



THE VITAL ROLE OF COLD CHAIN LOGISTICS IN ENSURING DRUG INTEGRITY FROM LAB TO PATIENT

Abstract

From COVID-19 vaccines and biosimilars, to blood samples, cell lines, and advanced therapies, a growing number of medications require temperature-controlled environments from the point of manufacture to final delivery. In this high-stakes environment, even a degree can make the difference between life-saving efficacy and complete failure.

Pharmaceutical cold chain management, a complex network spanning lab to last-mile delivery, is essential to preserving drug potency, safety, and regulatory compliance across every link in the supply chain. As the global pharmaceutical industry continues to evolve, cold chain logistics has emerged as a critical enabler of quality and compliance.

Cold chain logistics refers to the management of temperature-sensitive products within a controlled environment, typically ranging from refrigerated (2°C to 8°C) to frozen and even ultracold conditions (-150°C and below). This level of control is critical because many modern drugs are highly susceptible

to degradation due to temperature excursions. A single break in the cold chain can render an entire shipment of medication ineffective or dangerous. For medicines like insulin, vaccines, oncology medications, and biosimilars, the cold chain is a lifeline.

The World Health Organisation (WHO) estimates that nearly 50% of vaccines are wasted globally due to poor temperature control, leading to approximately \$35 billion in losses from cold chain failures alone.

The expanding pharma footprint and the cold chain imperative

Valued at USD 341 billion in 2024, the global cold chain logistics market is projected to grow at a Compound Annual

Growth Rate (CAGR) of 15.3% through 2034, driven by rising domestic demand, biologics production, and expanded

global distribution, according to Global Market Insights.

As manufacturers scale biologics and biosimilars and reach into underserved geographies, robust cold-chain logistics in pharmaceuticals are becoming critical.



COVID-19 focus: The pandemic emphasised the need for resilient cold chains to deliver vaccines to both urban hubs and remote areas.

Biologics and biosimilars: These therapies are temperature-sensitive, with narrow margins for error, pushing companies to elevate cold chain precision.

Access in remote areas: Reaching rural or hard-to-access locations requires portable, tech-enabled cold chain solutions that ensure safe, compliant delivery.

Understanding the cold chain journey

The pharmaceutical cold chain begins in the lab and extends all the way to the patient, with every step requiring strict temperature control to ensure product integrity:



Manufacturing site

Once produced, temperature-sensitive drugs are stored in cGMP-compliant cold rooms, typically between 2°C and 8°C, or even lower for certain biologics, to preserve stability and efficacy.



Packaging and labelling

Specialised thermal packaging, including gel packs, dry ice, and phase-change materials, helps maintain cold conditions. Increasingly, smart packaging with embedded IoT sensors provides real-time visibility into temperature and handling throughout the journey.



First-mile transport

Reefer trucks or temperature-controlled containers transport products from the manufacturing facility to regional warehouses or airport hubs, maintaining the cold chain from the outset.



Customs and cross-border handling

At international transit points, efficient clearance processes, minimal delays, and continuous temperature monitoring are critical to avoid product degradation.



Storage and warehousing

Central and regional warehouses use cold rooms equipped with backup power systems, alarms, and monitoring tools to ensure stable conditions throughout storage.



Last-mile delivery

Final distribution to clinics, pharmacies, and hospitals involves insulated containers, validated delivery routes, and specialised couriers to keep products within the required temperature ranges until they reach the patient.

Challenges in cold chain logistics in pharmaceuticals

Cold chain logistics offers zero room for error and is highly sensitive to disruption. Here are some of the biggest challenges that make it especially difficult to manage:



Temperature control is non-negotiable

Many medications need to stay within a tight temperature range throughout their journey. Keeping this “cold chain” intact takes smart packaging, real-time tracking, well-planned routes, and careful handling. And with more treatments now needing ultra-cold (-70°C) or even cryogenic (-196°C) conditions, the bar is rising even higher.



Real-time visibility at every step

Visibility isn't just about knowing where a shipment is; it's about monitoring its condition, timing, and compliance status in real time. For cold chain products, visibility tools like IoT sensors and cloud-based dashboards are essential for detecting anomalies and triggering immediate interventions.



Preparing for the unexpected

Cold chains are vulnerable to a wide range of disruptions, such as weather delays, political instability, customs issues, and equipment failures. Companies need proactive risk management and contingency strategies, including diversified routes and predictive analytics, to stay ahead of potential disruptions.



Global scope, local complexity

With manufacturing, distribution, and end-use locations often scattered across continents, pharma supply chains are global. Successful cold chain delivery depends on hyper-local understanding. Customs protocols, climate conditions, infrastructure, and transportation norms vary widely. Without regional expertise, even the most well-planned international supply chain can break down locally.



Keeping pace with technology

As therapies become more complex, logistics must keep up. Digital tools, from electronic tracking and smart packaging to AI-powered route optimisation, are now essential. Automation, real-time monitoring, and data-driven decision-making are reshaping pharmaceutical cold chains into responsive, intelligent systems.



Balancing sustainability and safety

Pharma logistics carries an environmental footprint, especially with energy-intensive cooling systems and global air transport. Companies are under pressure to reduce emissions and waste without compromising drug quality. Strategies like reusable packaging, green warehousing, electric vehicles, and optimised routing are gaining traction, but safety remains the top priority.

Key technologies powering cold chain logistics

Technology companies can play a transformative role in cold chain logistics with innovative features such as:

IoT sensors and telematics

Smart temperature loggers and GPS trackers are embedded in shipments to record real-time data on temperature, humidity, and handling conditions. Any deviation triggers instant alerts for corrective action.

Blockchain for traceability

Blockchain-based systems can track every node in the supply chain, immutably from production and packaging to distribution and delivery, ensuring product authenticity and compliance.

Temperature-resilient packaging

Innovative materials and designs such as phase-change materials, vacuum insulation panels, and reusable containers reduce the risk of thermal shock and cut waste.

MES-ERP integration

The integration of Manufacturing Execution Systems (MES) with Enterprise Resource Planning (ERP) platforms eliminates silos between production and supply chain planning. When a production batch passes quality checks within the MES, the ERP system is automatically updated, triggering downstream actions such as packaging or distribution with zero lag.

These tech-forward approaches not only strengthen product integrity but also boost efficiency and cut costs across the pharmaceutical cold chain.

Cloud-based cold chain platforms

Centralised dashboards allow pharma companies to monitor their supply chain performance across SKUs, geographies, and transport modes, ensuring complete visibility and traceability.

AI and predictive analytics

AI predicts risks, detects anomalies, and automates compliance by analysing historical and real-time data, minimising delays, equipment failures, and temperature excursions across the cold chain.

Shop-floor automation and smart packaging lines

This automation helps to increase throughput and consistency. From robotic pickers to temperature-resilient materials, cold chains are becoming smarter, faster, and more secure.

Digital documentation systems

Electronic Batch Records (EBR) and e-signatures are replacing traditional paper binders, dramatically reducing delays and human error. Regulatory frameworks such as the United States Food and Drug Administration's 21 CFR Part 11 validate digital documentation and e-signatures as compliant, audit-ready alternatives to paper records.



Regulatory framework and quality standards

The pharmaceutical industry operates under strict regulatory oversight in the United States, European Union, Japan, and WHO member countries. Along the way, pharmaceutical exports face multiple

layers of national and international regulations, requiring companies to comply with stringent documentation and handling standards. From Good Distribution Practices (GDP) to product-

specific protocols, firms must navigate varying local requirements while ensuring global compliance. Adherence to both GDP and cGMP is, therefore, non-negotiable.

Key regulatory considerations:



- WHO guidelines on temperature-sensitive product transport
- Track and Trace Systems with serialisation and barcoding for export compliance
- National vaccine distribution systems using electronic inventory and cold chain performance monitoring

Since pharma companies must balance global expectations with local infrastructure realities, advanced pharmaceutical cold chain management is a strategic necessity.

Best practices for pharma and logistics providers

Maintaining drug integrity in transit requires a proactive, data-driven approach to risk mitigation. Here are key practices to strengthen your cold chain:



Conduct comprehensive risk assessments

- Evaluate product characteristics (e.g., fragility, temperature sensitivity)
- Analyse packaging and transport systems
- Assess environmental and route-specific risks
- Ensure compliance with regulatory requirements



Leverage AI and advanced analytics

- Use AI to filter signals from noise and predict disruptions
- Apply large language models to interrogate supply chain data and generate insights for faster decision-making.



Deploy temperature control and monitoring

- Use real-time sensors, data loggers, and humidity trackers
- Optimise routes and logistics using sensor data to prevent temperature excursions and shock damage.



Optimise packaging

Ensure packaging is robust enough to prevent physical or thermal damage throughout handling and transit.



Implement security measures

Use physical and digital safeguards, including container seals, cameras, cybersecurity protocols, and employee training.



Develop contingency plans

Prepare for delays with pre-defined response strategies to reduce impact and ensure continuity.



Enable cross-stakeholder risk communication

- Establish regular risk review boards involving QA, logistics, suppliers, and last-mile partners.
- Promote transparency and collaboration to develop unified mitigation strategies.



Monitor, review, and adapt

- Continuously monitor strategy effectiveness
- Use performance data to adjust operations and enhance resilience.



Train people across the chain

Frontline workers, from warehouse staff to last-mile couriers, should be trained in SOPs, device usage, emergency protocols, and compliance documentation.



Invest in tech partnerships

Collaborate with technology firms that offer smart logistics solutions such as AI route planning, IoT sensors, blockchain traceability, and cloud analytics.

Final thoughts

As pharma becomes more global, specialised, and patient-centric, ensuring the safe, compliant, and timely delivery of temperature-sensitive medicines is a frontline responsibility that must be guaranteed not just by manufacturers but across the entire supply chain.

By investing in intelligent systems, data-driven strategies, and collaborative partnerships, stakeholders across the pharmaceutical ecosystem can ensure that every vial, ampoule, and syringe reaches the patient as intended: safe, potent, and effective.

Whether you're a tech provider enabling visibility, a pharma company scaling exports, or a logistics partner serving last-mile clinics, your role in the cold chain is vital. The health of millions depends on it.

For more information, contact infosysbpm@infosys.com

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