



2019 Biopharma Cold-Chain Logistics Survey

What Matters Most – and What it Means for the Future





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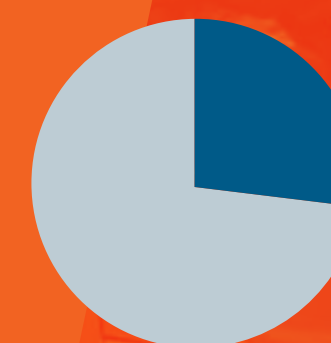
INTRODUCTION

Surging Demand for Temperature-Controlled Biopharma Logistics

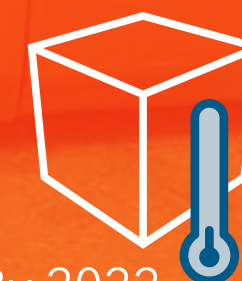
As strong growth continues across the global pharmaceuticals industry, the sub-category of temperature-controlled products is surging ahead. Sales volume for these highly sensitive products is growing at twice the rate of the industry overall, with \$318 billion in global sales in 2018 accounting for more than one-quarter (27%) of total sales volume.¹ This exponential growth also brings surging demand for specialized, temperature-controlled logistics services to safely, reliably and cost-effectively distribute high-value, high-sensitivity products. By 2022, 30 of the 50 top global biopharma products will require cold chain handling.¹ Fueled by this demand, biopharma cold chain logistics grew to \$15 billion in 2018. With projected 12.7% YOY growth, analysts predict it will reach nearly \$17 billion by 2021.¹

It's not difficult to understand the factors behind this growth: The shift to biologic and biosimilar drugs and precision-medicine treatments mean the majority of new and high-value drugs will be highly sensitive. Correspondingly, regulations governing these highly sensitive products are growing stricter. Finally, the biopharma supply chain has become much more global, as specialized products must make their way to every corner of the world, and emerging markets create new shipping demands.

TEMPERATURE-CONTROLLED BIOPHARMA PRODUCTS



27% of overall biopharma sales in 2018



By 2022, **30 of the top 50** global biopharma products will require cold chain handling

2x **FASTER GROWTH**
Than the rest of the industry

¹Pharmaceutical Commerce: 2018 Biopharma Cold Chain Sourcebook

Understanding Emerging Challenges & Critical Pain Points

The rapid growth in volume and complexity of temperature-controlled biopharma logistics presents new and evolving challenges that touch every stakeholder – from the manufacturers that produce the products and the 3PL partners that help distribute them, to the clinicians and patients that ultimately depend on them. The IQVIA Institute for Human Data Science estimates that the biopharma industry loses approximately \$35 billion annually as a result of failures in temperature-controlled logistics – from lost product, clinical trial loss and replacement costs, to wasted logistics costs and the costs of root-cause analysis.⁴ Those numbers fail to quantify the patient safety risks that can (and do) result from compromised products reaching unknowing patients.

⁴IQVIA Institute for Human Data Science

2019 BIOPHARMA SURVEY:

What Matters Most – and What it Means

To better understand these emerging challenges, Pelican Biothermal conducted a broad survey of key opinion leaders across the industry. This report details the compelling findings, revealing the concerns, trends and technologies that are top-of-mind for leaders in biopharma production and distribution. The report dives into these findings, illuminating the key trends driving top concerns – and offering a forecast of what each finding means for the future of the industry.

3 KEY TRENDS



INCREASING QUALITY DEMANDS

More sensitive products bring logistics complexity and greatly expanded risk.



EXPANDING DISTRIBUTION RANGE

Products are moving further – and through more climatic zones – than ever.



OPTIMIZING TOTAL COST OF OWNERSHIP (TCO)

Relentless competition and margin pressures demands better understanding of TCO.

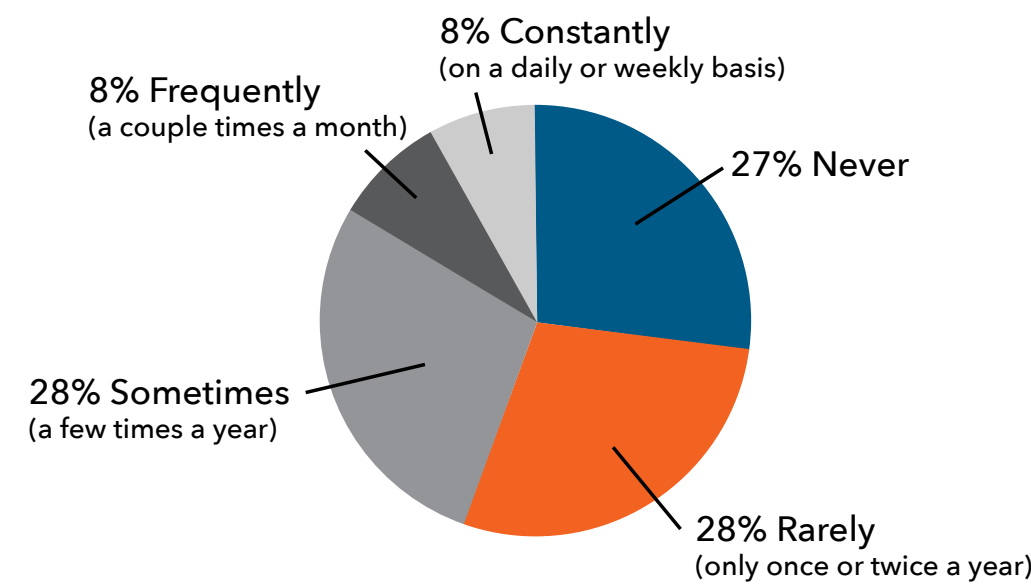
TREND 1

Increasing Quality Demands

More sensitive products bring logistics complexity and greatly expanded risk

KEY FINDING: Temperature excursions happen frequently – and they're not always minor.

Awareness of temperature-control requirements is higher than ever, but our survey suggests temperature excursions continue occurring at concerning frequencies. Nearly half (44.6%) of respondents report multiple temperature excursions per year, and 16% say temperature excursions are a monthly occurrence. Moreover, the reported excursions aren't a matter of a degree or two. Two in five excursions (41%) exceed four degrees, and 21% are more than eight degrees.



How frequently do your organization's shipments experience temperature excursions?

DRIVING FACTORS

Biologics & Biosimilars

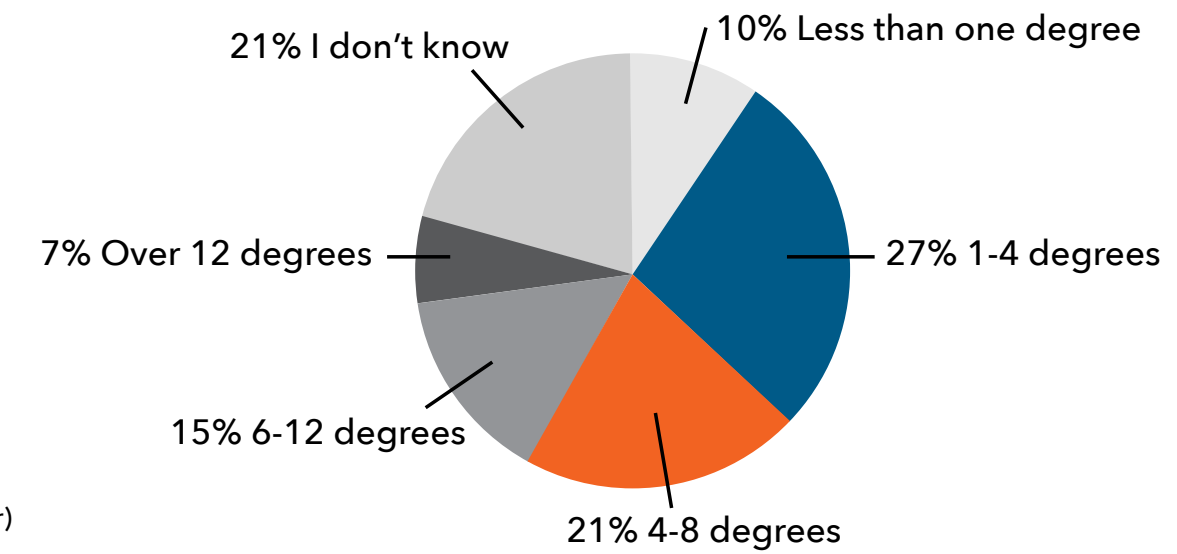
The entire pharma industry has begun a massive shift away from chemically-derived products and toward biologics and biosimilars. Analysts agree that the majority of new drugs coming to market in the next five to 10 years will be highly sensitive biologics or biosimilars.

Precision Medicine

Analysts expect the number of precision medicine drugs – e.g., gene-based therapies (such as CAR-T cell therapies), blood-derived treatments, and other tailored treatments developed for specific patients or patient sets – to increase by 69% in the next five years.⁵ These products are produced in small batches, with increased time and temperature constraints – and often involve the two-way transfer of highly sensitive biological material.

Clinical Trials

Behind the development of biologics, biosimilars and precision-medicine drugs is the continued growth of the clinical trials segment – where nearly every element requires temperature-controlled services. The demand for clinical trials logistics alone reached \$3.4 billion in 2018, and is expected to rise to \$3.7 billion by 2022.⁶



You mentioned that your organization's shipments experience temperature excursions. How many degrees (on average) are the excursions?

2020 Forecast: An increasing top-down focus on cold-chain reliability

Sophisticated biopharma products continue to create and expand cold-chain challenges. As the volume and value of temperature-controlled biopharma products continues to grow, biopharma C-suites will increasingly see the importance in rethinking their shipping and logistics strategies. But these emerging challenges cannot be solved with a simple retrofit of existing cold chain programs. Forward-thinking biopharma manufacturers will increasingly align themselves with specialized cold-chain logistics partners, leveraging this third-party expertise to create powerful competitive advantages in both product quality assurance and operational efficiency.

³<https://www.pharmalogisticsiq.com/logistics>

⁴Pharmaceutical Commerce: 2018 Biopharma Cold Chain Sourcebook

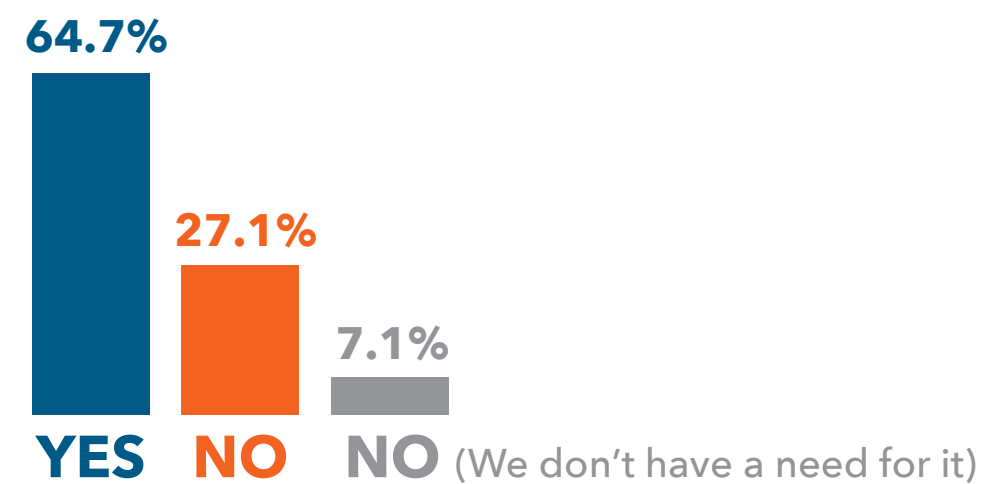
TREND 1

Increasing Quality Demands

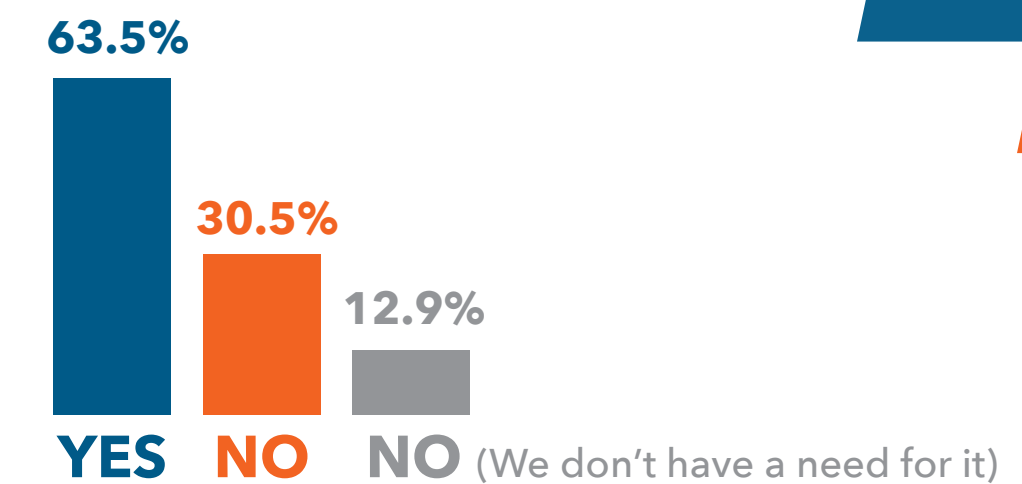
More sensitive products bring logistics complexity and greatly expanded risk

KEY FINDING: Visibility is critical

Biopharma manufacturers invest huge sums in quality assurance monitoring across their manufacturing operations. But without a logistics monitoring system in place, they completely lose quality control across the supply chain. The majority of survey respondents now see temperature and location logging as valuable and necessary. Nevertheless, about 1 in 4 respondents still do not use location and temperature monitoring – and, more concerning, around 10% don't see the need for such tracking services.



Are you currently using location tracking for your cold chain shipments?



Are you currently using temperature monitoring for your cold chain shipments?

DRIVING FACTORS

Increasing Regulatory Requirements

As the volume and value of temperature-sensitive biopharma products increases, so does regulatory attention. Global regulatory agencies are applying increasing pressure to ensure “ship-to-label” requirements are met – and requiring proof that products have been kept within approved temperature range during transport.

Serialization Requirements

The global adoption of serialization standards in the biopharma industry – while at different stages in different parts of the world – intensifies the demand for in-depth visibility across the supply chain, including location and temperature.

2020 Forecast: Temperature monitoring will become standard

More sensitive products and stricter regulations require true, end-to-end visibility that will make temperature monitoring a must-have for all biopharma manufacturers' cold-chain logistics operations. Forward-thinking biopharma organizations will increasingly begin leveraging temperature monitoring data to actively recognize issues and avert temperature excursions, identify excursions and send replacements sooner to minimize delays, and execute smart investigations into excursion incidents to expose the root cause and avoid future issues. Finally, continued improvements in temperature logging technologies will deliver near-real time visibility, helping organizations respond more quickly and even implement proactive strategies.

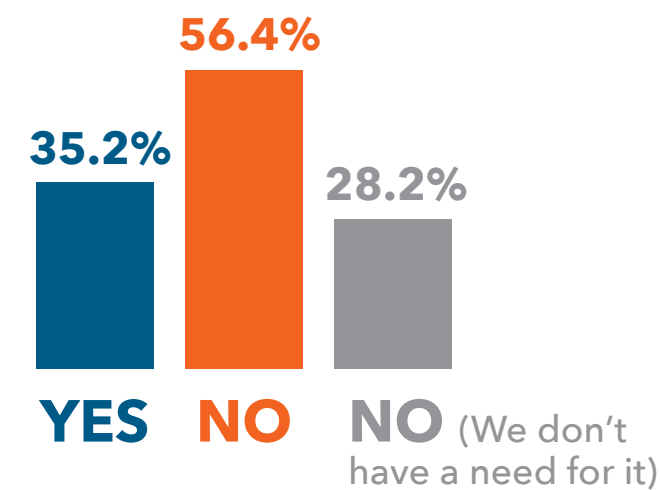
TREND 1

Increasing Quality Demands

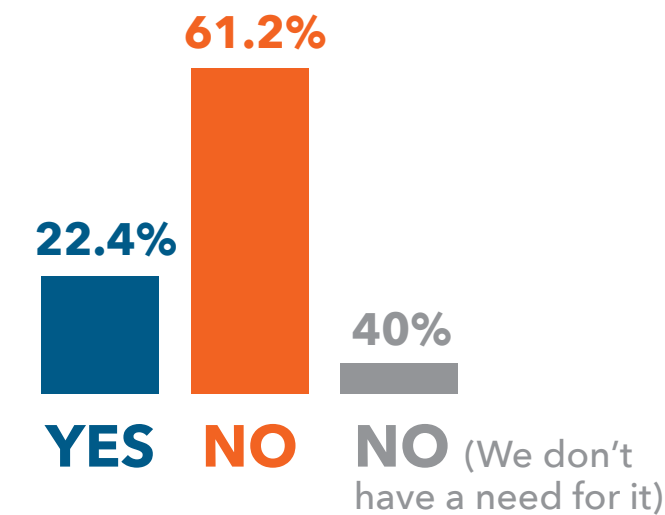
More sensitive products bring logistics complexity and greatly expanded risk

KEY FINDING: Temperature monitoring isn't enough

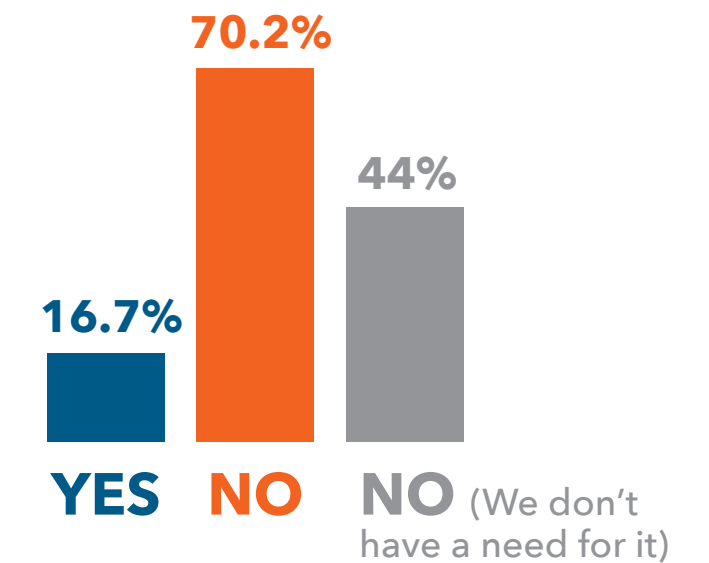
The last few years have seen industry terminology shifting from “cold chain” to “temperature-controlled” to account for the growing controlled room temperature market and the variety of other temperature-sensitive products. But as biopharma products grow more complex and more sensitive, those that truly understand the products know that temperature is just one element that can negatively impact efficacy and safety. Yet only one-third (35.2%) of survey respondents report using humidity monitoring, and less than a quarter (22.4% and 16.7%, respectively) report monitoring vibration and light. Most concerningly, nearly half of respondents say they see no need to monitor these factors which could lead to serious quality, compliance or even patient safety incidents.



Are you currently using humidity monitoring tracking for your cold chain shipments?



Are you currently using vibration monitoring tracking for your cold chain shipments?



Are you currently using light monitoring tracking for your cold chain shipments?

2020 Forecast: Advanced monitoring will become business-critical

Storage and transport specifications for highly sensitive biopharma products will continue to grow more complex. Moreover, the costs of failure to maintain product specs – from financial and brand damage, to patient safety incidents – will continue to rise. To consistently deliver products in safe and efficacious condition – and to comply with ever-increasing compliance requirements – biopharma organizations will be required to gain more complete and precise control of all factors that can negatively impact their products during transport. Forward-thinking organizations are already extending their supply chain visibility beyond basic location tracking and temperature monitoring, implementing advanced monitoring services that deliver real-time data on humidity, light and vibration. As discussed with real-time temperature monitoring data, these organizations will leverage this advanced monitoring to actively avert excursions and drive continual improvement in quality and efficiency across the supply chain.

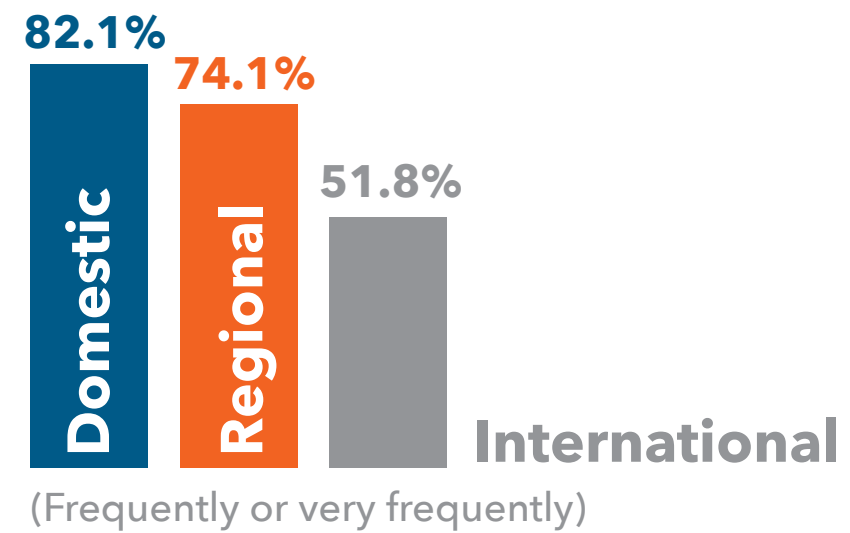
TREND 2

Expanding Distribution Range

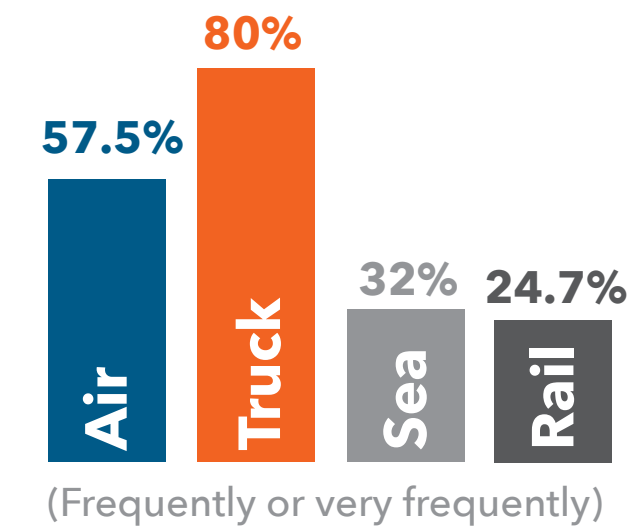
Products are moving further - and through more climatic zones - than ever

KEY FINDING: Business agility requires shipping flexibility

Biopharma is a truly global industry, with over half of respondents (51.8%) regularly ship products internationally. Moreover, just 1 in 6 (16.5%) report that they never ship across borders. But in practice, the biopharma supply chain is an increasingly complex web of local, regional and international connections that require a broad range of transport modes. Air and ground transport remain the most common, but most are leveraging a flexible portfolio that includes increasing sea and rail transport.



How frequently do you ship to the following locations?



How frequently do you use the following transport modes?

DRIVING FACTORS

Specialization

Specialized production of drugs, as well as high-value ingredients, means that many products are now moving much further – through a wider variety of climatic zones – in order to reach their end customers.

Emerging Markets

The rapid expansion of emerging markets – Russia, India and China, as well as smaller markets across Asia and South America – demand the creation of new and/or more efficient shipping lanes. In addition, many of these emerging markets present the challenge of distributing temperature-sensitive products to more extreme climates.

Last-Mile Delivery

The increase in highly personalized treatments is dovetailing with rising consumer expectations for faster, convenient access. Biopharma manufacturers must increasingly figure out how to deliver products directly to patients' doorsteps, solving the "last-mile" challenge.

2020 Forecast: Versatility in temperature-controlled logistics will be critical to capturing emerging opportunities

While the biopharma market continues healthy growth, gone are the days of the blockbuster drugs with a broad, easy-to-reach target market. Increasing specialization and personalization in treatments, along with expanding opportunities in emerging global markets, will require biopharma organizations to build agile logistics programs that can quickly build new solutions to reach niche markets. Forward-thinking organizations will lean on third-party partners that can rapidly deliver expert recommendations and build customized solutions – leveraging thermodynamics expertise and thermal testing to evaluate and qualify packaging and transport solutions that meet compliance standards and ensure product safety and efficacy, while optimizing costs.

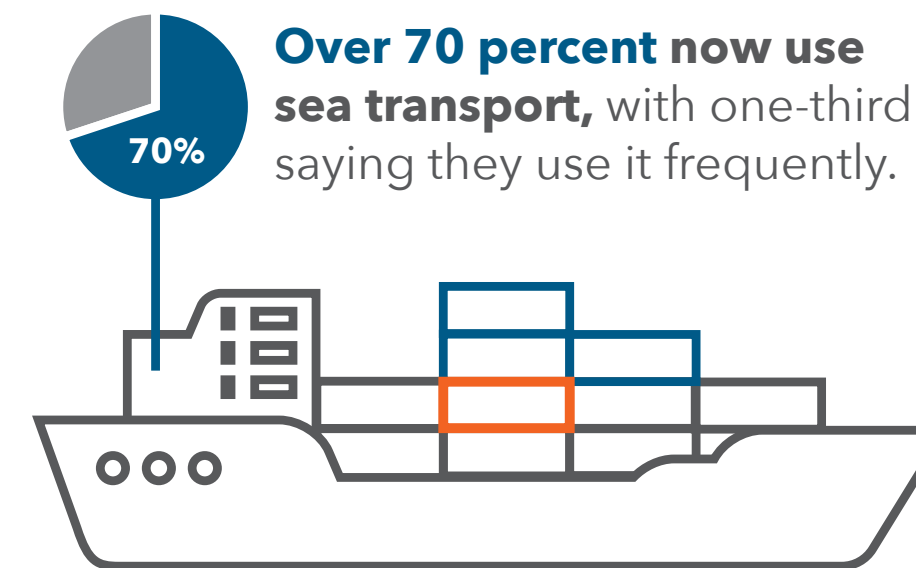
TREND 2

Expanding Distribution Range

Products are moving further - and through more climatic zones - than ever

KEY FINDING: Mode shift in freight transportation

Air transport has long been the gold standard for transporting highly sensitive biopharma products, with ground transport offering a more cost-effective option. But our survey reflects the growing use of sea transport for international shipping of temperature-controlled products. Over 70 percent (70.6%) now use sea transport, with one-third saying they use it frequently.



DRIVING FACTORS

Rising Costs of Air & Ground

Air freight is approximately 700% more expensive than ocean freight. Similarly, ground transport costs continue to increase, driven by rapidly rising labor costs in the ground transport industry.

Sustainability Goals

Biopharma organizations face increasing pressure – from consumers and from regulators – to adopt sustainable business practices. Sea transport is emerging as a preferred option to lower carbon footprints in comparison to sea and ground transport.

Temperature-Controlled Packaging Innovations

New advances in insulation allow shippers to use lower-cost passive containers to provide critical support for periods when power is not available – such as during transport between cold chain locations, or in the case of a loss of power. This enhances confidence and reliability for the added complexity and longer duration common in sea transport scenarios.

2020 Forecast: Enabling and expanding sea transport will drive operational advantages

The confluence of key trends – more temperature-sensitive biopharma products entering the market, stricter regulations, and increasing globalization – will lead biopharma organizations to look for new ways to enable and expand their use of sea transport to drive cost-efficiencies across their supply chain. To maximize these cost efficiencies, forward-thinking organizations will increasingly leverage state-of-the-art, reusable passive shipping containers to enable reliable, long-term temperature and quality control while reducing total costs.

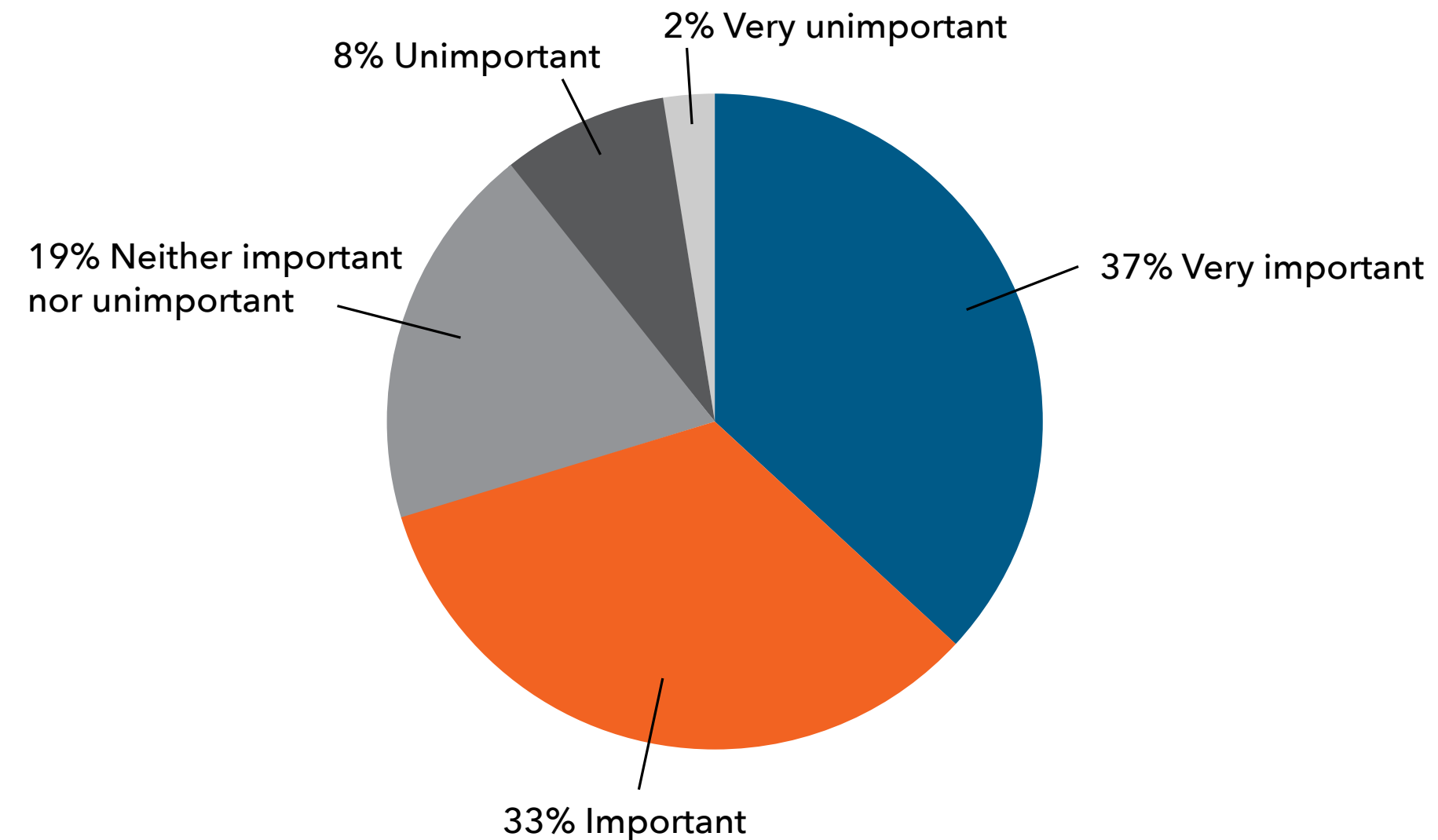
TREND 3

Optimizing Total Cost Of Ownership (TCO)

Relentless competition and margin pressures demands better understanding of TCO zones

KEY FINDING: TCO matters

The hypercompetitive and unforgiving biopharma landscape demands that organizations achieve consistency and control without eating into margins. Increasing cost pressures are leading organizations to take a closer look at defining TCO in their logistics and supply chain operations. A full 70% of survey respondents agree that TCO is important or very important. While a stubborn 10% are still looking at basic packaging costs and transport rates, the vast majority now consider complex contributing factors that could lead to unanticipated consequences that drive additional and related costs down the road.



How important is the total cost of ownership (TCO) calculation in your organization when it pertains to temperature-controlled packaging?

2020 Forecast: Understanding TCO will become key to driving competitive advantages

As biopharma organizations look to boost margins from the bottom up through smarter cost-management strategies, logistics solutions will become a popular focus for the TCO spotlight. Understanding the various risks – and quantifying the costs – of potential patient safety incidents, product and market share losses, and brand damage will become essential to evaluating the relative value of everything from packaging solutions to transport modes. Forward-thinking biopharma organizations will demand cost transparency from third-party service providers – and will look for partners that can help them build customized supply chain solutions that fully optimize TCO for each specific product and market.

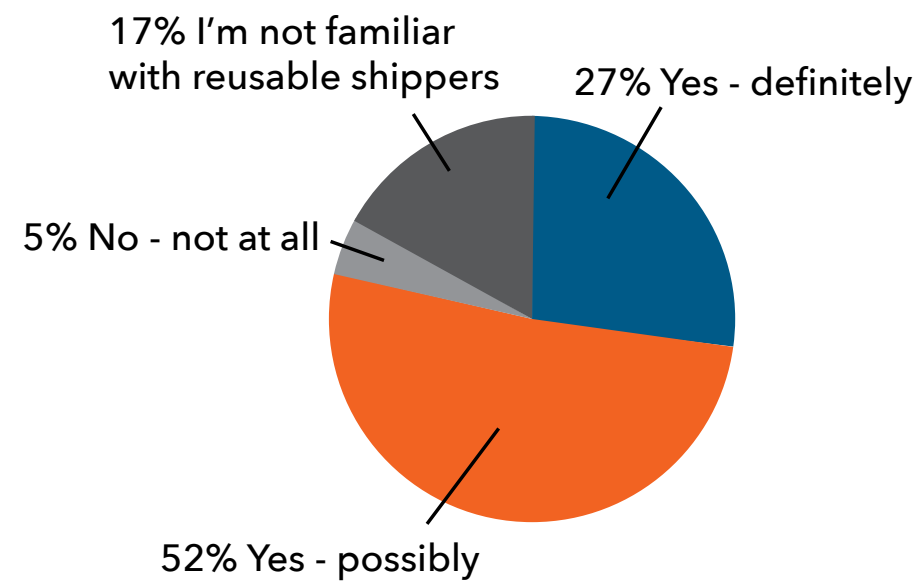
TREND 3

Optimizing Total Cost Of Ownership (TCO)

Relentless competition and margin pressures demands better understanding of TCO zones

KEY FINDING: Reusable rental is growing

Driven by a better understanding of TCO, biopharma organizations are increasingly recognizing the various benefits of using state-of-the-art reusable containers to protect and deliver their highly sensitive products. Four of five respondents (79%) say reusable containers – though more expensive than single-use containers – are worth the investment. Moreover, as reusable containers become a more attractive option, reusable rental is emerging as an ideal strategy for capturing the benefits of reusable containers – without all the costs. More than one-third (37.6%) of respondents are already using reusable rental programs in their cold-chain logistics operations, and another 25% are actively exploring this option.



Do you think reusable shippers are worth the investment?

DRIVING FACTORS

High-Value Products Demand Higher-Quality Containers

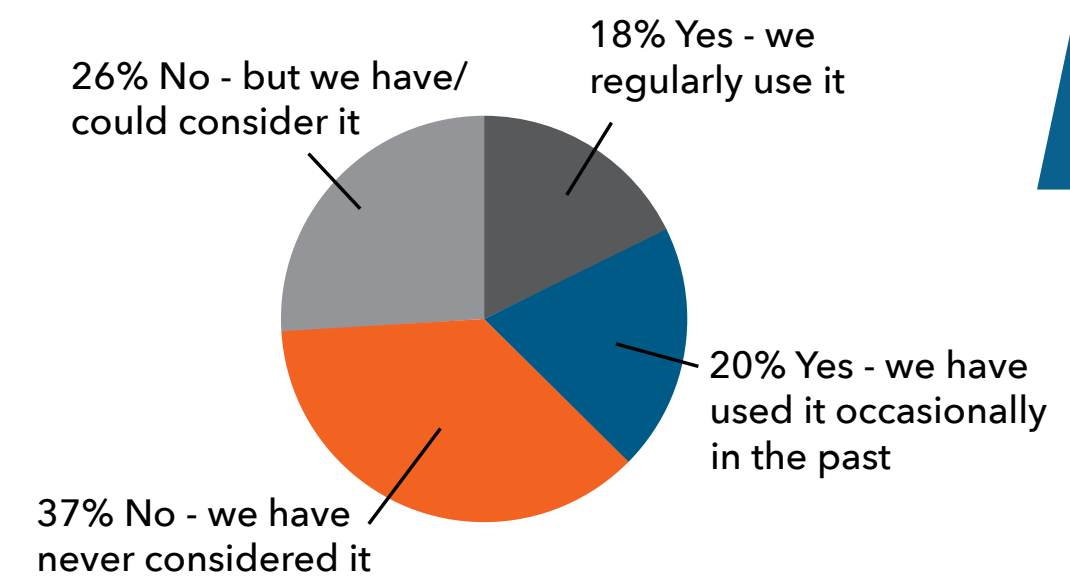
The increase in highly sensitive, high-value biopharma products increases the demand for more advanced materials – such as vacuum-insulated panels or advanced PCMs – that are typically only deployed in reusable containers.

Sustainability Goals

Advances in the production of the materials used in premium-quality reusable containers have decreased the overall costs of these containers. In addition, improved tracking and reverse logistics have reduced container loss, driving up cost-efficiency.

Temperature-Controlled Packaging Innovations

Consumer and regulatory pressure to pursue sustainable business practices makes the relative eco-friendliness of reusable containers more appealing.



Has your organization ever used a reusable shipper rental program?

2020 Forecast: Reusable rental will become a dominant business strategy

As biopharma organizations increasingly shift their focus to core competencies like research & development, many are looking to minimize TCO by leveraging reusable rental programs – capturing the quality-assurance and sustainability benefits without tying up CapEx budgets. Packaging providers will rush to serve this emerging market, but forward-thinking biopharma leaders will demand rental providers that fully deliver on the “as a service” (aaS) promise. Best-in-class reusable rental providers will offer comprehensive quality control and servicing of containers, deliver on the potential of Internet of Things (IoT) data monitoring to enhance supply chain visibility, and provide value-added consultative expertise to help organizations address emerging and evolving logistics demands.



THE FUTURE OF BIOPHARMA LOGISTICS: Keys to Success

The biopharmaceutical industry continues to develop transformative new treatments – from new biologic and biosimilar drugs, to innovative and highly personalized cell and gene therapies – that hold the potential to dramatically shift the course of public health around the globe. We celebrate the development of these treatments, and we closely watch how their delivery impacts patients. But the critical step in between – getting these products into the hands of clinicians and patients – remains an immense challenge that rarely makes headlines.

However, the confluence of increasing demands (more sensitive products and stricter regulations) with expanding pressures of globalization and market competition is bringing temperature-controlled biopharma logistics into the spotlight – increasingly recognized as critical to both biopharma businesses and the patients they ultimately serve. In this landscape of rising challenges, achieving success will depend on **three key factors:**



VISIBILITY

Complete supply chain visibility that drives reliable distribution, quality assurance and brand protection



FLEXIBILITY

Flexible logistics solutions that enable the agility necessary to capture evolving opportunities



TCO FOCUS

A relentless focus on understanding true TCO to protect the bottom line and maximize margins.

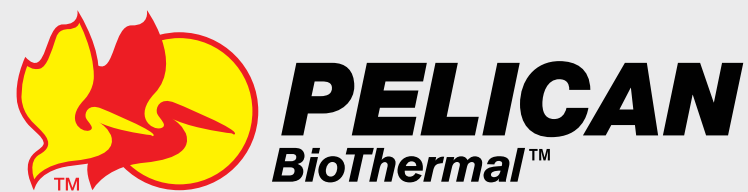


About Us

Pharmaceutical companies – and other organizations looking to make significant cost and quality improvements in their cold chains – are switching to Pelican BioThermal for single-use and reusable temperature-controlled packaging. Our innovative, patented technologies and consultative services ensure product quality, mitigate excursion rates, reduce packaging costs and drive TCO across your entire supply chain. Our global network of consultative cold chain experts provides our customers with consistent packaging and logistics experiences wherever they do business. Our temperature-controlled packaging solutions meet the complex needs of the world's healthcare organizations and comply with the strictest GMP, quality assurance and health and safety standards. Pelican BioThermal is a division of Peli Products, Inc., which is a portfolio company of Behrman Capital, a private equity investment firm based in New York and San Francisco.

RETHINK YOUR COLD CHAIN STRATEGY

Learn how Pelican Biothermal can provide innovative and cost-effective temperature-controlled logistics solutions that give you greater visibility to protect life-saving products and the flexibility to capture emerging opportunities and grow your business.



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