

## Biopharma cold chain will hit \$2.58 bn: FedEx APAC VP

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From a pan-Asia perspective, the biopharma cold chain logistics market alone is projected to grow 66.5 percent to \$2.58 billion by 2017. Taking an even broader perspective, the cold chain logistics market in the Asia Pacific region is expected to account for nearly 30 percent of the global market by 2017 .

The rapid increase in demand for biopharma products is due not only to advancements in medical technology and personalised medicines, but also to innovation-driven demand in emerging economies and increasing life expectancy globally.

Transporting healthcare and biopharmaceuticals is a complex and demanding operation, and, as the pharma trade flow gains

speed, the process of shipping pharmaceuticals has evolved significantly in order to meet the stringent requirements of the trade.

While pharma companies have traditionally been reluctant to outsource logistics to third-party service providers, this is changing rapidly as companies need to boost their revenue to supplement elapsing patents on blockbuster drugs. Against this backdrop, they are outsourcing their logistics operations to supply chain providers that have specialised and more cost-effective operations devoted to the pharmaceutical supply chain.

The evolution is also accelerated by government agencies such as the Federal Drug Administration (FDA) in the US. In the past, healthcare companies shipped mostly 'hard pharmaceuticals', such as pills or raw materials used to make the drugs. Today, healthcare shipments may contain high value products or compounds that can change their chemical, physical, and biological properties during shipping due to changes in the environment.

The nature of such shipments demands stringent time and temperature controls as government agencies such as the FDA have strict compliance to temperature parameters for customized medicines and biotechnology drugs. Maintaining product temperatures parameters and real time data visibility through the whole supply chain is critical to the healthcare companies to meet these regulations.

According to industry estimates, seven out of ten of the top pharmaceutical products will require temperature-controlled transportation by 2014, therefore increasing the demand for customised logistics solutions.

Many biopharma shipments require a refrigerated environment within a certain temperature range, and that has resulted in recent FedEx innovations including a new "cold shipping" packaging that can maintain cool temperatures for up to 96 hours.

As an example, one US-based multi-national biopharmaceutical company that FedEx services, transports liquid media between US and Singapore, and requires shipments to be maintained at a customised temperature range of between 2-8°C (chilled), or -20°C (frozen) throughout the entire shipping process, not only during flight, but also in the time that the shipment transits from a flight to an on-road vehicle. We provide the customer a time-definite, 3-day delivery from US to Singapore with the right temperature-controlled environment, the FedEx Custom Critical exclusive-use vehicles for pick-up and delivery, active monitoring in the FedEx Express network as well as a 24x7, 365-a day service availability.

One of the world's largest makers of laboratory equipment and instruments relies on FedEx to ship high-quality reagent chemicals across China domestically - medical cargo that must be kept at constant temperatures. All are journeys where regulation is high, the dollar value of the goods is high, and delivery reliability is vital. FedEx delivers an integrated transportation solution, including complete custodial control, healthcare control tower services, real-time inventory data and reporting through the FedEx Global Distribution System, a single point of contact for our customer's China business, and consulting for specialized shipments. In addition, we also align closely with our gateway operations to boost service delivery and speed through China's Inspection & Quarantine Bureau.

While speed and capacity are absolutely necessary, they are no longer sufficient.

As a result, global carriers are investing in sophisticated and comprehensive air and road infrastructure to enhance their fulfillment capabilities. Faster speed-to-market, shortened transit times and later cut-off times are just the beginning of customised logistics solutions.

Environmental sensors are also no longer specific to temperature, but are also increasingly focused on several other environmental parameters, such as exposure to light, humidity, pressure, shock and shipment location. The list of sensors will keep growing as pharma shipments become more complex and shippers require more and more information and visibility in their shipments.

Increasingly, we see 24/7 support from dedicated specialists who not only monitor the statuses of critical shipments, but also provide proactive recovery of them. Added services such as dry ice replenishment, gel pack reconditioning and access to cold storage are among some of the customised recovery services.

For example, one of China's leading pharmaceutical R&D companies had to quickly transport shipments of chemical compounds from China to the US. Their challenge was to ensure a constant controlled temperature of -20°C, and deliver a more cost-effective way to transport the compounds. FedEx worked with this customer and offered a closed loop and custodial process as part of its solution - a service that takes just two days from uplift to final delivery in the US. The end-to-end solution includes control tower monitoring and customized packaging (PCM cooling boxes) - all with same day clearance

and transfer to Shanghai's Pudong Airport.

Another trend that we are seeing is that many biopharma companies have established tighter internal procedures for assessing their vendors, including suppliers of services. The overall supply chain has come under intensive scrutiny by regulatory agencies, partly due to the increase use of outsourcing services and also partly due to new and more restrictive Good Distribution Practices (GDP) guidelines.

As a result of enhanced quality standards and a stronger focus on regulatory compliance, FedEx Express is experiencing a drastic increase in the number of inquiries about quality safeguards related to general quality matters with FedEx shipping practices and procedures, especially in Western Europe and North America.

FedEx offers many different types of services to support the healthcare companies' efforts to track performance and ensure a more efficient and effective supply chain. For example, through use of the FedEx innovations like the SenseAware platform, temperature measurements can be monitored in near-real time and analyzed afterwards. In the event any transportation-related problems arise, shippers can request Corrective and Preventive Actions (CAPA) or file a Supplier Corrective Action Request (SCAR) form or even decide to disqualify a vendor temporarily. Investigations are carried out internally by the vendor to determine root causes and find robust solutions.

Indeed, while multi-sensor devices such as the FedEx SenseAware platform are already available for use on all transport modes in over a dozen international locations, by 2033, the use of sensors will be ubiquitous.

We envision that the biopharma supply chain of the future will be underpinned by both visibility and flexibility. It will radiate visibility with tiny embedded sensors, enabling an unparalleled degree of real-time tracking and tracing.

In terms of flexibility, biopharma supply chains will continue to be optimised on an individual level, and every shipper will have access to a personalised command centre to monitor disruptions in the supply chain, with a new level of near-molecular precision. This level of data will also mean greater security throughout the supply chain.

This flexibility will also extend to a venerable fundamental of the supply chain - consolidation. In 2013, most shipments are consolidated, packed in containers in the belly of an aircraft or hull of a ship or back of a truck.

By 2033, pharma shippers will have the flexibility of removing a portion, or even a single item, from a consolidated shipment. It will provide the ability to expedite the customisation and delivery of a biopharma drug instead of sending it with dozens of other packages on the back of a truck.