Selecting a contract packaging partner

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Partnering with a contract packaging company gives manufacturers the expertise to comply with serialization requirements and the flexibility needed for global pharmaceutical logistics.

The global pharmaceutical sector is reshaping itself to be leaner and more responsive to market demands. That’s because, as always, manufacturers are seeking to reach global markets more quickly. To do so, they must navigate myriad new regulatory requirements across many countries. In short, new regulations and regulatory uncertainty have placed the pharmaceutical industry in a challenging and uncharted landscape.

Among the drivers of these changes is merger and acquisition (M&A) activity, layoffs, patent expirations and a fluid regulatory environment. Overall, M&A activity in 2014 increased by 4.1 from 2013, reaching $378.2 billion, and the number of deals rose by 37.5 percent to 153 [1]. In most M&As, supply chains also merge, and that alone is a complex process that must be well managed. When you add layoffs and patent expirations, the challenges grow larger as companies focus on cost cutting. These changes can lead to delays in delivering drug products, poor customer service, security and compliance risks, and a host of missed opportunities.

Meanwhile, the intricacies of logistics and the complexities of new regulatory requirements persist. Logistics—
from the time the product is produced, packaged, and labeled to its ultimate distribution—requires special care in terms of product shelf life, temperature control, storage, and shipping. From a regulatory standpoint, different governments take different views of drug products, their components, and how they must be handled and documented.

Using a contract packager

Contract packagers allow pharmaceutical companies to focus on their core competencies of developing and marketing needed drugs. When identifying the right contract packager, pharmaceutical companies need to consider compliance, capacity, and capabilities. There are many contract packagers to choose from. According to a 2013 technical market research 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, which equals an annual growth rate of more than 9 percent [2].

Outsourcing packaging is a beneficial business strategy because it enables pharmaceutical manufacturers to transfer non-core activities to external partners, allowing manufacturers to restructure their distribution networks, make better use of internal resources, and intensify their focus on research and development. Meanwhile, contract pharmaceutical packagers can focus on incorporating packaging innovations, which “are expected to create a major change in the way drugs will be packaged,” according to a 2014 report from Frost & Sullivan [3]. In many cases, outsourcing has improved supply chain management; it can also reduce total supply chain costs by 25 to 50 percent [4].

Serialization

The most critical issue today for people working in the pharmaceutical supply chain is serialization, also known as track and trace. It’s an area that continues to grow to fight drug counterfeiting, which is a multibillion-dollar industry. While its exact extent is unknown, in some areas of Asia, Africa, and Latin America, counterfeit medical goods constitute as much as 30 percent of the market, according to Interpol. In a single operation last year, its agents seized 9.4 million doses of fake medicines [5].

By 2018, track-and-trace regulations—including the Drug Supply Chain Security Act (DSCSA) in the USA—in the EU, China, Brazil, Korea, and Argentina, and other countries will be in force and apply to more than 75 percent of global medicines. Already in January 2015, more than 20 markets have in place or have pending pharmaceutical serialization requirements [6]. Instituting serialization, product tracing, product verification, and government reporting systems that comply with all these requirements is a complex undertaking, and the risk of missteps is high.

What to look for in a serialization and contract packaging partner

Every pharmaceutical company should be studying how it will meet serialization requirements, especially those with global reach. Today, serialization is front and center as the means to ensure the quality and safety of drug products as they move through the supply chain. Make sure the contract packagers you consider are well versed in that area. They should also understand brightstock labeling, which can help streamline drug product distribution in countries beyond where the drug product was manufactured. Every contract packager under consideration should also offer production flexibility in terms of packaging lines that can handle a variety of products and batch sizes.

Whenever drug products are shipped internationally, government agencies must be confident that you’re shipping exactly what you claim. That minimizes the risk of contamination and counterfeits, thereby promoting quality and patient safety. When the DSCSA became law in November 2013, it tasked the FDA with developing a means of tracking drug products throughout the supply chain. To that end, all pharmaceutical companies must add serial numbers to their packages in the next 4 years. Package labels must be upgraded to electronic codes by 2023 so that ownership can be traced to the original manufacturer or repackager.

Pharmaceutical companies should ensure that their contract packagers have a complete serialization program in place, one that tracks a given product’s chain of custody from the manufacturer to the point of dispensing and securely stores that history, known as an e-pedigree. Additionally, the e-pedigree should provide data about the batch from which the drug product was manufactured. That means contract packagers should affix a unique and traceable serialized number to every package,
bundle, case, and pallet associated with that drug product. That way, at each leg of the product’s journey from the manufacturer to the consumer, the serial number can be scanned and added to a database in order to document the product’s official chain of custody. These standards, used mainly to reduce counterfeiting, require that contract packagers understand how the requirements differ, often subtly, from country to country.

No matter where you plan to sell your products, every contract packager you consider should offer flexible production. That means operating several lines that run your product, not just one. It also means the company’s equipment should handle large and small batches and adapt easily to package your drug products in different formats. There are several additional factors to consider:

Project management. Ask the contract packager to describe its project management system in terms of who is handling your project, the expected turnaround time, and whether there will be a line dedicated to your product’s run for as long as it’s needed. Look for a plan that defines the requirements of each new project and describes how they will be met. Ideally, project management includes team planning and weekly or bi-weekly meetings.

Packager profile and history. Look at the experience of the management group and the team’s knowledge. Its employees should be confident in what they propose and should back up their proposals with documentation. Can the group provide turnkey solutions under one roof? That typically provides tighter control over the supply chain. How long has the packager been in business?

Regulatory capabilities and track record. Ask about FDA audits and how the contract packager performed. Find out when the last audit occurred, whether the site complies with current GMP, and if any 483s (warning letters) have ever been issued. If the company is involved in packaging dietary supplements, check its regulatory status. You need to know that the company has undergone an FDA audit and is registered with the DEA to handle your pharmaceutical products.

Dedicated resources. Depending on how many lots you anticipate running, the packager should be able to tell you whether they have the equipment and tools needed to produce your product and manage your project. Verify it during a plant visit.

Rest-of-world packaging and bright-stock labeling

Contract packagers can also help pharmaceutical companies extend the reach of their new drug products by helping them comply with the regulations in markets outside of the USA, Europe, and Japan. This can be done using the rest-of-world (RoW) packaging concept. With RoW, products specific to the country in which they will be consumed are held in inventory and, as needed, the contract packager labels the goods with the required information in the correct language. It’s similar to the concept of bright-stock labeling.

In fact, the practice of labeling products immediately after manufacture is disappearing. More often, drug products are manufactured in large batches and stored in unla- beled primary containers that bear only expiration dates and tracking information. These containers then receive compliant labeling in the language appropriate to their destination just prior to shipment. This is called bright-stock labeling and it’s beneficial to manufacturers of prescription and over-the-counter products because it allows companies to operate on a “just-in-time” or “made-to-order” basis, typically in cooperation with a contract packaging company that maintains the manufacturer’s inventory. (The term “bright stock” comes from the food industry, where it referred to metal cans of vegetables, soup, or other products that had yet to be labeled.)

Using the bright-stock approach, a US-based contract packager might receive filled and capped bottles of tablets from Europe and simply add a label and insert that suit the
market where the drug product will be consumed. Bright-stock labeling also eliminates many of the complications and costs of labeling and packaging the product at the time of manufacture. In addition, by labeling and completing the product's package closer to shipment time, manufacturers can forecast inventories more accurately. This prevents an underestimate of sales from leading to a shortage or an overestimate causing expiration-dated products to languish at the retail level. The logistical simplicity of bright-stock labeling also supports the goal of delivering drug products to the patients most in need.

**Conclusion**

Pharmaceutical companies want to make drug products, sell them quickly, and get the right product into the patient’s hands. Those are their core competencies. As the pharmaceutical industry has become enmeshed in a global supply chain, meeting those goals has become more challenging. A contract packager can eliminate many complexities and ensure that your company’s objectives are achieved.

**References**


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