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How to select a contract packaging partner

Better supply chain management has enabled some pharmaceutical companies to cut costs by 25 to 50 percent. Outsourcing packaging to a contract packaging organization (CPO), for example, transfers non-core packaging activities to a specialist and spares the pharmaceutical company capital outlays.

CPOs have capacity and capabilities not available in-house to most pharmaceutical companies. This includes readily-accessible floor space, equipment, processes, specialized workrooms (such as low-humidity primary packaging suites), and a workforce trained to handle a variety of packaging requirements.

Managing the risk of outsourcing requires that a pharmaceutical company trust its partner. You can determine if a CPO has the right equipment and timeframes from its pricing. However, it's more important to focus on a CPO's pre-production project management and its post-production speed-to-market. Those characteristics are based on a CPO's culture and often determine how trusting the relationship and efficient the supply chain will be.

When choosing a CPO, you should know what questions to ask and what answers to expect. Below are some examples.

Who is on your project management team?

You want team members with years of experience and diversity that can provide innovative approaches to your supply chain challenges. That is, you're looking not only for operations experience but also for regulatory, purchasing, and IT expertise.

Are scheduled meetings part of your process?

The CPO should schedule regular, brief update meetings and provide a contact list to ensure open communication.

Who are your current pharmaceutical customers? What type of drug products do they market? Judge the CPO by the company it keeps. Even with confidentiality agreements, a CPO can describe its typical customers and the types of pharmaceutical projects they handle.

What is your project management system?

A CPO should be able to tell you how it will define and execute your project. Ideally, you'll see a certain level of communication and documentation that reassures you and your team that the project will stay on track and follow the agreed timeline and packaging requirements.

How flexible is your production? How adaptable are your operations? Do they allow you to be responsive to our needs? Do you have several lines to run our project or just one? Make sure the CPO has the capacity on its primary lines (e.g., bottling or blistering) and on its secondary lines (e.g., labeling or repackaging) that your project requires. Request a production schedule indicating when packaging will begin and be completed. Ask how long the batch record review will take, what validation is required, and whether the CPO will help you develop contingency plans when needed. Make sure the CPO has reliable labeling suppliers that offer launch services.

Do you have the right equipment and tools for our project? Determine if the on-site packaging equipment meets your needs. Verify that the CPO has the right line setup for your project and that it has suitable tooling and cleanroom validation. Also, make sure the CPO has cold-chain storage and DEA security cages as well as other unique capabilities on site.

Do you have serialization equipment and IT systems in place? As the pharmaceutical supply chain comes into compliance with federally mandated track-and-trace regulations, new IT infrastructures will facilitate more insights into where products are in the system. Make sure the serialization and aggregation equipment are in use and ready for labeling, bundling, case packaging, and palletizing.

How has your company performed on FDA audits? When was the last one? Is your site GMP-compliant, and have any 483s been issued recently? A strong regulatory record is a sign of compliance. The more compliant your partner is, the more secure your supply chain will be.

Does your company comply with the Generic Drug User Fee Amendments (GDUFA)? Has it paid the facility fees? To answer those questions, make sure your chosen CPO is up-to-date on its fees. You can find this information on the FDA website at http://bit.ly/GDUFAPaid.

What is the average expected lead time for our type of project?

Find out how the CPO approaches your project after packaging and the release for shipment. How long do products sit on the floor before shipment? How quickly does the CPO handle nonconformance issues? Regardless of the size and scope of your project, make sure to discuss your delivery requirements. *T&C*

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