Leading the Charge: How Lane Monitoring Reduces Cold Chain Risks

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Keeping Track: Why Lane Monitoring Matters

According to the World Health Organization (WHO), pharmaceutical companies lose more than $35 billion worth of product annually specifically due to improper handling and storage of product while being transported through the value chain.

Based on specific temperature event data, product losses overall and loss ratios, this number is likely under-reported as pharmaceutical companies often attribute temperature excursions to public perception of product quality, safety and reliability and elect not to publish loss data. This demonstrates the urgent need for more robust monitoring and corrective measures throughout the cold chain process.

The Cost of Accepting Risk

For larger pharmaceutical companies (over $1 billion in revenue), the average company will experience a ~12% temperature deviation rate through the commercial supply chain with heavy emphasis within last mile and hand over points, and roughly 50% of these shipments will need to go through a disposition process involving root cause analysis (RCA) and corrective and preventive actions (CAPA). The financial and operational burden of managing these events underscores the importance of proactive measures.

CHAPTER TWO

Pharma Adopts Technology

In response to worsening loss ratios and suboptimal network performance, the pharmaceutical industry has adopted various technologies over the years. While these technologies address individual pain points, their collective efficacy often falls short. The industry still suffers increasing product losses year over year, and decision-making processes related to packaging, devices, routing, SOPs, and carriers remain expensive and manual.

Overview of Current Technologies:

Technology	Value	Shortcomings
Passive data loggers	Ensure temperature compliance	No real-time intervention
Visibility aggregation tools	Provide carrier/trailer visibility	Lack of product or temperature visibility
IoT devices	Offer real-time product visibility	Alert overload, expensive, and data not actionable
Risk management platforms	Identify external risks proactively	Focused on 'black swan' events rather than everyday performance
Logistics orchestration platforms	Aggregate insights for actionability	Manual, not AI-enabled, and workflows remain unautomated

The problem is simple: while these technologies allow transportation, quality, and supply chain planning managers to be more proactive around shipment monitoring, the overhead and costs associated with monitoring shipments often outweigh the benefit of saving a few extra shipments per year. Large monitoring teams must react to alert overload without the ability to efficiently prioritize interventions.

CHAPTER THREE

Lane Monitoring as a Solution

For this reason, cold chain innovations have focused on enabling companies to monitor lane performance and risk at scale, autonomously. Large pharmaceutical companies might have ~5,000 unique shipping lanes. Today, quality and transportation managers often know of issues anecdotally but lack real-time data to make quick optimization decisions. The data generated from one lane's shipments every week or month can quickly overwhelm manual monitoring capabilities. Even just 100 lanes would far exceed the capacity of a small data team.

Innovative solutions now aggregate completed shipments and autonomously break each lane into routes, segments, and waypoints, providing a more granular and actionable understanding of cold chain performance.

AFTER LANE MONITORING

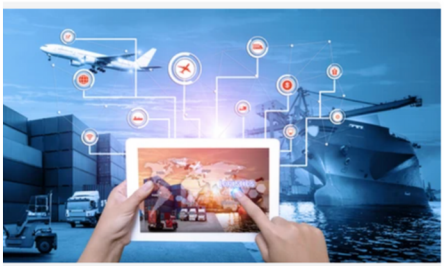
BEFORE LANE MONITORING

CHAPTER FOUR

Keeping Lane Standards Dynamic and Up-to-Date

STATIC PROCESSES HOLDING YOU BACK?

Much like the insurance industry adjusts premiums annually based on historical losses, the pharmaceutical industry has traditionally relied on expensive temperature mapping studies, distribution risk assessments and packaging thermal studies to justify changes to standard operating procedures (SOP). However, once lanes are qualified through a company's Quality Management System (QMS) and set up for production, systemic feedback loops leveraging real-world performance data are often missing. This leaves SOPs static and potentially misaligned with actual operating conditions.



An initial lane qualification process might consider variables such as packaging provider, packaging performance and thermal life, logistics service provider (LSP), IoT device, approved routing, an airline's flight schedules, mode of transport, etc. But when one or more of these variables change as they always do – or external changes such as environment, seasonality, geopolitical pressures, etc. -- come into play, that original qualification is at risk of becoming dated and invalid.

Real-time monitoring changes this dynamic. By continuously capturing IoT, product and other critical data and comparing it to qualification baselines, organizations can identify when lanes deviate from expected performance to proactively address emerging risks. This reduces reliance on months long studies and external consultants who rely performing their analysis on dated and static datasets.

The shift towards real-time data also empowers leaders to establish meaningful baselines for performance and risk. These baselines help identify systemic issues, providing clarity about lane configurations and allowing for more informed decision-making.

CHAPTER FIVE

The Value of a Strong Lane Qualification Process

Lane qualification typically occurs during new product launches or when setting up new shipping lanes, or material changes to an existing lane's SOPs must occur – thus a 're-qualification' process.

Key Considerations include:

- Temperature lane mapping and performance studies
- Distribution risk assessments
- Communication with logistics service providers (LSPs) and packaging providers to confirm relevant variables, such as flight schedules, cold room availability at airports, or thermal properties / validated test results
- Risk scoring based on various routes, packaging, IoT, and LSP selections
- Establishing approval workflows and version control
- Setting up a process to update changes and modifications within SOP documents

Despite their importance, these processes are often managed manually through spreadsheets and email, which creates several challenges:

- Decentralized, manual and time-consuming processes prone to errors
- Compliance-focused procedures that add little operational value
- Over-reliance on multiple tools that lack integration for communication, risk scoring, version control, and SOP maintenance
- Variability in carrier tools and formats for risk assessments, limiting ability to centralize & automate

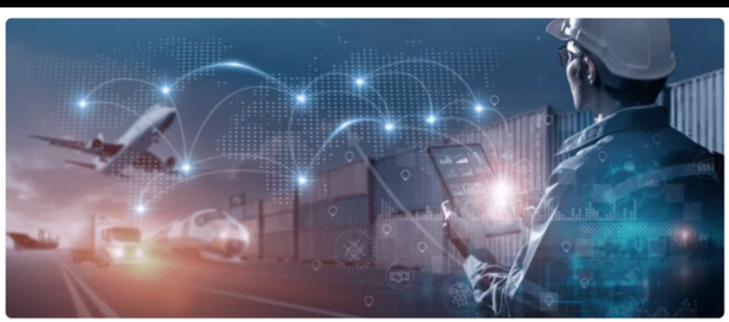
CHAPTER SIX

The Value of a Strong Lane Qualification Process

For companies that are more advanced, the challenges may include:

- Limited tools capable of qualifying risk based on the pharmaceutical company's own quality management system (QMS) logic
- Manual ingestion of existing SOPs, which is time-consuming
- Inability to dynamically assess tradeoffs without redoing entire risk assessments
- Lack of ongoing, continuous monitoring after initial lane qualification – capturing systemic failures in practice, not theory!

Once a quality leader qualifies a lane, the process is often considered complete. However, this static approach fails to account for changes in seasonality, weather, flight schedules, or LSP performance, which can render qualifications outdated within months. Without continuous monitoring, organizations risk operating with assumptions that no longer align with real-world conditions.



CHAPTER SEVEN

Striving Towards Continuous Improvement

Cold chain success depends on integrating tools and practices that:

Mass-ingest and standardize lane SOPs efficiently, streamlining communications and version control

Support effective and dynamic risk qualification scoring for new lanes that meets pharmaceutical companies where they are

Enable continuous monitoring of lane performance in real time

Centralized communication, version control, risk assessment, and SOP management provide a foundation for resilience. Continuous monitoring of lanes ensures that lane qualifications evolve alongside operational realities and develop a necessary feedback loop back into the SOP, which ultimately drive minimization of losses and optimization of supply chain performance.

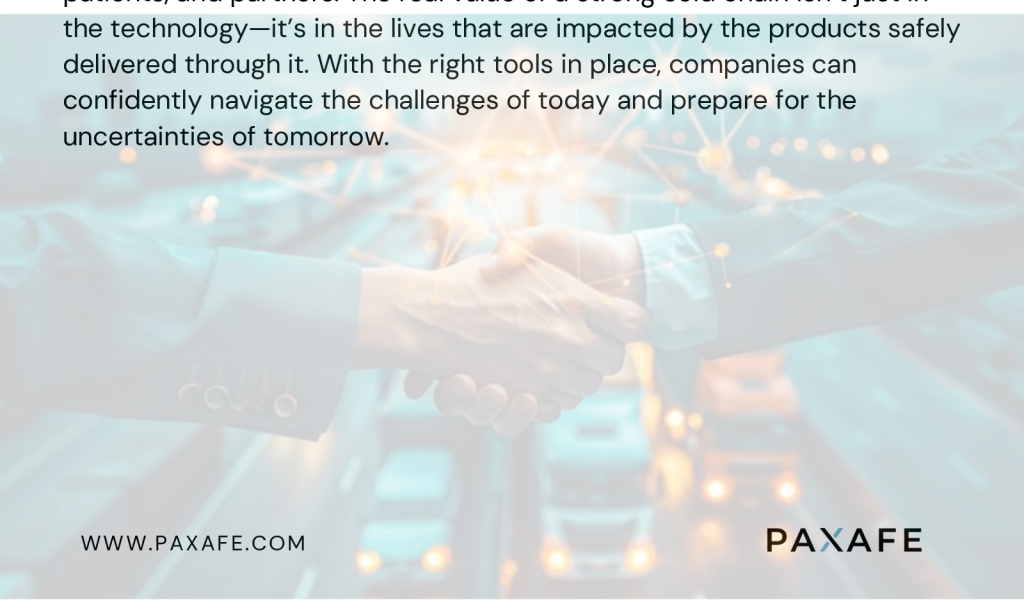
By adopting dynamic, data-driven practices, cold chain leaders can enhance visibility, reduce risks, and improve operational efficiency.

CONCLUSION

Building a Resilient Cold Chain for the Future

As the pharmaceutical industry evolves, the cold chain must adapt to meet growing demands for transparency and reliability. Lane qualification and performance monitoring, supported by autonomous tools and real-time data, are not just technical solutions—they are the foundation of resilient supply chains that can tackle today's unpredictable challenges. These advancements give companies the ability to focus on what truly matters: delivering safe, high-quality products to those who need them most.

In an increasingly complex and globalized world, the stakes have never been higher. The pressure to ensure that every product reaches its destination in perfect condition, without risk of damage or loss, is constant. By embracing these innovations, companies not only improve operational efficiency but also foster greater trust with customers, patients, and partners. The real value of a strong cold chain isn't just in the technology—it's in the lives that are impacted by the products safely delivered through it. With the right tools in place, companies can confidently navigate the challenges of today and prepare for the uncertainties of tomorrow.



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