



TRANSPORTATION ISSUES FOR THE GLOBAL BIOPHARMA INDUSTRY

A Pharmaceutical Commerce Roundtable in Print

The physical movement of pharmaceuticals has rarely, if ever, been as decisive a business factor for success as it is in high-weight, high-volume industries like automotive or food. But today, most industries' supply chains are being whipsawed by painful changes: skyrocketing fuel costs; international anti-terrorism precautions; uncertain trade policies. And every manufacturer feels the pressure of customers' expectation of "perfect order management"—getting what they want, when they want it, with the lowest possible delivery costs.

For biopharma, supply chains feel these pressures as companies look for competitive advantages in meeting customer demands. In addition, supply chains now stretch across continents, with APIs coming from Asia, finished goods from all points of the compass, and customers in every market. The threat of adulterated or counterfeit products entering the supply chain has generated headlines repeatedly over the past year. A seemingly insignificant misstep in material sourcing, or paperwork at an international free trade zone, can result in severe market disruptions.

Biopharma depends heavily on its supply chain service providers—shipping companies, freight forwarders and customs clearance houses, order fulfillment and reimbursement service providers. With this as a backdrop, *Pharmaceutical Commerce* brought together several shipper and logistics providers to share their insights.

I. The No. 1 issue facing any supply chain today is, arguably, rapidly escalating fuel costs. What effects is this having on shipping practices, and what can biopharma companies do to control these costs? What do you do to keep costs under control?

MOHR: Continental Airlines' number one expenditure is for fuel. For every \$1 increase in the cost of oil, our annualized fuel costs are increased by \$45 million. Of course, it's not just the airlines that are experiencing this phenomenon. All modes of transportation are being affected.

Mark Mohr, Manager, Product Development and Special Sales, Continental Cargo. Continental Cargo, part of Continental Airlines, provides domestic and international air transportation for temperature-sensitive goods under the ClimateSecure brandname. 2007 revenues were up 61% over 2006.

Micro management of shipment packaging requirements is critical in the quest to attain cost reductions. By utilizing faster transportation modes with defined ambient temperature management, shippers can reduce packaging materials with the end result being smaller boxes, less weight, and therefore, less expense.



Continental operates one of the youngest fleets in the industry. We have taken steps to reduce our fuel consumption by installing winglets on many of our aircraft, increasing our use of electric powered equipment on the ramp and we have recently begun taking deliveries of our Boeing 737-900ER, which features the lowest per seat fuel burn than any other 737-series aircraft. In addition to reducing costs, these initiatives have contributed to Continental being named as one of *Forbes Magazine's* "Green Giants" for our focus on the environment.

HOOK: Optimizing the biopharma supply chain means controlling the factors you can while also planning for the unexpected and factoring in variables outside of your control, like fuel costs. The key is to take a holistic approach to

the supply chain – a process which starts with having an accurate picture of a company’s total distribution costs.



Bill Hook, Vice President, Healthcare Logistics, UPS. UPS Healthcare Logistics provides a full range of 3PL services, including a dedicated network of warehouses globally. The parent UPS organization has a network of 350 licensed customs brokers in more than 60 countries, and is North America's largest customs broker.

Supply chain value is driven by four factors, which must be balanced to create business advantage: operational costs and expenditures; service delivery/ revenue generation; fixed capital and working capital. A recent study of financial reports issued by corporations shows that companies who get this balance right are those that are adept in the following four areas:

- actively managing product preparation (packaging and pallet preparations)
- actively managing modal routing (multi-modal transportation strategies to contain inventory, prevent markdowns, write-offs and product obsolescence)
- actively managing suppliers (supplier management solutions that include all global vendors and partners)
- actively managing information (visibility across the supply chain)

The key word is “active,” and it’s crucial that biopharma companies have a supply chain strategy and plan in place that enables them to actively manage these areas.

KUSSOW: I think that companies can benefit by changing the traditional decision making process for choosing their mode of transportation. Biopharma customers really need to look at their overall costs to ship, especially in the temperature-controlled arena. This includes packaging, the risks and costs of product loss, costs associated with recovering from temperature excursions during transit, and the transportation itself. The transportation solution with the best value is one that incorporates all of these factors, not necessarily the one with the lowest per-mile rate.



Karl Kussow, Manager of Quality and Validation, FedEx Custom Critical, a unit of FedEx Corp. FedEx Custom Critical has a dedicated air and ground fleet, including straight trucks and tractor-trailers handling deliveries throughout the U.S. and Canada. The company also provides quality management and validation support.

II. Supply chain security is growing in complexity and regulatory difficulty. Let's look at cross-border security first. Can you comment on how requirements such as C-TPAT and Europe's Authorized Economic Operator (AEO) have or will impact the services you provide to biopharma? How do you attempt to gain competitive advantage based on how well your organization deals with these security issues?

BANG: Finding the exact healthy balance between compliance and effectiveness is the competitive advantage. We have partnered with the biopharma industry to give the transportation side of supply chain more flexibility and visibility. At the end of the day, the fundamental antidotes to supply chain breaches are flexibility (or contingency), visibility and control. Lack of those in any part of the supply chain is the weak link vulnerable to many threats and risks.



David Bang, CEO LifeConEx. LifeConEx is a joint venture of two of the largest logistics providers, DHL and Lufthansa Cargo. It is a leading provider specific to healthcare, offering end-to-end temperature-controlled transportation solutions by integrating, managing and measuring all supply chain partners.

KUSSOW: FedEx Custom Critical is a C-TPAT member carrier. Our historical emphasis on the importance of security in shipping led us to be a participant in this program. I feel these security practices are necessary steps to secure the supply chain. In the case of C-TPAT, being a member carrier often reduces the time it takes to import product into the U.S. We'll continue to work with government agencies to be on the front end of these programs. We really view them as opportunities to assist our customers and keep their shipments secure.

MOHR: Continental Airlines Cargo is a C-TPAT certified carrier. While having the obvious benefit of doing our part to support global anti-terrorism efforts, a secondary benefit is that we are paying even more attention to all shipments passing through our system. This is especially true for sensitive commodities such as Pharmaceuticals.

HOOK: UPS has been a C-TPAT participant since 2002, and UPS Freight is designated by both the U.S. and Canadian governments as an approved, Customs-compliant Free and Secure Trade carrier and a Customs-bonded carrier.

To address security concerns while ensuring that products often worth millions of dollars per pallet shipment are not delayed at the borders, it is crucial that biopharma companies have the right cross-border transportation solution. Lost time at borders could mean reduced speed to market of critical drugs, spoilage of temperature-sensitive biopharma products and unmet customer needs.

UPS has the relationships, infrastructure, global network and expertise to help biopharma companies address security through solutions that ensure: minimal product hand-offs; 24/7 visibility of shipments; expedited customs clearance and leading track-and-trace and proactive notification monitoring systems.

III. Now let's look more specifically at biopharma supply chain security. Does your company have policies in place for meeting pedigree and serialization rules for packages flowing through your systems? If you are providing security consulting or advisory services to biopharma, what is your advice for how your biopharma customers should be addressing these issues?

GAHAN: BAX/DB Schenker has a dedicated team of security experts that are active members of ASIS and TAPA, and have been recognized as developing "Best Practices" corporate security programs. Some of the methods of a BAX/DB

Schenker program include, audits of carriers within the supply chain, photo capture of customers goods upon departure, in-transit and at-destination, and vehicle escorts. In the U.S. market, we offer a constant surveillance service (CSS) a product developed by BAX and utilized to monitor a shipment every step of the way by qualified professionals with full compliance accountability, and tracking.



Bob Gahan, leader, Global Healthcare/Life Sciences vertical, BAX Global/DB Schenker. Healthcare/Life Sciences is the fastest-growing part of the Air & Ocean unit of this international shipper and logistics provider.

HOOK: UPS is currently receiving and sending e-pedigrees for clients in several of our U.S. distribution centers. Though California legislation has been delayed for implementation, the UPS e-pedigree solution will support serialization with modifications to the warehouse management system.

KUSSOW: We strive to have complete, uninterrupted custodial control of a customer's product from pickup to delivery. On the ground we accomplish this by offering exclusive use of our vehicle, so only one customer's shipment is on the truck with constant temperature and location monitoring. In the air, by using the FedEx Express air network we are able to monitor and control our shipments as well. This is where operating under an integrator model with your own company assets is key. In either case we provide the customer with a documented audit trail to facilitate the customer's regulatory compliance.

BANG: Emergence of new markets as well as new or consolidated production and packaging sites surely add to the complexity of the supply chain due to regulations and infrastructures with highest security concerns ever. Globalization is one of the most influential factors to the very reason why there is such emphasis on supply chain excellence in many mainstream talks of top executives from pharmaceutical and biotech companies. Your strategic logistics partner(s) should have the bandwidth and flexibility to overcome these by continuous infrastructure investment and alliances where needed (i.e. India, China, etc.), proven security and regulatory leadership, and process driven end-to-end controlled logistics services.

IV. For pedigree as well as for overall supply chain performance, IT platforms and services are a key investment. How do you provide supply chain visibility to your customers? What should they be looking for in state-of-the-art supply chain IT systems?

BANG: We have a unique process management and quality compliance IT platform called LifeTrack that gives the biopharma customers far more comprehensive visibility data with condition and quality assurance of sensitive goods in transit. Complying with 21 CFR Part 11, LifeTrack allows our customers to securely access sensitive data and have real time assurance of temperature integrity of their products while easily preparing them to be regulatory audit-ready.

KUSSOW: At FedEx Custom Critical we monitor our shipments real-time, including temperature and location, throughout the transportation chain. Our customers can also monitor this information while the shipment is moving on our secure Web site. Once a shipment is complete the customer can receive audit-trail documentation for their compliance efforts. In addition to electronic visibility, FedEx Custom Critical has dedicated operations personnel monitoring each shipment. They contact customers proactively to keep them informed of activities involving their shipments from pickup to delivery. The combination of our strong IT systems and our dedicated 24/7 customer service team gives our customers end-to-end visibility of the details of their shipment.

HOOK: Visibility across the biopharma supply chain is critical, especially when you are dealing with high-value products that are temperature-sensitive and have limited in-transit duration. One of the biggest trends we're seeing is the demand for proactive notification of shipment status and corresponding services that allow companies to manage exceptions, such as the ability to intercept packages and refrigerate or re-ice temperature-sensitive shipments.

UPS has a 24/7 proactive monitoring service called UPS Proactive Response, which is especially designed for monitoring these types of high-value and patient-critical products. We have several other visibility solutions such as UPS Flex Global View, which allows companies to track the status of their shipments at any time.

My advice to biopharma companies is to ensure that you have a technology/visibility solution that allows you to:

- Know where your products are at all times;
- Gain real-time information on inventory levels and compliant storage of products;
- Get proactive notifications when products are delayed in the supply chain;
- Maintain documentation for compliance record-keeping; and
- Make critical product decisions in real time.

MOHR: Continental Cargo provides track and trace information for all shipments moving in our system. In addition, all temperature-controlled ULDs are monitored and internal temperatures are logged on an accompanying log sheet and in our track and trace system in accordance with our SOPs.

V. The most dynamic aspect of biopharma transport is temperature-controlled shipping (TCS). How has your organization addressed TCS? What is your advice to your biopharma customers in dealing with the tradeoffs between packaging technologies, business practices, and shipping time and cost? What defines "best of breed" TCS providers?

KUSSOW: The best temperature-control shipping providers work to understand the needs of their customers. They should be looking to provide solutions that offer the best value for customers by considering not only transportation mode, but also the quality, compliance and security needs that are unique to the biopharma industry. Quality carriers work with their customers to consider all the costs involved with transportation. This includes everything from packaging, development and testing, to the costs associated with recovering from temperature excursions or even product losses, in addition to the cost of the transportation itself. It's really bottom-line thinking. If a carrier provides a lower-cost solution for a customer, but the customer loses product, the ultimate cost ends up being much greater than simply the shipping costs.

GAHAN: We provide specialized logistics solutions, including planning and communications between our customers' packaging engineers, packaging companies, cold chain monitoring and measurement companies, specialized temperature controlled surface transportation providers, airline partners—all geared to producing a robust, sustainable and secure cold chain from point of origin to our clients' final destination.

BANG: What's needed and can be available now is a true end-to-end temperature controlled transportation process management incorporating these available technologies in practical terms. In next 2-5 years, I believe certain insulation passive and active packages will be somewhat standardized while more near-real-time condition data (temperature, humidity, shock, orientation, etc.) will be available for intercontinental transportations as well.

For life science organizations, it is imperative that they focus on obtaining the proper process, intervention management, documented milestones, continuous amendments to procedure and overall documentation in order to move products and materials as efficiently as possible. Many government regulators and health ministries want to see the process for temperature-sensitive healthcare products ahead of actual transport.

Ultimately, as companies scale back on costs, having a company dedicated to virtually integrating the process of all points of contact, allows companies to pool internal resources and rely on the "experts" to process map, process manage, and intervene for the overall safety, security, and quality of the shipment.

MOHR: Continental Airlines Cargo is the only U.S. airline currently offering structured TCS programs via our ClimateSecure product offerings. For bulk shipments moving on narrow body aircraft and not traveling in temperature-controlled ULDs, we are developing new handling equipment designed to manage ramp and warehouse temperatures to 15-25 C regardless of ambient conditions. This innovative equipment and the corresponding new product offering will assist customers in reducing packaging materials required in their current shipping processes.

Best of breed means having a business partner and not just a vendor. Collaborative relationships are a must. All of your partners must be adept at working together in creating out-of-the-box solutions to address specific needs. You have to have partners that are nimble, flexible and creative so that solutions become commonplace and not the exception.

HOOK: Managing temperature-sensitive products in the biopharma industry must include a comprehensive supply chain strategy that addresses not only shipping, but storage, distribution, visibility solutions and contingency planning. To help customers manage the entire supply chain process for temperature-sensitive products, UPS has addressed temperature-controlled shipping through a broad range of solutions. These include: PDMA- and cGMP-compliant facilities; shipment refrigeration intervention services; a UPS Packaging Lab that offers temperature and humidity chambers for testing; a Temperature-Sensitive Shipment Monitoring Desk dedicated to monitoring over 21 milestones; the ability to move both passive and active airline containers depending upon customer preferences and product requirements; and transportation contingency plans ranging from alternate modes of transportation to temporary cold storage that are combined with an escalation plan to provide 'no excuses service'.

VI. Looking generally across the range of your biopharma customers, what are the most common or most impactful problems that they have? What do you wish they could do better, or what systems or business practices do they have that are most in need of improvement?

HOOK: Among the top issues we are hearing from our biopharma customers today are: the need for greater temperature mapping for temperature-sensitive products; the need for greater insights into how to best manage inventory and exceptions; the need for greater visibility into their supply chains; and concerns over the lack of consumption data for their high-value products.

We also see very specific needs based on our individual customers. For example, UPS is working with a company on the vaccine side of the business. For this company, managing inventory around flu season and having a flexible enough supply chain to ramp up inventory between July and October and then ramp back down after flu season to focus on R&D is critical.

Overall across the industry, two areas stand out as most in need of improvement in the biopharma supply chain. These are:

Planning: This is the critical step in ensuring that companies have a holistic view of the supply chain and a supply chain solution that meets their specific business needs. Supply chain planning must include MRP planning, solutions for how to manage exceptions and inventory, temperature mapping, visibility solutions and all other critical components of the biopharma supply chain.

Tracking: This goes back to the need for greater visibility across the supply chain. Not only do companies need to know where their products are at all times in order to make decisions about products and notify customers of changes, but they also need better tracking for regulatory purposes. For example, if companies get audited, they need access to shipping records, time-in-transit information, etc.

BANG: Many of our customers struggle with the complexity and security requirements of both their product origins and destinations. Following close behind are documentation requirements for filings for government agencies. Other issues include outside weather conditions that do apply not just to ensuring products stay cool, but ensuring products do not freeze in the winter months.

Every organization has its own set of strategies to expand its market share while increasing shareholder values. However, in my opinion, one of those strategies should definitely include the quality and security of your supply chain, because its benefits can directly impact your abilities to move your goods faster and safer to the markets, to retain

customers, and to reduce total supply chain costs. I think the transformation should start happen where the least attention were having being made. Do you consider “transportation” as an expenditure and commodity spent or critical steps of your new product developments or market expansion? The later will bring such ROI that makes pure transportation costs look not so significant.

Are you looking at simply how much your transportation cost is when your bigger concerns should also be market share, corporate image, compliance, etc.? Do you partner up with a logistics partner in early phase of your product development or leave the last leg of transportation up to the last weeks and days before the products get delivered to the consumers?

For an example, a design of a unit and over pack packaging for temperature sensitive products should be done well in advanced working with strong process driven transportation partner because the actual transportation infrastructure from Puerto Rico to Dublin, Ireland may seriously cripple your distribution strategy because of your limited packaging options. PC