

## Forging Links



### Faced with the demands of a global biopharmaceutical market, Eric Isom of Sentry Logistic Solutions investigates ways of strengthening the cold chain

Eric Isom brings years of experience to his role as Sentry's Manager of Warehouse Operations, where he is responsible for maintaining the security and stability of client products throughout all phases of shipping and storage. Eric is a frequent speaker at cold chain distribution conferences and a contributor to influential warehouse and logistics trade publications. He is also a member of the PDA's Pharmaceutical Cold Chain Discussion Group.

Biopharmaceutical products are generally more fragile and temperature-sensitive than their pharmaceutical counterparts, thus globalization has introduced new risks into the biopharma supply chain. Longer transit times, extreme climate change between origination and destination, and shipping delays caused by more stringent and diverse customs and security regulations all increase the risk that these products can go out of optimal temperature range during transport. Product compromise due to temperature fluctuation can cause millions of dollars in revenue loss and delay delivery of drugs and therapeutics to patients.

Since industry projections indicate that the global biopharmaceutical market will reach \$100 billion by 2010, manufacturers must make a concerted effort to strengthen their international supply chains and protect future revenues and market share as the industry moves toward globalization (1).

#### THE EMERGENCE OF COLD CHAIN MANAGEMENT

Five to 10 years ago, 'cold chain management' was still a buzz phrase that only a few niche companies could actually deliver. However, the unique transportation challenges of biopharma products have driven the need to control thermal variability throughout the supply chain which, in turn, has transformed cold chain management into a burgeoning industry (2). Specialized providers now offer dedicated services designed to preserve the integrity of biopharmaceutical products throughout all phases of the supply chain. Biotech organizations large and small are increasingly turning to these specialized providers in a shift from the traditional in-house logistics model to an outsourced one. This new operating paradigm offers biopharma manufacturers new options for controlling costs, maximizing operational efficiencies and focusing their resources on core competencies, such as research and development (3).

#### SELECTING A COLD CHAIN PARTNER

Although outsourcing to a specialized cold chain provider can provide many benefits, not every potential partner has the capability to provide services on a global scale. A qualified cold chain logistics expert must be experienced and compliant in all facets of biopharma cold chain management. This includes domestic and international shipping, product handling and tracking and short- and long-term temperature controlled storage. The provider must have the experience, systems and processes in place to handle the diverse and changing needs of the global biopharmaceutical supply chain. Criteria that manufacturers should consider when evaluating potential partners include: compliance with global cold chain regulations and best practices; anti-counterfeiting controls; impeccable quality and customer service records; an efficient, reliable cold chain network; specialized cold storage facilities and a reputation for technological innovation.

#### COMPLIANCE WITH GLOBAL COLD CHAIN REGULATIONS AND BEST PRACTICES

As cold chain management has become a more critical component in the global biopharmaceutical supply chain, regulatory agencies and industry associations have been launched solely to develop standards for compliance in this market.

Achieving regulatory compliance was a much simpler task in traditional supply chain models of the past. Now, due to an increasingly complex set of social, scientific and political pressures, industry mandates and international regulations have become significantly more stringent. Each country has its own body of rules and guidelines governing the shipment and handling of pharmaceutical and biopharmaceutical products. A qualified contract cold storage and logistics partner must demonstrate compliance with international guidelines such as:

- ◆ The World Health Organization's (WHO) *Guidelines on the International Packaging and Shipping of Vaccines*
- ◆ Health Canada's *Guidelines for Temperature Control of Drug Products during Storage and Transportation*
- ◆ The Irish Medicines Board's *Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances*
- ◆ The US Pharmacopeia (USP) <1079> *Good Storage and Shipping Practices*

In addition to mandates prescribed by external regulatory agencies, the industry has begun to develop its own body of industry-accepted standards for biopharmaceutical shipping and handling. Several prominent groups have been formed throughout the world to discuss regional challenges and issues; collaborate on problem-solving; examine emerging trends; and define industry best practices. A cold chain management partner should be familiar with the standards being developed by leading international logistics groups such as: Europe's Pharmaceutical Logistics Forum (PLF); the US-based Pharmaceutical Cold Chain Discussion Group (PCCDG); and Europe's Cold Chain Committee (C3).

These three groups joined forces in October 2006, and formed another organization called the Temperature-Controlled Pharmaceuticals Group (TPG). This group's mission is to bring together experienced, interested and committed industry representatives from around the world to help standardize cold chain logistics best practices across international borders. One of TPG's first initiatives has been to revise the PCCDG's Technical Report #39 (*Cold Chain Guidance for Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment*) to address the needs of an international audience.

### ANTI-COUNTERFEITING CONTROLS

Counterfeit drug production has become an international epidemic and is another driving force behind increased control and regulation in the biopharmaceutical supply chain. The US Center for Medicines in the Public Interest estimates that counterfeit drug sales will reach \$75 billion in 2010: "a shocking 92 percent increase from 2005" (4). The FDA's Counterfeit Drug Task Force recently announced steps to guard against this growing risk. Counter-measures for safeguarding the integrity of the US drug supply include a host of regulatory guidelines that focus on key areas such as (5):

- ◆ Chain of custody: by 2007, the FDA will fully implement regulations related to the Prescription Drug Marketing Act of 1987, which require drug distributors to

document the chain of custody of drug products (the 'pedigree') throughout their entire supply chain and distribution channels.

- ◆ Technology: the FDA has identified specific technologies that could be instrumental in tracking and authenticating pharmaceuticals from manufacturing to final distribution. These include radio frequency identification (RFID) tagging of products with unique serial numbers; color shifting inks; holograms; and chemical markers incorporated into drugs or labels.
- ◆ Infrastructure: the FDA has made a general recommendation that each pharmaceutical manufacturer strive for continuous improvement in their supply chain infrastructure to combat the proliferation of counterfeit products on the market. Areas that each company must continually assess and enhance include transportation, inventory tracking and data management systems; logistics processes; standard operating procedures; facilities; supply chain partnerships; and personnel training and certification.

Supply chain-wide accountability is the intended objective of the industry's growing anti-counterfeiting focus. This initiative is being driven from the top down. Not only will biopharmaceutical manufacturers themselves be required to comply with strict countermeasures in each country where they conduct business; they will also be held responsible for the actions (or negligence) of their contracted supply chain partners.

### REPUTATION FOR IMPECCABLE QUALITY AND CUSTOMER SERVICE

A contract cold storage and logistics partner must be committed to excellence in quality control and customer service. As an extension of a biopharmaceutical manufacturer's business, the third-party service provider must operate as a vested stakeholder to protect product integrity as well as the manufacturer's business viability and reputation in the marketplace. Measures of excellence in the supply chain include: a corporate culture of accountability to the customer; demonstrated knowledge of best practices for storing, handling and shipping biopharmaceuticals; skilled and experienced quality assurance, logistics and operations personnel; well-documented standard operating procedures (SOPs); a uniformed process for tracking and improving quality, operations and customer service; independent quality control personnel, processes and evaluations and a singular focus that allows the contract service provider to be an expert in its niche area (6)

### AN EFFICIENT, RELIABLE COLD CHAIN NETWORK

The traditional supply chain model is built on deploying inventory to a network of national or international distribu-

tors, where products often await shipment for long periods of time. The emerging, more-efficient model is based on a smaller regional network of a few highly-specialized third-party logistics (3PL) and cold storage providers that can receive and ship a larger volume of inventory on a 'just-in-time' basis, enabling greater efficiency, economies-of-scale and workforce flexibility (3).

This model enables 'shared-user logistics' wherein the service provider spreads infrastructure, administration and overhead costs among its clients, providing each with significant cost savings. The end result for manufacturers is reduced time-to-market and new supply chain efficiencies (3). When selecting a contract cold storage and logistics provider, manufacturers should ensure that potential vendor partners have well-established processes, systems, distribution alliances and relationships with reputable air and freight carriers regionally, nationally and internationally.

### SPECIALIZED STORAGE FACILITIES

At various points in the supply chain, biopharmaceutical components and end-products may need to be stored for varying lengths of time, from a few days to a few months. Short-term or long-term storage facilities might be needed to temporarily house: inventory overflow from a primary warehouse; product components that are awaiting assembly; finished products that are awaiting distribution; and/or shipments that are clearing customs. While pharmaceutical compounds remain stable under a broad range of temperature conditions such as +2°C to +8°C, many biologic products must be maintained within tighter tolerances in cold (+1°C to +5°C), frozen (-30°C or -40°C) and even cryogenic storage (<160°C). Most traditional supply chain storage facilities are not designed to accommodate these conditions. In these situations, a cold chain logistics partner must provide access to a state-of-the-art storage facility that has been designed to meet the unique requirements of biopharmaceutical products. It must offer: validated, temperature-controlled storage and temperature-monitoring equipment; redundant power, cooling and environmental monitoring systems; redundant data storage capabilities; and sophisticated data security systems.

### REPUTATION FOR TECHNOLOGICAL INNOVATION

Maintaining real-time visibility into inventory is critical to the efficacy of the just-in-time biopharmaceutical supply chain model. In addition to becoming an industry standard, on-demand inventory tracking and management is also vital to controlling costs and increasing operational efficiency. To this end, biopharmaceutical developers and manufacturers should choose third-party logistics partners that embrace this trend toward total visibility. This can manifest itself through innovative product tracking and management tech-

nologies such as RFID and internet-based inventory management software that enables manufacturers to:

- ◆ Guarantee product integrity: by tracking products through all stages of the supply chain and incorporating chain-of-custody details and temperature data with product tracking information, manufacturers gain auditable records proving that their temperature-sensitive products are secure, genuine and uncompromised.
- ◆ Introduce new efficiencies into the supply chain: real-time, internet-based tracking systems can allow manufacturers to access their inventory online and schedule 'just-in-time' shipments to create greater supply chain efficiency.
- ◆ Improve visibility and facilitate future planning: successful technology solutions create a window into manufacturers' product inventories that helps them operate with minimal inventory, prevent stock-outs and better manage and plan production and distribution.

### COMPETING SUCCESSFULLY IN THE GLOBAL ECONOMY

Globalization presents enormous opportunities for biopharmaceutical developers worldwide. However, as with most great opportunities, it also presents new challenges and risks. In this case, biopharma firms face a series of supply chain obstacles that, if not properly managed, can jeopardize the integrity of their temperature-sensitive products and components and, ultimately, corporate revenues.

To successfully navigate this changing terrain, biopharmaceutical firms must develop comprehensive, innovative go-to-market strategies that don't end at the supply chain. They must look beyond the familiar and adopt new cold chain processes, best practices and alliances that can help them efficiently and cost-effectively deliver products of the highest quality anywhere in the world. Partnering with service providers that specialize in transporting and storing biopharma products internationally can offer a critical advantage, positioning manufacturers to compete more effectively in the growing global market. ◆

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