitigate risk and cost.

With patient safety and compliance as guiding principles, companies can explore opportunities to minimize costs through predefined allowable excursions supported with stability studies to justify the variability. This creates a new set of objectives for logistics teams that now need to broaden skill sets to work more closely with stability study teams, quality and regulatory affairs, to assess the risks of distribution channels in relation to product characteristics.

The three interdependent elements seen in Figure 3 need to be at the core of any risk evaluation program concerning cold chain logistics, and involve a wide range of stakeholders that go far beyond just the logistics team's traditional accountabilities.

Figure 3. Three Key Elements to Consider in Evaluating Risk in Your Cold Chain Distribution Network



Source: Gartner (April 2016)

Know Your Product

The first step is to establish a cross-functional team, which will typically consist of supply chain, stability and quality personnel tasked with assessing the risks associated with moving temperature-sensitive products through the supply chain. In larger organizations, this team often sits within a center of excellence (COE). This team will typically evaluate environmental conditions that influence temperature such as air, humidity, light, vibration, handling and delays during transportation, assessing these risk factors in relation to the product characteristics, and determining if an excursion would pose a critical consequence on the products quality. Leading companies are finding operational and cost efficiencies in logistics by exploring the "area under the curve." That is to say, they can access stability data to determine allowable excursions depending on the nature of the product. For example, some products, such as biologics, cannot tolerate any form of out-of-range excursion. If exposed to freezing, they can lose their therapeutic properties. Other products are proven to be tolerant for specified periods of time.

Know Your Customers

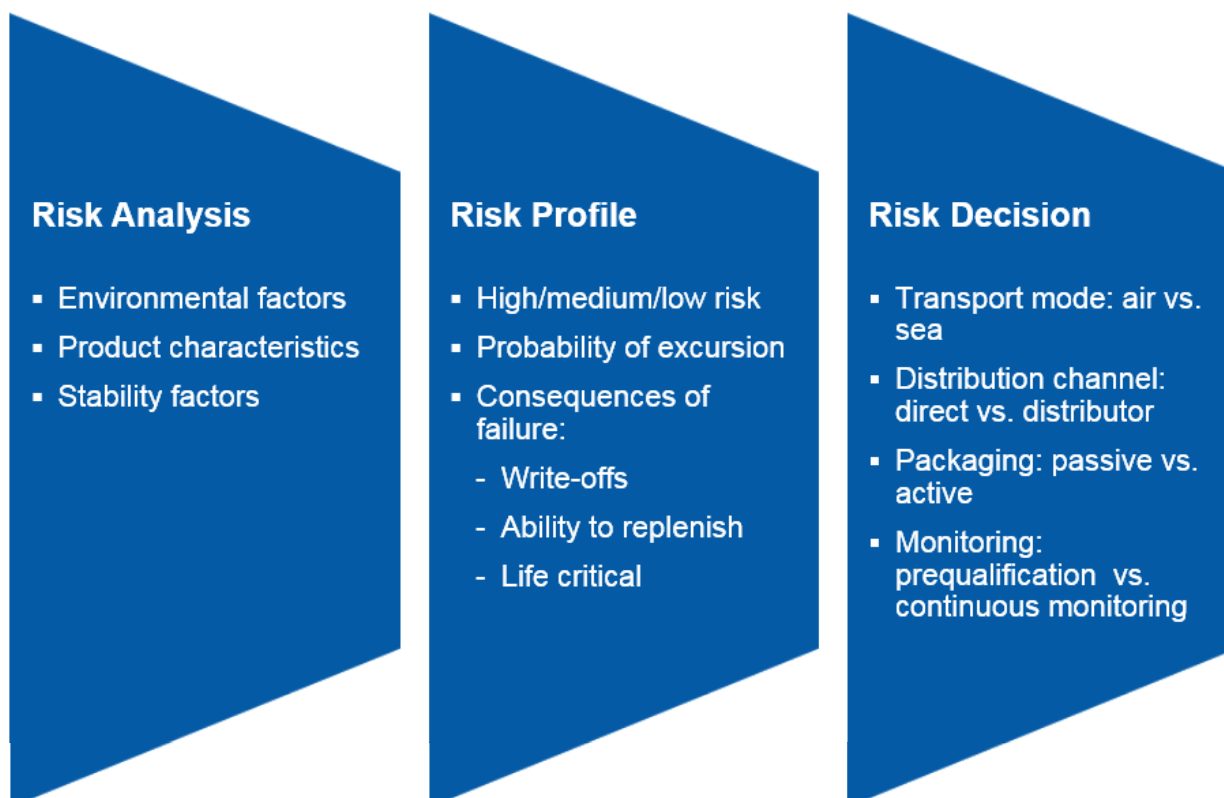
The next step is to know your customers, and how the patients will receive and use the products. Points of handover are high-risk zones, in terms of cold chain compliance. In our survey of life science companies, over 80% stated that the last mile is the highest risk zone in their temperature-sensitive supply chain. Involving the customer can add valuable insight, which can be incorporated in the overall cold chain logistics strategy design. During the risk assessment, the location of the customer at the point of handover is critical. For example, cold-storage capacity could be an issue for smaller hospitals and community pharmacies. Advance communication with customers prior to delivery can anticipate cold-storage capacity constraints, which avoids the product potentially being left unrefrigerated for periods of time postdelivery.

Know Your Distribution Channels

Finally, the cross-functional team should assess the distribution channel network in relation to the overall risk profile of the products. This step will help prioritize the actions that are most relevant to decrease the consequences of temperature excursions. For example, a high-value, highly temperature-sensitive product can be delivered via a direct distribution channel from the manufacturer into a hospital, reducing the number of handling points by eliminating the wholesaler.

Through careful assessment of the product characteristics, the customer needs and the distribution channels, predefined allowable excursions can be determined. For logistics leaders, this means that the risk parameters for cold chain distribution are clearly defined, excursion tolerances are well-understood, and informed choices can be made to build a robust distribution network for these sensitive products (see Figure 4).

Figure 4. Cold Chain Risk Analysis, Profile and Decision Framework



Source: Gartner (April 2016)

Ensure Cross-Functional Teams Are Aligned to the Most Recent Regulatory Guidelines on Temperature-Sensitive Distribution

One of the biggest challenges for logistics professionals is that there is not one global standard to define how temperature-sensitive products should be transported throughout the distribution network. Good distribution practice (GDP) is the most widely recognized standard globally. It sets out requirements that medicines must be obtained from a properly licensed supply chain, and must be consistently stored, transported and handled under suitable conditions, as required by the Marketing Authorization Application (MAA) or product specification.

Many life science companies are still faced with the challenge that across geographies, regulations are not aligned; in some countries, particularly in some emerging markets, there are no established guidelines. Even cross-functionally within the same organization, huge disparity can exist regarding interpretation of guidelines, exposing the organization to noncompliance – and putting patients at risk. It is also important to note that health authorities have issued guidelines rather than legislation pertaining to the transportation of temperature-sensitive products, which deliberately leaves room for interpretation. Leading organizations are collaborating with local health authorities, seeking clarification where needed, and involving them in the development of their cold chain distribution strategies.

It is important to re-emphasize that the Marketing Authorization (MA) holder, most usually the manufacturer, is accountable to the authorities and to the patient in terms of product safety.

Recommendations:

In the absence of definitive legislation, life science manufacturers should:

- Reference established standards such as GDP.
- Define internal policies that are aligned across the end-to-end supply chain, and also across interdependent stakeholders in product development, manufacturing and quality.

Life science manufacturers clearly understand the consequences of temperature excursions during product storage and transport from their manufacturing site to patients. An excursion can result in significant product write-offs. More importantly, it can compromise the safety of patients if not addressed in time. Product portfolios are shifting toward specialized medicines; increasingly, these products are sensitive to temperature, and must be stored and transported appropriately.

Logistics leaders must have a well-defined cold chain distribution strategy to:

- Build efficient networks.

- Minimize costs.
- Ensure regulatory compliance.

Evidence

¹ This research is based on the Gartner Life Science Distribution Survey – interviews conducted from September 2015 to January 2016 with 38 life science companies with significant temperature-sensitive product portfolios.

² ["Medical Cost Trend: Behind the Numbers 2016."](#) Health Research Institute. June 2015.

³ ["China Shandong Illegal Vaccine Scandal Sparks Anger."](#) BBC. 21 March 2016.

⁴ S. Haigney. ["Challenges in Managing the Cold Chain."](#) BioPharm International. 1 November 2013.

Recommended by the Author

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