Is Selecting A CDMO Based On Contract Price Really Saving You Money In The Long Run?

"We contracted a CMO to make a very expensive drug substance. They could only achieve drug purity of 70 percent, not the 95 percent we needed. We had to involve two full-time staff for a year to salvage as much API as possible from the poor material and to detect and correct the problem."

Hidden costs

Whether you're developing a drug substance or finished dosage form – or both – you need to complete the project before you use all of your funds, so choosing a CMO or CDMO is a big decision. You calculate costs for technology transfer and per-unit manufacturing. But your biggest costs may be hidden. Depending upon your CDMO's location, you may incur added costs for transportation, customs, duties, taxes and QP reviews. And worse, mistakes, manufacturing problems, and dysfunctional relationships with your CDMO may cause you to spend even more on do-overs. They also require your own ongoing oversight, pulling your staff away from other important projects.

If you have to switch CDMOs entirely, tech transfer will cost you a bundle in new regulatory filings and travel fees for site audits; project-specific equipment you may have to purchase; extra CDMO fees to perform the process transfer; plus additional, often scarce, API for new test batches.

Before you sign on the dotted line, do a little digging to unearth potential costs that could turn your development program into a cash-burning exercise.

Scenario: Your CDMO takes your tech transfer "as is," and your lab-based process falls apart during scale-up.

Talent

Manufacturing drugs is complicated. One misstep and your batch is blown, along with your precious API. You want a CDMO that counts securing and retaining the best talent as a top strategic priority.

- Do they have a formalized plan for attracting and maintaining a high-caliber workforce? What does it entail?
- How much does the CDMO invest in ongoing employee training and development?

Quality culture

Many CDMOs tout a quality culture: Look for evidence. CDMOs with a culture of quality view quality as everyone's ongoing responsibility, not just the quality department's. For a quality culture to exist, every employee must believe he or she "owns" quality every day.

- Does the CDMO have incentives and goals for doing things right the first time? How are they measured and tracked?
- An onsite visit is often revealing. Are metrics prominently posted on relevant data such as adherence to manufacturing schedules, batch cycle times or batches without deviations? How do employees speak about their work?
- Ask for references. CDMOs that put quality first are usually proud to show it, and their customers are usually proud to back them up.

Scenario: During process validation, your CDMO's lyophilizer malfunctions. This sets your program back by months and incurs significant costs to repeat the batches.

Compliance

The finest CDMOs organizations that fiercely protect their brands and don't skimp on manufacturing quality. If compliance issues arise during your partnership, CDMOs would have the technical and regulatory expertise (and funding) to resolve them in a reasonable timeframe. Especially if you plan to introduce your compound in global markets, you don't want to risk rejection of your registration or export license due to lack of adherence to quality guidelines that vary around the world.

- Do the CDMO's internal auditors define and measure quality metrics equally across all manufacturing sites?
- What is the CDMO's track record for regulatory and customer inspections? How many inspections do they host each year and by which global regulators?
- How many drugs has the CDMO launched in the past few years?

Financial strength

Contract manufacturing is a difficult, competitive, low-margin business. If your CDMO doesn't have deep-enough pockets to continuously invest in their facilities' maintenance and upgrades, that's a problem. For example, if equipment fails during your process validation batches, you'll have to replace material and repeat manufacturing, costing you more and consuming your team. Or worse, say your CDMO suffers a serious structural failure or loses their largest customer, and they don't have enough reserves to recover. You may be forced to start over with a new CDMO.

- What has the CDMO invested in their facility and equipment over the past 5 years?
- What are their cash reserves in case of emergency?
- Have they run into a budget crunch before that affected their customers? If so, what did they do?

Scenario: Your CDMO has persistent compliance issues and eventually goes bankrupt.

Regulatory depth

Most CDMOs know about mixing, filling and packaging. Many don't know how the medicines they produce gain market approval or stay on the market. Look for a CDMO that has in-house regulatory experts with practical regulatory filing knowledge of markets around the world. When questions arise and you need a quick response, they'll have the context, along with the documentation you need.

- How many regulatory experts does the CDMO have on staff?
- What is their experience with writing new registrations, Drug Master Files, and GMP renewals? In what markets?
- What is their experience across different product types? For example, if you aim to develop a combination product, such as a prefilled syringe, you'll need your CDMO to help you with both drug and device regulatory filings.

Commercial savvy

Payors are increasingly seeking better value, and end-users want efficiency. If your final injectable dosage is in frozen form, nurses may not want to deal with storing and thawing it for use. Your drug might be passed over

for an alternative therapy that is more convenient to administer. And if you have to make a fresh start creating a non-frozen drug form, that will cost you.

Your CDMO should develop a strategy with you for delivering your drug in the most practical form, not only today but throughout its lifecycle.

- Does the CDMO have the commercial insight to know what payors, patients and clinicians are looking for in your target markets?
- In what markets do they have on-the-ground commercial experience?
- What are some lifecycle management strategies they have successfully employed?

Longevity

CDMOs that have stood the test of time with their biopharma partners are likely to be there for you for the long haul.

- How long has the CDMO been in business?
- How many partners do they currently have with multiple products; that is, do their partners come back for more?

It's worth the effort to find a CDMO partner that's likely to do things right the first time and support you across multiple dimensions. After all, you rely on them to get your clinical materials to trials, ready your drug for submission and market launch, and maintain commercial supply continuity.

When you find an experienced CDMO that can prove their commitment to quality manufacturing and one that also continuously re-invests in their talent, facilities and infrastructure, *choose them*. They will deliver your compound to awaiting patients with greater assurance and more long-term success.

Reference:
Is Selecting A CDMO Based On Contract Price Really Saving You Money In The Long Run? (pharmaceuticalonline.com)