

# Does the CDMO Manage Multiple API Development Projects Well?

By Ed Price, President, [PCI Synthesis](#)

Finding the right-sized Clinical Development and Manufacturing Organization (CDMO) for an API Development Project can be tough. There are many choices. There are, of course, the big players, whose revenues run in the hundreds of millions. On the other end are the small labs staffed by a few people who can provide initial chemistry. However, that chemistry would need to be transferred for further development to a larger lab with the resources and equipment to advance the project.

In our blog on [technology transfer](#), we addressed the higher overall project costs of technology transfer from one lab to another. Processes need to be repeated. Raw materials need to be sourced and tested for quality, potentially leading to delays. A great deal of interaction is required between scientists during any technology transfer, as the new CDMO needs a great deal of information such as the number of times the procedure has been performed, the largest batch size produced to date and much, much more.

You get the drift—there are pros and cons to every choice. The trick is to find the CDMO with the experience, the equipment, the know-how and the resources and one that makes every effort to get the project done on time and on budget.

There's one more thing: how well a CDMO handles multiple projects. Whether preparing product for a Phase I clinical trial or manufacturing an NCE for Phase III, you'll likely be choosing a CDMO that will be handling multiple API development and manufacturing projects, not just yours.

This article is a continuation of our series on how to choose a CDMO, with a focus on how to choose a CDMO that can manage multiple API development and manufacturing projects well. Other related articles in the series include how to determine if a CDMO is [qualified](#), how to conduct a [quality assurance audit](#), and how to [assess project management capabilities](#), among others.

## What to know, what to ask

**Bigger isn't necessarily better.** Unless you're in the same league as Pfizer, Novartis or other big pharmaceutical company, your project may wind up being pushed further down the priority list by a large CDMO eager to get projects completed for their largest customers. In truth we all do that to some extent at times. But it shouldn't be the regular course of business.

**Smaller isn't necessarily better either.** For the reasons stated above, transfer from a small lab can erase any initial cost savings, as every analytic and every process will need to be repeated when processes are transferred. Some balance between the two may give you the best of a broad range of experience combined with the dedication of a smaller team that won't overlook you.

**Experienced + big enough.** When outsourcing API development, among the key considerations is a CDMO with experience with the type of chemistry that needs to be developed. After narrowing down on that basis, find one that is big enough to have all the technology, manufacturing, and analytical capabilities that the project may require. Usually that's a CDMO that has multiple projects going. It's a sign of efficiency. When a process takes six hours to complete, the scientists can be putting the time to use on another project while waiting for the results.

**Choose good jugglers.** We reveal in our series about key considerations in choosing a CDMO the critical need to vet a CDMO's project managers, who are often overlooked, and that's wrong. These are going to be the point people who determine what project moves forward this afternoon and which one will have to wait for tomorrow morning – or next week. That person, although not a Ph.D., should be someone well-respected by the R&D and manufacturing teams as well as management.

A CDMO's operation is much like a jigsaw puzzle, with pieces constantly moving until the day the project is completed and shipped off.

## Ask these questions

**1. Can I meet the managers who are assigned to my project?**

You'll get a good sense of competency, confidence, personality and temperament when talking to a prospective project manager. These are all important traits to look for.

**2. Who has decision-making power?**

At PCI Synthesis we have trained and empowered not just our project managers, but also our team leaders to make project decisions so work can continue at a rapid pace without impacting quality.

**3. Given multiple ongoing projects, how are project priorities set?**

Listen for an answer that suggests *every* project is a number one priority. You want to know work on your API will continue unless there's a major issue such as a vendor's delivery of poor quality raw materials that, like the rejected tuna in a recent Legal Seafood TV commercial, just wasn't good enough to meet PCI Synthesis' high standards

**4. How are equipment priorities set?**

What happens if two or more projects require the same equipment or manufacturing suite at the same time? Prioritization is a topic that speaks to the entirety of the complicated process of drug development. It's an important question that should generate a lengthy response that includes the rationale and the protocols involved.

## The 2 secrets to juggling multiple API projects successfully

To manage multiple projects simultaneously, here's what's required, and it's the reason you want to pay special attention to the project manager and project leads.

**1. Confidence**

There's a need for take-charge people with good sound decision making skills, who can make the tremendous number of decisions that need to be made every single day. What assets do we need? Which instruments need to be scheduled? When? How can we get the material

going into GMP reduced as quickly as possible so we don't hold up the manufacturing operation? Is the paperwork done? Was the equipment released for use by Quality Assurance and if not, what alternatives are there? Are the analysts scheduled? Does the work need to continue on the weekend? It never ends.

These are weighty decisions that need to be made all day long. But the worst decision is no decision at all. We work hard to train and empower our people to do what's best for the project and yes, what's best for our business. We know full well that sponsors are always in a rush, and we make every effort accommodate since we like to get projects done on time. There's no room in our organization for someone who would idle a project waiting for someone else to make decisions, unless there's a real problem.

## 2. **Ability to manage details well.**

There is a tremendous amount of detail in every chemistry project, especially in the regulated environment in which we operate.

The CDMO's scientists and project managers can't let details fall through the cracks. What's helpful in this regard is an **integrated team**. Our teams are typically comprised of a lead chemist, analytics person, quality assurance expert, engineer and of course a project manager who, among other things, oversees the transition from lab to manufacturing. The teams are chosen based on experience with similar projects, and their availability to see the project through scale-up and manufacturing.

## Summary

In choosing a CDMO to develop and manufacture APIs, first look for experience with similar chemistry. Then choose a CDMO that can handle multiple projects simultaneously, as that organization is likely to have all the necessary resources and equipment required should unanticipated issues arise, as they often do. Meet and assess the point people on the project for their confidence, empowerment to make decisions and attention to detail. Finally, ask about how priorities are set when projects overlap.

For more articles on tech transfer and project management, check out the following: "[5 Important Things to Look For in Your CMO's Project Management Capabilities](#)"; "[Project Management: The Key to Success for API Manufactures](#)"; "[Do's and Don'ts of API Technology Transfer in Phases 1, 2 and 3 Clinical Trials](#)" and "[Transferring API Technology to a CMO? Use This Checklist.](#)"