

Five Qualities to Look for in a CMO

Let's face it. Only three in ten biologics make it through clinical trials and are approved. And it's your job to make sure your clinical program has the best chance of success. One major success factor is your CMO. Not only must your CMO manufacture your product correctly, they must also be able to do it on-time and on-budget. But how do you choose a CMO that has the expertise and technology to successfully deliver?

Here are five qualities to look for when evaluating a CMO to support your clinical program:

1. Transparency

Go ahead and prepare yourself mentally - your CMO will encounter technical challenges during production. Hey, it's biologics development! When challenges do occur, you'll want your CMO to be as transparent as possible and not hide issues to try and save face. A change to your manufacturing process needs to be approved by you because you need to be aware of anything that can affect the product. Remember, you are ultimately responsible for the outcome of the trial and more importantly, patient safety. And the last thing you want is to get blindsided by the FDA because your CMO had an issue and made a change that they decided to keep from you.

So how do you determine if a CMO is transparent or not? The best way is to ask former clients - a tactic you will become very familiar with in this report. Next, spend some time talking with the principles in the organization. You can quickly gauge the experience and collaborative nature of a CMO simply by describing your project and challenges you have faced in the past. When they give you an answer, do you believe it? Or are they just telling you what they think you want to hear?

2. Quality

One thing to never lose sight of when evaluating a CMO is product quality. It goes without saying that if the quality of your product is bad (i.e. low purity, contaminated, etc.), there is a good chance your trial will produce less than optimal results or worse. But how can you be certain a CMO has the chops to manufacture your product correctly? Here are a few suggestions:

1. Have a small-scale trial batch made using the same process as large scale production.
2. Hire a consultant to thoroughly audit the CMO's quality systems. It is too easy to make quality claims in marketing presentations, make sure you understand the true quality of an organization before entrusting them with your critical supply.
3. Talk to former clients. Ask them about specific quality measurements such as endotoxin levels and percent genomic DNA contamination.
4. Search the Internet for the name of the CMO paired with terms like "clinical hold" and "manufacturing issue".

3. Experience

Experience means you've done it before. And because of this past, well experience, you are better able to do it again. The same goes for a CMO. The more experienced a CMO, the more likely they will be able to successfully manufacture your product. An experienced CMO will have already encountered and overcome many problems. This can save you a lot of time both avoiding and overcoming problems when they do occur.

But how do you measure experience? Experience can be difficult thing to ascertain. Sure, lots of companies add up all the years their employees work and claim to have 3,500 years of experience. Here are several suggestions on how to measure the experience of a CMO.

1. Once again we return to asking former clients. Ask them if the CMO really knows what they were doing and how adept they were at overcoming challenges.
2. Ask to see resumes of key managers. Is this their first rodeo or have they made similar products to yours in the past. The last thing you want is for your project to be the one a CMO uses to get their feet wet.
3. Does the CMO focus on your product type, or do they only make it occasionally?

4. Timeliness

If your CMO isn't on time with deliverables it does more than cost you time - it costs you money. Your CMO must be able to deliver on time. Granted there can be unforeseen issues with the project, and if this occurs it is very important for your CMO to be experienced enough to quickly overcome problems. A few good ways to measure how "timely" a CMO will be is to evaluate at the very beginning how long it takes to receive information, answers to your questions, and by checking their track record through references.

Make sure you as the client have sufficient time to ensure a quality product can be produced. If you are not proactive in your CMO sourcing, you may be stuck with a suboptimal supplier.

5. Reputation

We are constantly being bombarded with marketing messages with every company claiming to be the best. So how do you personally choose a product? What is usually the most important factor in your decision making process? It often involves asking the opinions of people you trust. This should also be part of your decision making process when choosing a CMO. It's important for you to ask others in the industry about a CMO that you are considering.

You can learn a lot of important information about a CMO simply by asking former clients and the information you get will be a lot more objective than the CMO's website, marketing materials or what the sales person tells you. One of the best questions you can ask is "What percentage of your clients is doing a repeat project with you?" And "How many of your former clients are with another CMO?" If clients aren't doing repeat business, it's a red flag. Nothing speaks louder than when a client doubles down on a CMO for a repeat project.

Choosing the best CMO for your project takes time and effort. Hopefully these 5 guidelines make it easier for you to find the best CMO for your clinical program.

VGXI, Inc.

Phone: (281) 296-7300

www.vgxii.com

About VGXI

VGXI is a contract manufacturing organization that specializes in the production of DNA plasmids under GMP for human clinical trials. With over 13 years experience, we have produced products for numerous clinical trials in the U.S., Europe and Asia. Our patented AIRMIX® manufacturing technology produces the highest quality plasmids in the industry with plasmid supercoil percentages up to 99% and final product concentrations as high as 15 mg/ml. Our highly experienced team can work with your project's unique requirements to create a manufacturing solution that ensures the success of your clinical program.



**2700 Research Forest Drive, Suite 180
The Woodlands, Texas 77381**