Whitepaper

Envirotainer

Building a Reliable API Supply Chain

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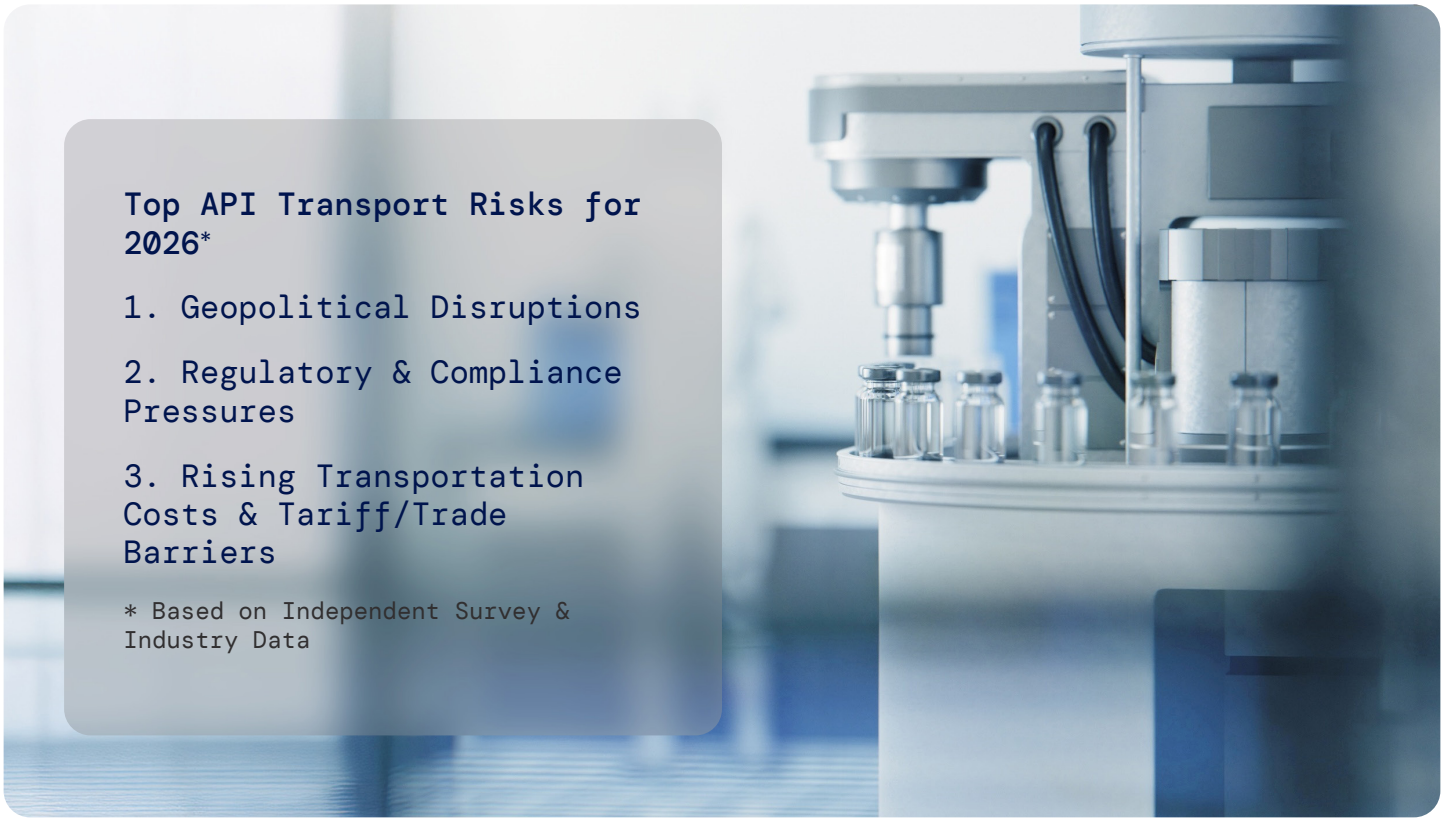
Executive Summary

Shipping Active Pharmaceutical Ingredients (APIs) is one of the most critical steps in the pharma supply chain. APIs are often shipped frozen in bulk over long distances and can be highly sensitive to temperature shifts and handling conditions. Even minor deviations during transport can compromise quality, trigger costly investigations, and disrupt downstream production.

Industry analysis shows that up to 20% of temperature-sensitive products are damaged during transport due to cold-chain failures, and time spent on the airport tarmac is the greatest source of temperature excursion risk. When patients depend on lifesaving pharmaceuticals, the stakes are high and the margin for error is small.

In this whitepaper, we will explore why APIs are so challenging to transport, the operational realities facing many U.S. API manufacturers, and the optimal solutions for protecting high value APIs during transportation.



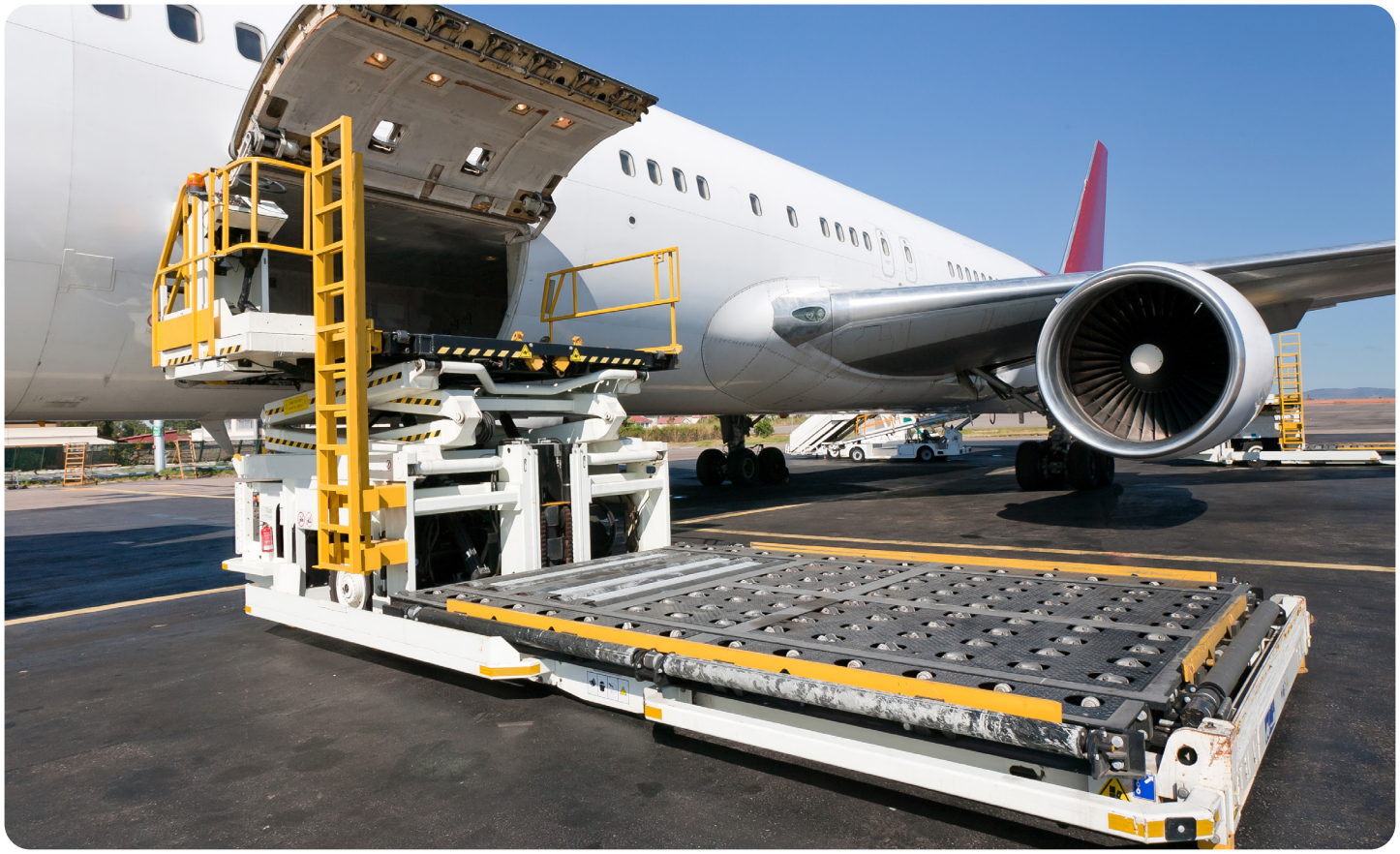
Industry Context: Why APIs Are Challenging to Transport

API logistics sit at the intersection of complexity, risk, and regulation. These materials move through long, multi-step routes (including production facilities, airports, Customs, and warehouses) each handoff increases uncertainty and exposure. With bulk API shipments representing significant financial and operational value, a single deviation outside the validated range can initiate investigations, batch holds, or product loss, quickly disrupting formulation and filling timelines and manufacturing schedules.

APIs are vulnerable to more than temperature: humidity, vibration, and even light exposure can degrade sensitive materials, so each shipment requires precise, consistent protection aligned to its product stability profile. Where product stability data is not yet available, even tighter environmental controls are required to ensure the API does not degrade due to unknown sensitivities.

The wide range of API formats shipped (including frozen bulk solutions, deep-frozen lyophilized intermediates, and humidity-sensitive solids) adds significant complexity, with each requiring tightly managed stability controls. When those controls falter even briefly, the consequences can be dire, triggering investigations, delaying batch release, and pushing production schedules off track.

Successful API shipping requires a solution engineered for precision, resilience, and regulatory alignment. The right packaging solution isn't optional; it's the difference between uninterrupted production and costly disruption.



The Operational Reality for U.S. API Manufacturers

For U.S. exporters, the risk intensifies. A pharmaceutical company shipping high-value APIs from a U.S. site to formulation facilities in Europe and Asia can encounter persistent, compounding challenges tied directly to the U.S. export environment:

Route complexity & handovers

Long, multi-stop international lanes and multiple handling partners increases the likelihood of temperature excursions and operational variability.

Hub-driven exposure

Airfreight handling is a critical stress point, and the US is no exception. Tarmac exposure, loading delays, and congestion at major gateways (e.g. Chicago, Newark, Atlanta, Los Angeles) heighten excursion risk, especially during heatwaves and winter storms.

Cost pressure

Rising airfreight rates, increasing operational complexity, and the high financial impact of shipment delays or temperature excursions are putting growing pressure on manufacturers to reduce total shipping costs while maintaining product protection. At the same time, recurring costs associated with single-use packaging, dry ice management, and compliance requirements are driving demand for more efficient and reliable transport solutions.

In response to these challenges, manufacturers need a qualified, reliable and reusable packaging solution, offering long thermal autonomy, repeatable performance across unpredictable airfreight conditions, and precise protection.

ProofTainer: Ensuring Stability and Continuity for API Shipments

For pharma teams shipping sensitive APIs, ProofTainer provides the temperature ranges, resilience and predictability supply chains depend on. By combining long thermal protection with a reusable, high-performance design, it reduces risk, simplifies operations, and keeps critical API programs on schedule. With a product that is both pivotal and sensitive, using a solution that has a long history of successful transport across a variety of APIs is paramount.

Broad Qualified Temperature Range (-70 °C to +20 °C)

ProofTainer offers a single solution that covers deep-frozen, frozen, and controlled ambient (CRT) temperatures. Utilizing a single solution for all API formats simplifies procurement, SOPs, and training across U.S. manufacturing sites and global CDMOs – without the need to requalify multiple packaging types for different temperature profiles.

>120 Hours of Thermal Autonomy

Validated long-duration performance (e.g. 120+ hours, scenario-dependent) ensures resilience to U.S. export volatility (tarmac waits, weather holds, ground-handling backlogs at hubs like ORD/EWR/ATL/LAX), reduces excursion risks and keeps batches moving even when schedules change.

Scalable Family of Six Sizes (96 L – 2 US Pallets)

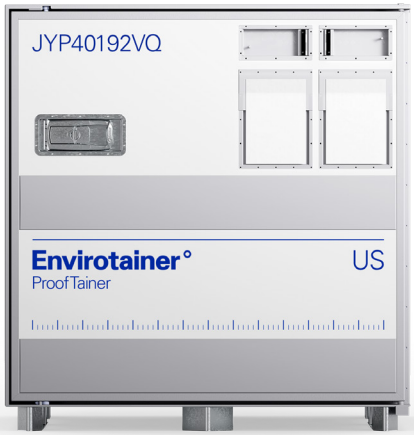
By utilizing a solution that is available in different sizes (case, single-pallet, and USA/Euro dual-pallet units) manufacturers can scale up or down depending on their needs. Higher payload efficiency and the ability to consolidate into bulk shipments ensures operational efficiency, lower cost per shipment and lower CO2 emissions.

High-Performance Advanced Passive Design (PCM + VIP Insulation)

Phase change materials (PCM) and vacuum insulation panels (VIP) deliver reliable, repeatable thermal protection without the need for mechanical support. Capable of maintaining temperatures as low as -70°C, the solution helps protect sensitive APIs across complex global shipping lanes and extended transit times. While shipments can be transported without dry ice, the flexibility to incorporate dry ice remains available for deep-frozen products and specific customer requirements, helping reduce operational complexity while maintaining consistent product protection.

Qualification Support for Global Lanes

While many suppliers require six to eighteen months to qualify a new solution, Envirotainer accelerates the process through hands-on qualification support and fully documented test reports covering all major shipping scenarios. Backed by extensive real-world performance data collected over the past 20 [BM1.1]years, we can help to simplify trade-lane assessments and reduce audit burdens, making it easier to launch or modify U.S. export routes with confidence.



Meaningful Results for High-Value APIs

Typical performance improvements observed when pharma teams transition from passive packaging to ProofTainer in U.S. export environments are:

Lower Excursion Risk

Validated long-duration performance (120+ hours) and high-performance PCM/VIP provides a wider safety buffer, lowering the likelihood of excursions across complex U.S. export lanes.

Standardization Across Global Sites

One qualified packaging solution covering -70°C to +20°C and multiple shipment sizes streamlines SOPs, training, and asset management across CDMOs and manufacturing sites.

Flexible Dry Ice Strategy

High-performing PCM-based design can maintain required temperatures down to -40 °C without dry ice, simplifying handling and reducing operational complexity. For products requiring -70°C or where dry ice is preferred, dry ice can also be incorporated to support specific customer requirements and temperature profiles.

Lower total shipping costs

ProofTainer reduces the ongoing costs associated with single-use packaging, dry ice replenishment, disposal, and shipment handling. Combined with its long thermal autonomy and high payload efficiency, this can lower overall transportation and logistics costs while maintaining precise thermal protection.

Why This Matters for U.S. API Exports

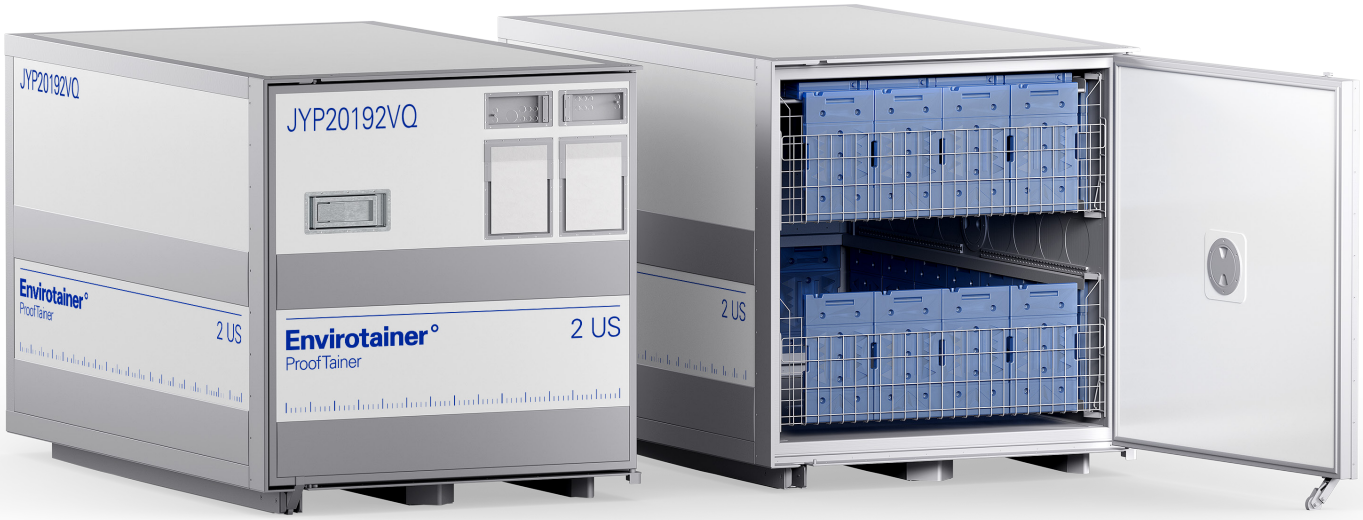
For U.S. API exporters, these advantages translate directly into greater shipment reliability and fewer operational disruptions. Long-duration thermal protection enables cargo to withstand the unpredictable mix of weather events, tarmac exposure, and ground-handling delays that characterize major U.S. gateways. By reducing the likelihood of excursions and the investigations that follow, pharma teams can keep production schedules on track, protect high-value inventory, and maintain confidence across all export lanes.

Conclusion

APIs are the foundation of every medicine and among some of the most sensitive materials to transport. Long, complex routes, variable handling conditions, and stringent regulatory expectations demand a logistics solution engineered for resilience.

ProofTainer delivers the stability, flexibility, and long duration thermal performance required to safeguard high value APIs across global supply chains.

With qualified ranges from -70 °C to +20 °C, six scalable sizes, and validated autonomy beyond 120 hours, ProofTainer helps pharmaceutical manufacturers reduce risk, improve efficiency, and protect the integrity of their most valuable materials.



Ready to Learn More?

Visit www.envirotainer.com

About Envirotainer

Envirotainer transports life-saving pharmaceuticals around the world with innovative temperature-controlled solutions.

With 40 years leading the industry, the world's largest pharmaceutical companies trust us to deliver. We offer the widest choice of cold chain solutions with a range of shipment monitoring services, all backed by our extensive global network to get your product to where it needs to be, precisely when it needs to be there.

When it comes to sustainability, we lead by example. Our ambitious science-based targets guide us, so we can reduce not only our emissions but our customers', too. Our transparent reporting, data-driven approach, and precise CO2 calculations allow us to measure our environmental impact all the way down to emissions per vial.

From research and development all the way to commercial distribution, we can deliver large quantities down to single patient samples. So, no matter what the pharma industry produces, we can ensure the safety and efficacy of medicines for every phase of the pharmaceutical life cycle.