WHITE PAPER

Solutions to Global Pharmaceutical Supply Chain Challenges

PHARMA PACKAGING SOLUTIONS

AGILE. COMPLIANT. INNOVATIVE.

Solutions to Global Pharmaceutical Supply Chain Challenges

Find out how a contract packaging company can deliver the expertise and flexibility needed to ship pharmaceuticals internationally.

The global pharmaceutical sector is embarking on a transformational journey in which the supply chain will play an increasing strategic role. There will be a need for greater agility and improved speed to market – while ensuring compliance with myriad regulatory requirements in countries – forming a challenging landscape for the global pharma industry.

One of the drivers of this change is the merger and acquisition (M&A) activity in the industry. According to PricewaterhouseCoopers, M&A activity in the pharmaceutical sector surged in the second quarter of this year with 62 deals announced representing almost $170 billion of total value. Merging supply chains is a complex process, and anyone who questions the impacts should consider what happens when supply chains break down: Drugs are delayed to market, customers experience poor service, security and compliance risks heighten, and a host of missed opportunities occur.

Also impacting pharma supply chains are complexities around logistics and regulatory requirements. Logistics encompass the time from when the product is produced to when it is packaged and labeled to when it is distributed and includes special care regarding product shelf life, temperature control, storage, and shipping location. And from a regulatory standpoint, different government agencies have different opinions about approving drugs – some are approved in countries and some are not.

Finally, and probably the most critical issue driving change in pharmaceutical supply chains is the area of serialization, also known as track and trace, because drug counterfeiting has become a multi-billion dollar industry. In fact, earlier this year, INTERPOL seized 9.4 million doses of fake medicines. Compliance with US DSCSA (Drug Supply Chain Security Act), China, Brazil, Korea, Argentina, EU and other track and trace regulations will cover more

than 75 percent of global medicines by 2018. The serialization, product tracing, product verification, and government reporting requirements are complex and the risk is high.

Use a Contract Packager

In response, the pharmaceutical industry is turning to contract packaging companies, as is evident from a technical market research report, Global Markets for Contract Pharmaceutical Manufacturing, Research and Packaging. According to the report, the global market for pharmaceutical and biopharmaceutical contract manufacturing, research, and packaging was valued at $219.9 billion in 2012 and is expected to reach nearly $374.8 billion by 2018. Outsourcing packaging has become a viable and a beneficial business strategy that is enabling pharma to transfer non-core activities to external partners in order to restructure their distribution networks, leverage resources, and intensify focus on research and development. For many, this strategy has resulted in improved supply chain management and can yield a 25 to 50 percent reduction in total supply chain costs.

Contract Packager Capabilities

There are some specific capabilities that a contract packaging company should offer to a global pharmaceutical company. For instance, as the issue of serialization has become front and center in ensuring the quality and safety of drugs as they move through the supply chain, a contract packager should be well versed in this area. Second is the issue of bright stock labeling, which can help streamline drug distribution in countries other than where the drug was manufactured. And finally, a contract packager should have flexible packaging lines to handle a variety of products and batch sizes.

Preparedness for serialization e-pedigree

Whenever drugs are being shipped internationally, the government agencies involved all have to feel confident that what is being purported to be the drug is the drug. In November 2013, the Drug Quality and Security Act became law

in the U.S. FDA is tasked with developing a means of tracking drug products throughout the supply chain to minimize the risk of contamination and counterfeiting. All pharmaceutical companies are required to add serial numbers to all packages in the next four years. The labels must be upgraded to electronic codes within the next ten years.

Any pharma company using a CP should ensure that the CP has a complete serialization program is in place to track the history of a given product's chain of custody from the manufacturer to the point of dispensing. Additionally, an e-pedigree (electronic history) should provide data on the history of a particular batch of a drug. Contract packagers can affix a unique and traceable serialized number to every package, bundle, case and pallet. This serial number is read many times as the product moves from manufacturer to consumer and, each time, an entry is made in a database to document the official chain of custody.

These standards are used mainly to reduce counterfeiting and a contract packager should be familiar with the subtle differences in requirements defined for each country.

Bright stock labeling

Products are manufactured in large, cost-efficient batches and stored in unlabeled primary containers with expiration dates and tracking information. These containers are then labeled with the compliant labeling in the correct language just prior to shipment. Beneficial for the Rx and OTC markets, bright stock labeling allow a pharma company to deliver "Just In Time" or "Made to Order" inventory using a contract packaging partner.

For example, a U.S.-based contract packager will receive capped bottles from Europe, and then label and shrink wrap the product with inserts adapted for the domestic market where the drug will be consumed. Labeling and packaging the product closer to the shipment time allows for a more accurate inventory forecast. This can eliminate the costs involved in labeling and

packaging the product at the time of manufacture, which results in over-forecasted items languishing at the retail level as their expiration dates quickly approach. A contract packager serving the U.S. market, for example, can accept a bright stocked label from a drug manufactured in Europe. The U.S. packager will be more familiar with the market, language, and regulations in the U.S. Bright stock labeling also supports the goal of delivering drugs to the patients most in need in North America through logistical simplicity.

Rest of World labeling

If a pharma company's aim is to create a worldwide development program for their new drugs not just on humanitarian grounds, but also for economic gain in emerging markets, then compliance with global regulatory agencies must be met. Rest of World (RoW) packaging is similar to bright stock labeling in that inventories specific to the country in which the product will be consumed will be labeled with compliant information in the correct language, but it specifically relates to packaged product which will be sold in developing global markets outside of the US, Europe, and Japan.

Flexible primary and secondary packaging lines

How flexible is the contract packager's production? Do they have several lines to run your product or just one? Equipment should handle large and small batch sizes and can change over easily to be more adaptable to a variety of drug delivery systems.

Choosing a Contract Packager

When selecting a contract packager to handle your international drug shipments, there are several factors to consider:

Project Management—Ask the contract packager to describe their project management system in terms of who is handling your project, expected turn-

around time, if there will be a dedicated line just for your product's run–and for as long as it's needed. Look for a structured plan to define and execute the requirements of each new project. Project management promotes "team" planning and communications through weekly or bi-weekly meetings.

Packager profile and history—Look at the experience of the management group and the team's knowledge. The employees need to deliver confidence and trust in their communication and documentation. Find out how long the packager has been in business and that turnkey solutions are provided under one roof for tighter supply chain control.

Regulatory capabilities/track record—Ask about FDA audits and how the contract packager performed. Find out when the last audit occurred, if the site is cGMP compliant, and if any 483s have ever been issued. Caution: if the company does mostly nutraceuticals, check into their regulatory status to ensure they are FDA-audited and DEA-registered so that they can handle your pharmaceutical needs.

Dedicated resource availability—Depending on how many lots you anticipate running, the packager should be able to tell you whether or not they have the right equipment and tools needed to produce and manage your project.

Summary

Pharmaceutical companies want to make drugs and want to sell them, sell them quickly, and get the right drug in the right patient's hands; this is their core competency. As industry has become a global supply chain, meeting those goals has become more challenging. A contract packager can eliminate those complexities and ensures that pharma's objectives are achieved.

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