WHITE PAPER

Outsourcing Strategies - Selecting the Right CPO Partner

PHARMA PACKAGING SOLUTIONS

AGILE. COMPLIANT. INNOVATIVE.

A Little History

The pharmaceutical supply chain has been in a state of evolution ever since it began. At varying points along the timeline, mini revolutions occurred. Around the turn of the century, apothecaries and the makers of dyes and textiles merged sciences and efforts to take advantage of unique discoveries on both sides. Companies such as Bayer, Schering, Sandoz, Abbott, Pfizer, Smith Kline, Eli Lilly, Squibb, and Upjohn emerged as apothecaries and drug suppliers between the early 1830s and late 1890s. Their production had a profound effect on human health. In 1900, one third of all deaths were from pneumonia, diarrhea, and tuberculosis. Today, only pneumonia remains on the top ten killer list (mainly as a side effect of cardiovascular disease and cancer).

In the early 21st century, the nascent pharmaceutical industry combined drug manufacturing, marketing and distribution under one roof. Post WWII, when the “wonder drugs” arrived including penicillin, another mini revolution occurred. Wonder drugs not only changed human and animal life expectancy considerably, they also increased mass production of pharmaceuticals to new levels. After the 1950’s, advances in technology and molecular science drove pharmaceutical companies toward drug development and glimmers of today’s more specialized production environment began to appear.

The turn of the next century brought new economic realities to pharmaceutical companies who faced expiring patents, growing threats to intellectual property, weak pipelines, shrinking profit margins, heavy competition, and growing regulatory pressure. To address these issues, pharmaceutical companies have pursued an aggressive strategy of consolidations via mergers, acquisitions and joint ventures so they can gain access to new markets. Part of this new strategy includes outsourcing to enable focus on their core business of developing and marketing pharmaceuticals.

Today's Reality

Over the last several years, the biggest pharmaceutical companies have evolved, and they now look more like companies in the consumer packaged-goods industry. Today, major pharmaceutical companies outsource up to 60% of their manufacturing. Because of less production and manufacturing in-house, tighter margins, and a need to focus more intensely on specific customers and segments, new rules require that pharmaceutical companies rely on aligned, specialized partners like a contract packaging organization (CPO).

A Shift In Strategy

The cost to bring a new drug to market is about $2.5 to $4 billion according to Tufts Center for the Study of Drug Development leading major pharmaceutical players to grow through acquisition instead. Mergers and acquisitions have never been more active since they allow a company to sidestep drug development costs and instead deliver drugs already pegged as “winners” to the market. Expiring patents also require drug manufacturers to manage diminishing margins.

Outsourcing packaging to a CPO has become a viable and beneficial business strategy that enables pharmaceutical companies to transfer noncore packaging activities to a specialist. Let’s face it, not all pharmaceutical drug launches are blockbusters. One strategy used by pharmaceutical companies is to build in cost savings on the packaging end. Using a packaging supplier's infrastructure helps avoid capital outlays and it is much easier to manage fluctuations in demand at the critical pharmaceutical lifecycle points. The minutiae of drug packaging, which now includes the complexities of serialization, may not be the wisest investment of time, equipment, and resources for a pharmaceutical company. Instead, it makes more sense for a CPO to bear the costs of new legal requirements, new state-of-the-art packaging equipment, and new processes.

Core Competencies

This means of course, that each part of the pharmaceutical supply chain must play its own unique and distinctive role – with each part of it focusing on a core competency. When each supply partner contributes their own unique skill and knowledge set, efficiencies emerge. Pharmaceutical companies can choose from a variety of models including one where they focus on the branding and marketing of the product and outsource all other functions such as research and development, drug formulation, packaging and distribution. Improved supply chain management using the core competencies of each member, including the CPO, has yielded between 25-50% savings for some pharmaceutical companies.

Examples

Most pharmaceutical companies consider their core focuses to be in research and development, drug formulation and marketing. Shire Pharmaceutical, which outsources almost all its functions beyond drug formulation and marketing, says that you cannot tell the difference between their products and ones produced in a vertically integrated environment. Their complicated supply chain is legendary for its efficiency and versatility. Shire refers to all their vendors as partners. That is probably not a coincidence. Closely aligned, communicative, responsive, adaptable partners are the key to any outsourcing success. The minutiae world of drug packaging, which now includes the complexities of serialization, may not be the wisest investment of time, equipment and resources.

Outsourcing Means Trusting

To manage the risk of outsourcing, pharmaceutical companies have to have faith in their partners, with not only clear communication but also end-to-end supply-chain visibility. Technology is fueling that visibility. As the pharmaceutical supply chain comes into compliance with federally mandated track-and-trace regulations, new IT infrastructures will facilitate more insight into where products are in the system. With variable floor space, equipment, and processes and a trained workforce that can handle a variety of packaging requirements, CPOs can provide capabilities and capacity not available in-house to a pharmaceutical company.

Trust, however, is the most important component in developing a relationship with a partner. You can figure out if a CPO has the right equipment and timeframes just from their pricing which will demonstrate competitiveness and efficiency, but what you really need to judge carefully is the pre-production project management and the post-production speed-to-market. It will be based on a CPOs culture and personality that you will gain the most trusting relationship that ultimately leads to supply chain efficiencies.

To help you choose a contract packager, ask the questions below to make sure you can build your trust in their ability to meet your needs.

The Questions To Ask, The Answers To Hear

1. Q's:

   Who is on the project-management team, and what is their level of experience? Are regularly scheduled meetings part of their process?

   A's:

   You want a team with years of experience, but with diversity. You are looking not only for operations experience, but also regulatory, purchasing and IT expertise. You want creative people who can help you with innovative approaches to your supply chain challenges. You want a contact list and a schedule of brief meeting updates so you can ensure communication lines are open at all times.

2. Q's:

   Who are the CPO's current pharmaceutical customers? What type of drugs products do they market?

   A's:

   Even with confidentiality agreements in place to protect all stakeholders, a CPO can typically tell you the types of customers they work for and the types of projects they handle and you can judge them by the company they keep.

3. Q's:

   What is the CPO's project-management system? Can they describe the way they put together a structured plan to define and execute a project like yours?

   A's:

   You want to see a certain level of communication and documentation to reassure your team that their project will stay on track within the mutually agreed time line and packaging requirements.

4. Q's:

   How flexible is the CPO's production? How adaptable are its operations? Do they allow the company to be responsive to your needs? Does the company have several lines to run your project or just one?

   A's:

   Make sure your CPO of choice has the capacity on their primary lines (for bottling or blistering for example) and secondary lines (for labeling or repackaging for example) needed for your project. Ask for a schedule of when packaging will begin and will be completed in production. Ask how long Batch Record review will take. Ask how long validation will take. Ask if your CPO will assist in developing contingency plans when needed. Make sure your CPO has reliable labeling Suppliers that offer 'Launch Services."

5. Q’s:
   Does the CPO have the right equipment and tools for your project?
   A’s:
   You want to make sure that a CPO has the right line setup for your project. You are looking to see that the right tooling is available (ask if they have clean room validation); that the types of packing equipment on site will work for your needs; if cold chain storage and DEA security cages are available and what other unique capabilities are on-site.

6. Q’s:
   Is the CPO’s serialization program ready? Do they have the equipment and IT systems in place?
   A’s:
   Make sure the serialization and aggregation equipment are in use and ready for labeling, bundling, case packaging and palletizing.

7. Q’s:
   How has the CPO performed on FDA audits? When was the last one; is the site cGMP compliant; and have any 483s been issued recently?
   A’s:
   A strong regulatory record is a sign of compliance. The more compliant your partner, the more secure your supply chain is.

8. Q’s:
   Is the CPO compliant with the Generic Drug User Fee Amendments (GDUFA)? Do they pay facility fees?
   A’s:
   To answer this question, make sure your chosen CPO is up-to-date on their fees here: http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm351219.htm

9. Q’s:
   What is the average expected turnaround time for your type of project?
   A’s:
   Since speed to market is an important issue, find out how your CPO approaches your project once it has been packaged and released for shipment. How long does it sit on the floor before it ships, how quickly do they handle nonconformance issues, etc. Regardless of the size and scope of your project, make sure you have discussed the delivery requirement of your project.

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