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# Marine Transportation for Pharmaceuticals

# Marine Transportation Becomes Feasible for Pharmaceuticals from AIR to OCEAN

### Low Costs, Fail-safe Temperature Control, and 24-7 Visibility Are Attractive

Ocean shipping has long been the transportation mode of choice for low-cost goods with long shelf lives. Items that were high-value, high-tech or had limited shelf lives were shipped air cargo or, once on the continent, by truck or train.

That is beginning to change. Marine carriers are automating and digitizing shipping. With improved services, even pharmaceutical manufacturers and logistics providers are using ocean shipping for all or part of a journey.

Ocean shipping for pharmaceuticals accounts for only one-tenth of one percent (0.1%) of the global shipping container volume. But the shipping volume by weight has nearly doubled between 2000 and 2016, when it totaled 5.4 million metric tons. During that time, some of the world's largest pharmaceutical companies began looking seriously at marine options and testing routes. Their willingness to consider an alternative to air cargo is based upon three things: declining profit margins triggered by markets' increasing attention to pharmaceutical prices, which is forcing the industry to trim margins; increased globalization, which opens remote, often developing, markets; and improvements in temperature control and monitoring capabilities. Consequently, Pharma Logistics IQ and IQPC formed the Pharma Sea Freight Working Group in 2015 to address marine logistics challenges.

## Pharmaceutical Cold Chain is Growing Fast

Pharmaceutical cold chain products represent about $319 billion (27%) of a global pharmaceutical market valued at $1.19 trillion, according to the Pharmaceutical Commerce Biopharma Cold Chain Sourcebook. As more biologics come to market, this percentage will continue to grow. Even the term "cold chain" has been enlarged from the traditional understanding of 2°- 8°C for most cold chain products and -20°C for frozen products to include the large – and relatively new – controlled room temperature (CRT) category of 15°C and 25°C. Cold chain logistics services have grown from $13.3 billion 2016 to $15 billion in 2018.

Regulators throughout the world are scrutinizing the growth of temperature-sensitive pharmaceuticals, but there is no single, global standard for good distribution practices or agreement on the range of temperatures for some terms. Instead, countries craft their own regulations (with slight variations) and have expanded their attention from the historic temperature rangesto include CRT.

Much of that growth in cold chain and CRT pharmaceuticals is in emerging regions. For example, refrigerated warehousing capacities in India and China grew 43 and 35 percent respectively between 2008 and 2014, compared to only 9 percent in the U.S. Worldwide, the compound annual growth rate for cold chain logistics is expected to grow at 16 percent into 2019.

As the supply chain lengthens, margin pressures are increasing. Consequently, pharmaceutical shippers are looking for transportation options to lower the costs of air shipping, their traditional transportation mode.

## Intermodal

In late 2012, some of the world's major pharmaceutical companies teamed with two innovative pharmaceutical logistics providers to pilot intermodal transportation for less urgent shipments. The intermodal options combine air, road, and – innovatively – ocean freight, and monitor cargo temperatures throughout transit.

For pharmaceuticals, the inclusion of water-based transportation for even a part of the journey was revolutionary. When shippers think of intermodal transportation, they typically first think of planes and trucks, but "intermodal" means the combination of multiple modes. For example,

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cargo may be air-freighted to Singapore and barged to destinations along the coasts of Malaysia and Indonesia before being trucked inland. This combination of transportation modalities provides a low-cost alternative for product arrivals that are not time-critical. Pharmaceutical logistics providers suggest that a significant portion of pharmaceutical shipments could be accomplished using ocean transportation.

Because many pharmaceutical shipments cannot fill a 20 or 40 foot reefer, pharmaceutical logistics providers are exploring options to lower transportation costs by cooperating with competitors to ship goods with similar handling requirements. Consolidation has been used successfully in other industries for less than truckload shipping, and holds promise for pharmaceuticals, as well.

### Considerations

Low costs are the obvious advantages of ocean shipping. Typically, ocean cargo is shipped for 80 to 90 percent less than the same cargo could be air-shipped. Consequently, demand for ocean freight from all industries is growing steading and fleets are expected to grow between four and five percent in 2018. As a result, individual fleets are expected to add more cargo ships than the market can use. That excess inventory could lead to even lower shipping fees. That's a compelling incentive, but other factors must also be considered.

Transoceanic transit times are measured in weeks rather than hours. For example, rather than two-day air cargo, ocean freight leaving North America may take 35 to 40 days to reach India, China, or other distant markets. Because that extra time increases the carrying costs for the product, transoceanic transportation may be reserved for lower cost, bulkier products with long, stable shelf lives. Increased transit time may be offset by enhanced security. Refrigerated containers – reefers – are packed and sealed and, once loaded onboard ship, generally cannot be opened until they are unloaded at their destinations. Therefore, the entire transit can be made without risk of pilferage.

Available in 20 and 40 foot sizes, a generator in the reefer's nose circulates conditioned air, maintaining frozen, cool, or controlled room temperatures throughout the journey. Special reefers can keep products frozen at temperatures as low as -60°C, though others can maintain the 2° to 8°C common for pharmaceuticals, or the 15° to 25°C

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increasingly used for CRT shipments. The most advanced reefers now offer digital temperature controls that provide a high degree of precision. Some containers also control atmospheric pressure and humidity.

Some new reefer designs also offer dual refrigeration systems. The backup system is activated if power is lost for any reason, including during loading and unloading, or if refrigeration equipment malfunctions. Such systems ensure that proper temperatures are always maintained.

Advances in remote monitoring technology offer another safeguard. By monitoring temperatures inside the reefers 24/7, wireless data monitors can provide a continual view into the environmental conditions the products are experiencing. Reports meeting the stringent standards of the FDA's 21CFR part 11, the PDA 1079, and other good distribution and chain of custody guidelines may be issued daily, weekly, or monthly. This constant monitoring provides accurate, objective, proof of conditions and is accepted by the U.S. courts in product liability cases.

The potential danger with ocean shipping is that if something does go wrong, remediation may not be easy or, sometimes, possible. The container in question may be stacked tightly or high in the shipment, making it inaccessible for days or weeks. Shipping lines recognize this problem. Some, like Maersk, now monitor reefers round the clock, and door to door. Therefore, their reefer consultants can take action if reefers aren't prechilled, aren't powered, or have other issues at any point throughout their journey. This gives shippers round-the-clock insight into the condition of their high value cargo so problems can be resolved before they endanger cargo.

No shipping method is completely safe from the potential for failure. Air cargo, for example, relies upon active containers and, often, upon passive solutions systems that

depend upon insulation, refrigerants, or vaporized liquid nitrogen. Active systems still depend upon an external power source. Passive options, typically used for pallet and smaller sized shipments, can maintain temperature for several hours with refrigerants or for several days with liquid nitrogen vapor systems. If, however, flights are delayed or diverted, or if customs clearance is slow, personnel on the ground may need to take actions to prevent or minimize product loss.

### Risk Assessment

The Sea Freight Working Group advised shippers to assess the risks associated with each of their shipping lanes and to put mitigation strategies in place. Identifying the environmental conditions of each lane and how those conditions change throughout the year and by mode of transport is an important part of that assessment. For example, temperatures vary not only by season, but also based upon their location in the cargo hold and mode of transportation. Air cargo faces different extremes than ocean or truck freight, for example. Temperature variations between the point of origin and final destination can be significant, too. But, unless packages sport temperature monitors, shippers may not appreciate the extent of these variations and how their products are affected.

Once the actual environmental conditions are identified for each route and mode of transportation, logistics professionals can make informed decisions regarding the best and most cost-effective transportation mode, lane, and route for specific types of pharmaceuticals, as well as the most effective packaging.

When considering marine transportation specifically, point of origin affects the availability of reefers – refrigerated containers – and the age and types of reefers from which to choose. Because reefers are used to transport flowers, fruit, seafood, and other products, carriers should pre-qualify their reefers to ensure they are clean and dry and that temperature settings match the type of cargo they are handling now. Also ensure that generators are available so the reefer is guaranteed to have power during any transfers, including customs inspections.

Temperature monitoring is an important element of ocean shipping, from the point of manufacturing, to the loading dock, throughout transit, warehousing, and last mile delivery. A variety of data loggers are available. Some, like the SpotSee Logic Temperature Recorder, use wireless technology to log temperatures between - 30°C to 75°C. (-22° to 167° F). It features 4,000 logged data points, and lets data be downloaded during transport. With a three-year battery life, it's appropriate for multiple uses.

### Process Development

Container validation is another concern in a highly regulated industry. In a manufacturing environment, specific equipment may be validated. In shipping, however, a class of equipment or packaging may only be qualified. This is done by a series of steps that includes component qualification, operational qualification, and performance qualification. Combined, these steps assure that the shipping container is capable of its task, performs well at operational extremes, and performs well under real-world conditions.

New shipping options also require pharmaceutical shippers to update their standard operating procedures to account for these changes. For example, procedures must be developed to ensure temperatures are maintained throughout transit, and to be able to react if deviations occur.

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The longer ocean transit times also must be considered for pharma companies using ocean freight. The differences between ocean and air delivery times affect not just shelf life, but when finished products or raw ingredients must be ordered and shipped. Shippers should also ensure that ports of entry have the needed facilities and expertise to handle controlled temperature pharmaceutical shipments.

Logistics providers can address many of these issues. For example, logistics organizations now test and document conditions during shipping and, in some cases, are championing innovative options and technologies to make shipping safer and more efficient for their clients' products.

Advanced analytics, for example, may help pharmaceutical shippers boost efficiency by 10 percent efficiency, according to Pharma Logistics IQ. Temperature data loggers, as IoT devices, are part of that. The use of these devices let shippers track cargo in real or near-real time, so they can react quickly to temperature excursions and related events (including cargo being opened when it shouldn't be) to prevent damage and minimize pharmaceutical recalls. Just as importantly, they enable shippers to easily gather enough data to discern trends within their logistics networks.

Ocean shipping is feasible for pharmaceuticals, for at least part of the journey. Intermodal options now include marine transport as a low-cost solution for stable products that have the luxury of longer delivery times. And, new technologies, including round-the-clock remote monitoring systems, are providing the additional safeguards needed to provide the visibility and documentation to support stringent, regulated, pharmaceutical good distribution practices throughout the world.


## SpotBot BLE

The device was created in partnership with Bosch to make the supply chain transparent. Once attached to the shipment, the SpotBot BLE measures and records temperature, humidity, tilt, and shock, with the data visualized through the SpotBot BLE app. The limits of each parameter can be individually configured, and any violation is traceable and assignable.


## LOGIC Temperature Recorder

Designed to be low-cost and help optimize the cold chain by alerting manufacturers, handlers and shippers when a product has been exposed to temperature conditions beyond a specified threshold. All LOGIC units are water resistant (NEMA 4) recorders with USB in addition to integrated wireless
capability that allows for fast data downloads.


## WarmMark

Single-use, ascending time-temperature indicator which alerts users of exposure to unacceptable temperature conditions.

**Contact SpotSee to learn how temperature data loggers provide added protection for ocean shipments.**

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