

GLOBAL PHARMA LOGISTICS OFFERS MORE OPTIONS

Dramatic traffic downturn makes providers more eager to offer service options; meanwhile, TSA 100% inspection rule looms for air carriers

Between 2008 and 2009, the global logistics industry suffered a downturn of historic proportions, with cross-border traffic dropping by 30-40%, depending on the lane and transportation mode. Carriers responded by mothballing planes and ocean freighters. Trucking suffered dramatically as well (although, obviously, cross-border trucking is a smaller subset of domestic trucking), with YRC, one of the biggest long-haul trucking companies, flirting with bankruptcy.

CONTINENTAL AIR CARGO LOADING THE CSAFE/ACUTEMP CONTAINER. credit: Continental



A lot of this pain has created cost savings and more service options for biopharma as service providers cut costs to preserve client relations and stretch their businesses. Third-party logistics providers (3PLs), who are often the intermediary between carriers and manufacturers, have suffered as well—but it's worth noting that both dollar value and numbers of shippers have held up nicely during the economic maelstrom, which should translate into relatively stable shipping volumes for biopharma, attesting to the resilience of the industry.

Besides the unpleasant business conditions, air carriers have had to contend with two other crises during this year—one manmade, one natural. The Iceland volcano, Eyjafjallajökull, disrupted North Atlantic and Northern European air traffic severely during the late spring (in early June it was still projecting ash high into the atmosphere), and air authorities limited traffic to prevent aircraft damage. “We scrambled to re-route cargo

traffic into Spain and Southern Europe,” says one business manager of a 3PL with cargo through that region, “but guess what: there was an immediate shortage of refrigerated storage and trucks to carry temperature-controlled cargo by ground into Northern Europe.” High-value pharma logistics cargo will usually take preference over other types of cargo, but the disruption has caused delays and extra costs.

Who's your CSSP?

Meanwhile, the imposition of the 100% inspection rule by the US Transportation Security Administration (TSA) has a well-known deadline of August 1 approaching fast. The rule, created by the 9/11 Commission Act passed in 2007, mandates the inspection of each parcel (including breaking down pallets) carried on passenger aircraft on that date; 12 months earlier the target was screening of 50% of such cargo, and in late May, TSA announced that it had successfully reached 75% of cargo screening. Because many types of pharmaceutical packaging (especially temperature-controlled items that are packed with insulation and coolants) preclude opening it at intermediate points, pharma transportation managers recognized early on that a problem was looming.

As the 9/11 Act was coming into force, TSA set up an alternative to at-airport inspection: the Certified Cargo Screening Program (CSSP). Under CSSP, manufacturers, freight forwarders and certain other logistics participants can set up onsite inspection programs, then deliver already-inspected cargo at the airport, avoiding tie-ups there and making intermediate re-opening of packages unnecessary. Many pharma companies and their logistics providers have an advantage over conventional manufacturing: the requirements for GMP manufacturing, packaging and shipping already take care of many of the program's elements, including having restricted-access docks, security-licensed personnel, and procedures for tamper-evident or other security seals on packages. (The program provides for screening by visual inspection, or by explosive-detection systems such as X-ray equipment or chemical sensors.) The catch is that the CSSP candidate must be pre-certified by TSA; this process can take upwards of 60 days, meaning that if a pharma facility (or its 3PL or transportation provider) has not already applied to the program, it's already too late.

TSA has been running regional seminars and Q-and-A sessions nationwide for over a year, and many manufacturers, 3PLs, airport warehouse managers and others have already been certified. "We expect there to be hell to manage in some places, and smooth operations in others, come August 1," said a TSA official at a regional meeting this spring. The 100% inspection rule applies only to passenger aircraft cargo, not dedicated cargo aircraft; and most cargo aircraft are wide-body 747s or similar planes that take palletized shipments, while narrow-body aircraft take mostly parcels. "If you're at an airport with few wide-body aircraft, and lots of narrow-body passenger planes, there may be some delays."

"There's an incentive to bring already-inspected cargo to the airport" said David Brooks, president of American Airlines Cargo, in a webcast presented in early June. "I doubt that any flight is going to be delayed while waiting for cargo to be inspected. Our clients use us because of the reliability of our cargo service schedule; if the cargo's not ready, the plane will leave without it."

"Participation in the TSA's Certified Cargo Screening Program (CCSP) at the manufacturer's warehouse-level is the only way to ensure that security screening downstream does not contribute to product efficacy issues," says Mark Mohr, product development manager at Continental Air Cargo (Houston). "For the most part, the airlines will not have the facilities, equipment and staffing available to preserve the cold chain while screening product to the piece level, especially anything tendered in a temperature-controlled unit-load device. In addition, during the screening process, if we have an alarm that requires resolution, product efficacy will likely be impacted by the invasive processes required to resolve the alarm."

Many of the major 3PLs are hustling to complete their CSSP certification. "We have our CSSP operations up at our main freight operations, and we'll have swing capacity among our facilities," says Bill Hook, president of UPS Healthcare Logistics, which has 24 dedicated facilities worldwide. Ceva Freight, DHL, FedEx, Kuehne+Nagel, Panalpina, Schenker, World Courier and others are also certified (a not-complete list, because some companies

might choose not to be listed, is at http://www.tsa.gov/assets/pdf/ccsp_iacs.pdf).

Smaller 3PLs who focus on healthcare are also filing for certification, or are working with other logistics partners to ensure continuity. “It was clear to us in 2009 there was only one option that worked: to embrace the changes and proactively put ourselves in a position whereby our customers would receive clear and tangible benefits from using Cavalier,” says Tim Holdaway, president of Cavalier Logistics (Dulles, VA), which has received CSSP certification. “In our BioPharma division alone the prospect of having the airlines responsible for screening temperature controlled product or frozen cell lines was just not viable. Our staff is highly trained in this arena and it would be impossible to replicate the processes Cavalier has implemented in an airline environment.”

“We’ve been working with TSA since they came into being back in 2001,” says Mark Sell, president of MD Logistics (Plainfield, IN). “We will be able to offer clients the time and cost savings of having the screening done even as cold-chain or other shipments are being packed,” he says, noting that MD Logistics has freight-forwarding capabilities, and, as MD Packaging, kitting and packing for pharma shipments. The company is in the process of obtaining its CSSP certification.

US pharmaceutical exports increased 19% in 2009 to \$41 billion, imports were up 6% to \$56 billion

\$ billions	2007	2008	2009	Change 2008-2009
US Exports	\$29	\$34	\$41	19%
US Imports	\$49	\$53	\$56	6%

US pharmaceutical exports to Canada and Mexico increased substantially in both value and mass in 2009

	2007	2008	2009	Change 2008-2009
US Exports value (\$ billions)				
Canada	\$3.2	\$3.0	\$4.4	37%
Mexico	\$0.6	\$0.9	\$1.1	88%
US Exports mass (million kg)				
Canada	68.3	70.9	83.0	21%
Mexico	13.3	18.9	18.0	35%

source: US ITC Dataweb

More services

3PLs and carriers alike are competing more intensely for pharma and healthcare products business, and while the past year has been a painful one for the providers themselves, one result is a growing range of service offerings. These include cold chain services, expanded tracking capabilities, and the opening up of ocean freight to pharma. Temperature-controlled pharma shipping is a field enjoying **double-digit growth**, and many carriers have built out their service offerings, including American Air Cargo, Delta Air Cargo, World Courier, Cathay Pacific and Emirates Air Cargo. Continental Air Cargo, which has been in the business for several years, says that it is the first

in the US to obtain the [QEP certification](#), a program managed by Envirotainer (Lagga Marma, Sweden), which pioneered the actively-powered unit load device (ULD) for temperature-controlled palletized shipping. “The QEP program could actually be considered as a jumping-off point for a big part of the recently enhanced and expanded Chapter 17 PCR (Perishable Commodity Regulations) from IATA,” says Mohr. “For Continental, QEP has offered us a platform in which to assist with the global harmonization of our handling process for temperature-controlled shipments.” (IATA is the International Air Transportation Assn.)

At FedEx, a new program called SenseAware is about to be rolled out to the entire life sciences industry. The program was “soft-announced” last autumn, and in the meantime the company has been piloting it with selected clients, according to a spokesperson. SenseAware entails an IT system that not only tracks where a shipment is at a given time, but also reports temperature and other package-status elements in near real-time. The company worked with an unnamed device manufacturer to develop a GPS-enabled, Web-connected sensor—including in-flight communications—and then created the IT infrastructure internally. According to a FedEx representative, the intention is to create an open-source platform that any device or sensor manufacturer can plug into; at the same time, the network could be opened to logistics partners of FedEx for an end-to-end communications network. There are numerous tracking systems for logistics available through many providers; at the same time, there are numerous vendors of sensor systems (which usually collect data in-transit, and then are downloaded at the end of a trip). SenseAware appears to be the first logistics system that combines both capabilities.

APL LOADS A REEFER CONTAINER IN SINGAPORE. credit: APL



Meanwhile, APL, the Singapore-based ocean carrier that serves 140 ports worldwide, has just announced SMARTemp, a service that uses the low-orbit Iridium satellite network with a patented communications module to monitor shipping conditions for freighter-based refrigerated containers (reefers) during ocean-crossing transits. The SMARTemp communication module decodes data from a microprocessor controller fixed to the cargo container, which records temperature and humidity levels and transmits this via satellite to APL’s central

server. Customers can retrieve real-time data via APL’s HomePort e-commerce portal. If freight reaches a predefined threshold in transit, the system provides e-mail or text alerts to APL’s on-call cargo teams for immediate action.

“The unique SMARTemp features could lead to a significant expansion of the type and volume of sensitive high-value cargoes transported via ocean,” says Eric Eng, VP, APL Global Reefer. “SMARTemp will give shippers greater confidence that ocean freight is an increasingly viable transportation option for cargo which has traditionally moved by air.”

Cold chain is also in the spotlight at LifeConEx (Plantation, FL), the joint venture between DHL Global Forwarding and Lufthansa, the Austrian airline. The company announced an expanded cold chain service last fall called LifeCube that provides an all-inclusive pricing and delivery system for temperature-sensitive biopharma

products, and with a specified, pre-validated container whose delivery and return LifeConEx takes responsibility for.

LifeConEx has also announced an ocean-delivery service for life sciences, brandnamed H2Cargo. Traditionally, pharma has had an awkward relationship with ocean carriers, partly because the value of the products are so high, relative to their volume, that insurers were reluctant to cover ocean delivery, and because of uncertain delivery dates. Industry sources say that in the past year or so, ocean carriers became more willing service providers as a way to capture business going to air freight. H2Cargo enables LifeConEx to qualify the ocean carrier (and the containers used), including for cold-chain deliveries. Insurance requirements, however, are still carrier-specific.

UPS Healthcare Logistics has also been building up its ocean services, acting as a non-vessel operating common carrier (NVOCC; a specific classification for brokers of ocean services as opposed to ocean carriers). “There’s some logic to this trend,” says UPS’ Bill Hook, “because ocean transportation rates are so much cheaper than air. But there was a lot of ocean capacity put in mothballs over the past year, just as there has been for air capacity. The result is that as of the middle of this year, ocean rates have been rising again, and vessel operators have still been reluctant to bring on more capacity.” PC