

From The Editor | February 20, 2023

6 CDMO Selection Tips From An Experienced Start-Up

Does your process to select a CDMO emerge from within and without? To begin with, it's always important for your selection model to have an internal expert who can 'fact check' the CDMOs.

It is a clinical-stage company advancing a new cell-therapy approach to immunotherapy, specifically for solid tumors. They've been picking CDMOs as service providers, and soon as technology partners. First, it is perfecting and de-risking that technology by [building out its own facility](#). Once that is accomplished, it will then require an intricate transfer to CDMOs, close cooperation and troubleshooting, and further learning together.

How will it know which of these CDMOs will fit that bill?

The experience has taught them if you ask the right questions, "you can actually figure out quickly what type of CDMO they are." "Already, we've learned there are really good, established CDMOs out there that want to be a partner, and some that see you as a dollar sign and prioritize – or de-prioritize – based on the size of the company. Those don't last very long."

Which brings us to our first four tips:

1. *Have an internal outsourcing expert (who can be a consultant); ensure the entire company learns from them.*
2. *Stay as close to home as possible to mitigate supply-chain (and other) risks.*
3. *Verify the CDMO's "mission"; obtain an assurance of alignment with your goals.*
 - a. *Accomplish this initially by asking the right questions, and thinking in terms of strategic partnerships.*
4. *When necessary – considering all factors, e.g. funding, external expertise (or lack of), etc. – build your own facility as a component of our strategic plans.*

Below we'll describe two more tips:

5. *Select CDMOs based on your specific program needs, and their specific capabilities*
6. *Verify CDMO track records with others; meet directly with CDMO project-team members to verify skills and longevity.*

Who Passes The Exam?

In the development space, for us it's been "quite a mix of big, small, new and more experienced CDMOs – with that caveat they are all located in North America." And not the relationship kind, but the actual chemistry involved with it programs helps drive these selections. "We found the smaller shops had more of an established research arm ready to invest the time and effort to help us understand the chemistry."

In some cases, these smaller – more focused and specialized – CDMOs have unique analytical tools, "so we could look at the chemistry from different angles." Conversely, "The big CDMOs, especially during the recent supply-chain challenges, tend to have the upper hand in regard to more access to vital items, such as vials for drug products."

So why not contract to get the best of both breeds to de-risk various aspects of the outsourcing process? But in all cases, it's been a solid consideration of the internals that drive where and with whom to externalize.

Next, when it comes to comparative price-shopping, “the entire CDMO world is highly competitive. The pricing ranges tend to be in the same ballpark.” Therefore, price alone won’t ferret out many CDMOs from others – which adds importance to these enumerated tenets of the outsourcing strategy. (And when there are notable price discrepancies, it’s important to learn why. Perhaps the CDMO didn’t fully understand the project, or *you* aren’t understanding all that is essential for ultimate success. It’s worth following up.) So with price off the table (relatively), we know “it ends up with sponsors having to carefully assess a CDMO’s history.”

One way to understand that track record is to independently ask other sponsors who have worked with a CDMO; another is to seek references directly from the CDMO – and follow up closely on those. Within that CDMO history, skilled worker availability and retention should be carefully noted; you can learn a lot by directly meeting those who would be working with you.

The skilled-worker profile is something we are hyper-focused on.

Source

[6 CDMO Selection Tips From An Experienced Start-Up \(outsourcedpharma.com\)](https://outsourcedpharma.com/6-cdm-selection-tips-from-an-experienced-start-up/)