

Selecting a CMO: Criteria to consider

Ed Price, president of **PCI Synthesis**, looks at what an emerging pharma company should look for in CROs and CMOs

Imagine this scenario: You have just joined a relatively new emerging North American pharmaceuticals company which licensed a first-in-class technology from a top research university several years earlier.

To date, some limited process development has been done both internally and at several contract laboratories. A fair amount of money and time has already been expended but it is clear that the synthesis route is still far from ideal

It is your job to select a CMO and get kilogram quantities made for toxicological studies and maybe even some early trials that are to take place in less than a year. By the way, investors are holding back funding for the company until certain successful milestones are achieved. The clinical supplies needed to achieve these milestones are your responsibility.

Although the task you are facing may seem daunting, the fact is that, with a little research and hard work, you can be a hero within your organisation by following some straightforward guidelines. There are six important criteria that you will have to balance and consider.

The first is **intellectual property**. Your IP may be the only true asset your company has. If what you have is truly novel and unique, you need to select carefully. Only work with firms with strong reputations in this area. There are a number of very reliable and trustworthy firms throughout the world and even in emerging market countries as well. The problem is deciding what the risks and possible recourses are.

If something were to happen overseas, what could you do? In an Asian country, there is almost nothing you could do. In Europe, you could pursue litigation but in a foreign country it is expensive, time-consuming and often difficult to prevail. Working in North America may seem to be the only choice but it may not be the right choice, depending on the nature of the project.

Under tight **time lines**, efficiency and organisation are critical. The CMO must have a thorough appreciation for the entire scope of what is going on with this entire project and not just the material they are producing.

Ask direct questions on how the company operates and how it views itself within the overall supply chain. Proximity can be a huge advantage if you need to visit the site frequently or if the complexities in the technology require other members of your firm to do so.

The organisation should have reliable and professional project management capabilities, with individuals who are empowered to make deci-



sions. Obviously, barriers with language and time zones can make this more difficult but they can be overcome if needed. The most significant project delays are usually caused by errors in communication.

The fact is that, for some projects, there may be only a few companies in the world that can offer a particular **technology** that you need. No matter how much you may like a particular firm, be sure that they have the background and experience to do what you need. If more general chemistry is required then you can cast a much wider net and consider more firms.

Quality is crucial. Has the site been FDA-inspected? Does it produce any commercial materials for any FDA-approved products? On average, how many audits does its QA group have per quarter? This is all important information to ask for and it will give you an idea how robust the firm's quality systems really are.

If your company is virtual and you do not have a QA group, then retain the services of a reliable consultant. Your QA function should be engaged from the very beginning of the process. This is money well spent and can prevent significant problems down the road.

The **technology transfer package** is where a little hard work can pay huge dividends. First, compile all the information you have in a clear concise manner for your potential CMOs to eval-

uate. Always include if possible any information on ideas or methods that have been tried but did not work. Do not ask your CMO to re-invent the wheel!

Be honest with yourself and the CMOs as to where the gaps are and what you think is needed to be successful. Depending on where those gaps are, this process can help you decide on which CMO to use.

No two CMOs are the same - they all have their strengths and weaknesses. Usually strong manufacturing companies are weaker in development and vice-versa. If the gap is in the analytical area, consider using a CRO to do all the analytical development to transfer to a CMO that fits your other criteria.

Finally, consider the CMO's **reputation and reliability**. What is its track record with projects similar to yours, when working with companies of your size and with similar chemistries? You can and should ask for references.

The fact is that every CMO has had projects that were not successful for one reason or another. The questions you need to ask are: Is this an organisation that I can trust to be open, honest and up-front when things go wrong? Does it have a system in place to solve and address issues encountered when a project is over? Does it implement changes as needed to avoid repeating the same problems over and over?

Of course, nothing can substitute for visiting and touring the facility you are considering for selection. You should meet the heads of any technical or functional group you may interact with during the course of your project. If suddenly people are not available or seem to be 'hidden' by the business development managers, take this as a bad sign.

Everyone should have a high level of comfort with working together. As difficult as the selection process may be there are a number of very reliable high quality manufacturers throughout the world.

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