How to Choose the Right CMO for Your Pharmaceutical Product

Contract manufacturing can enhance the drug development process by creating effective processes, increasing manufacturing efficiencies, and reducing overhead costs. Selecting a CMO with two essential characteristics: capability and partnership-chemistry is often difficult and challenging. This white paper contains an all-inclusive, ten-step guide for selecting the best CMO for all your product development needs.
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CMO’s Increasing Role in the Development of Pharmaceutical Drugs

The development of a new drug is a complex venture associated with in-depth analysis and difficult decisions prior to commercialization of the product. A lot of drug sponsors find themselves lacking experience, equipment, or both in development of their molecule. As a viable solution, an increasing number of biotech and pharmaceutical companies are choosing to outsource many of their drug manufacturing needs. There has been a simultaneous growth in the biotechnology industry and emphasis on science-based technology. This has compelled the industry to create a variety of CMOs that offer competitive pricing and highly specialized services. Contract manufacturers range from large, international full-service organizations to small, niche organizations that specialize in certain developments.

CMO services can range from: pre-formulation, formulation, pre-clinical research, clinical research, method development, scale-up, and commercialization. You can partner with a contract manufacturer to help you with certain phases of the drug manufacturing process or throughout the entire development phrase. The choice of services you wish to use for the development of your molecule is entirely up to you.

Why You Should Consider Partnering With a CMO

Contract manufacturing can help enhance the drug development process by creating more efficient processes, increasing manufacturing efficiencies, and reducing overhead costs (CMO can save you costs anywhere from 30-35%). Other than through effective and efficient efforts, contract manufacturers can help validate and increase value of your product with their expertise. By delegating control and responsibility of a product to an organization with experience and knowledge, you can save yourself time and unnecessary headaches.

Reasons for contracting out to a CMO include:

- **Cost-effective solution**: For assessments where there is large volume under capacity for a product, it’s often more cost-effective to outsource the work to a CMO.
• **Experience and expertise:** Letting the experts handle your molecule is often more feasible than trying to get the product to commercialization yourself. They have the right technical equipment that may be difficult to acquire if a firm were to operate on their own without the help of CMO.

• **Capability and faster time to market:** Large companies use outsourcing as a way to increase asset management and gain access to emerging markets. They have the scheduling flexibility that allows for making necessary accommodations to unexpected/sudden changes in the process. These reasons make the process more lean and cost-efficient.

• **The low success rate of drug commercialization:** There are costs associated with product validation, staffing, and support in manufacturing a product. CMOs often have financial stability, which is a good buffer for projects high in risk. By sharing mutual responsibilities through a partnership with a contract manufacturer, you concurrently mitigate the risks and share the potential success associated with the product.

**The Client’s Challenge**

Selecting the CMO with the two essential characteristics: (1) The capability to satisfy all needs and requirements of the product and (2) have the right partnership-chemistry is difficult and challenging. The most critical moments are when a company has to find a CMO to strengthen its weakness in limited internal resources for production, testing, and control of its pharmaceutical products. This process is often daunting and clients are at a lost regarding who to contact, where to look for resources, and the best way to select the right CMO for their drug. For your convenience, we have built an all-inclusive guide for selecting the best CMO for all your product development needs in ten simple steps.
Selecting the Right CMO in 10 Steps

1. Assess Your Product’s Needs. The first step in selecting a CMO is to evaluate the needs of your product. Every partnership is different and in order to have a successful one, you need to clarify the requirements and considerations of the contract manufacturer. If you're looking to bring a molecule all the way from development to commercialization—you'll want to make sure they have the services you need to make that possible. On the other hand, if you're only looking to outsource the packaging of your drug, you won't require an exhaustive list of services. Once you have your key requirements written down, the next step will be to assess and evaluate each CMO’s level of satisfaction for each requirement.

2. Assess Your Company’s Needs and Risk Tolerance Level

Your company should conduct an assessment for the kind of partnership it wishes to seek with the contract manufacturer. This includes the people they want to work with and the working-relationship they would like to have. It doesn’t matter how capable a CMO is if their values don’t align well with the culture and work ethics of your company. You may also wish to assess your company’s risk tolerance for financial losses and delays that may be experienced during the contract. Are you prepared for these risks that are often a reality of contracting to an outside source? If so, be sure to establish guidelines and bottom lines for what risks are considered acceptable and what is considered non-negotiable.

3. Build Criteria for CMO Selection. For key considerations in your criteria list, you will have necessary characteristics that fall under “must haves” and other attributes that would be considered “nice-to haves”. It is suggested to differentiate “must-haves” from “nice-to-haves” in order to properly weigh the attributes when making the final decision. Important guidelines such as Good Manufacturing Practice (GMP) compliance should be considered here. Consider using a chart to help list the criteria, along with a description of each requirement (Table 1).
### CRITERIA FOR CMO SELECTION (Table 1)

<table>
<thead>
<tr>
<th>CRITERIA:</th>
<th>DESCRIPTION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Range of services available</td>
<td>Do their services fulfill your product's needs?</td>
</tr>
<tr>
<td>2. Reputation and Reliability</td>
<td>Has their history with previous clients revealed them to be trustworthy and dependable?</td>
</tr>
<tr>
<td>3. Geographic Location</td>
<td>Is their location geographically convenient for you?</td>
</tr>
<tr>
<td>4. Capability</td>
<td>Does the manufacturer have the capability and right scale of equipment available to manufacture your product?</td>
</tr>
<tr>
<td>5. Experience and Expertise</td>
<td>Have they manufactured your product or a product similar to your product before?</td>
</tr>
<tr>
<td>6. Quality and Compliance History</td>
<td>Do they have a good track record with GMP compliance and regulatory bodies?</td>
</tr>
<tr>
<td>7. Confidentiality</td>
<td>How do they protect your confidentiality? Are they ethical?</td>
</tr>
<tr>
<td>8. Scale-Product and Faculty Size Match</td>
<td>Does the volume of your product match with their operating capacity?</td>
</tr>
<tr>
<td>9. Commitment and Communication</td>
<td>Are they sensitive, responsive, and attuned to your needs?</td>
</tr>
<tr>
<td>10. Scheduling and Flexibility</td>
<td>Are they available to formulate and develop when needed?</td>
</tr>
<tr>
<td>11. Cost</td>
<td>Do the costs of the CMO partnership fit in your budget?</td>
</tr>
<tr>
<td>12. Personality</td>
<td>Can you foresee working with the CMO in a successful partnership?</td>
</tr>
</tbody>
</table>
4. Create a List of Potential CMO Candidates

You can discover potential CMOs by doing your research online, asking your industry colleagues, or through word-of-mouth. Your best resources are probably through referrals and recommendations from your fellow colleagues as they are most likely to be unbiased and reliable. After creating a list of potential CMO candidates, the next step is to initiate contact through email or phone call. At this stage, be prepared to fill out information that relays all relevant information about your product to them.

5. Contact CMO Candidates and Record Information in a Matrix.

Record all contact with CMOs in a chart such as an information matrix (Table 2) to help you keep track of communication between each candidate. Below is a template of an information matrix that keeps track of date of initial contact, time proposal was received, and other important information that is relevant for the client’s consideration.

<table>
<thead>
<tr>
<th>CMO CONTACT INFORMATION</th>
<th>DATE OF INITIAL CONTACT</th>
<th>PROPOSAL RECEIVED</th>
<th>COMMITEMENT TO SCHEDULE</th>
<th>PREVIOUS EXPERIENCE WITH OUR MOLECULE</th>
<th>TECHNICAL CAPABILITIES AND EXPERTISE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name #1 Name, phone #, email</td>
<td>Month/date/year</td>
<td>Month/date/year</td>
<td>YES/NO</td>
<td>YES/NO</td>
<td>YES/NO</td>
</tr>
<tr>
<td>Name #2 Name, phone #, email</td>
<td>Month/date/year</td>
<td>Month/date/year</td>
<td>YES/NO</td>
<td>YES/NO</td>
<td>YES/NO</td>
</tr>
<tr>
<td>Name #3 Name, phone #, email</td>
<td>Month/date/year</td>
<td>Month/date/year</td>
<td>YES/NO</td>
<td>YES/NO</td>
<td>YES/NO</td>
</tr>
</tbody>
</table>
6. Narrow the Scope of Potential Candidates

You can use the information matrix as a guide to narrow down your choices. You can start scratching the CMOs that don’t qualify under your top requirements off your list. At the end, it is recommended to have three potential CMOs left on the list.

7. On-Site Visits

On-site visits reveal to drug developers how the contract manufacturer operates. This is the client’s opportunity to check the cleanliness and functions of the facility. It is recommended to devote a minimum of four hours to the site visit and to make an effort to get to know the most relevant departments: Engineering, Quality, Scales and Corporate, and the Project Management team. Once you leave the site with enough confidence in the CMO’s abilities and match with your company, the next step would be to schedule an audit and request for proposal.

8. The Audit and Proposal

It is ideal to evaluate 3 CMOs and ideally spend two days at each site. Auditing potential CMOs will answer most of the questions you might have had from the criteria chart (table 1). The audit will give you some idea of whether you want to do business with them or not. Chances are if they satisfy most of your criteria, you should expect a high chance of partnering with the CMO candidate. You can review the CMO’s documentation systems and discuss the project further in depth. All parties are expected to be involved and prepared to draft you a proposal in response to the audit.

9. Negotiation of Contracts

Consider negotiating contracts with two CMOs as there is always a risk for the partnership to fall through before the business contract is signed off. You don’t want to say goodbye to potential candidates before you’ve reached a mutual agreement with one.
It is recommended to keep the top three CMOs within consideration and regular communication until a final contract is signed.

10. The Start of a New Partnership.

Congratulations on your new partnership! You have embarked on a journey of collaboration in bringing a unique molecule to new medical lengths. It is our hope this new partnership will bring both you and your CMO great success. The end of the partnership is usually stated in the contract; although desire to renew is entirely up to you and the CMO.

Challenges and Risks of a CMO Partnership

As all business partnerships go, there is potential for the collaboration to end with less than optimum outcomes. The risk is higher when it has to do with development pharmaceutical drugs, as the nature of the business ranks high in risk of failure. Dissolution of the partnership between CMO and the client is not always an amiable separation. The choice to go separate ways can be due to many reasons such as: the CMO was unable to deliver on time, the manufacturer demanded an increase on a previously agreed-upon budget, or sometimes simply a breakdown in communication occurs between two parties. Other hostile separations include disagreement of liability when regulatory bodies become involved or when a CMO tries to create a win-lose situation for themselves.

Conclusion

The way a pharmaceutical company contracts with the CMO has a direct impact on the realization of its goals. It will impact all stakeholders involved, including investors and patients who are depending on the drug’s success. Both parties should feel like the partnership is positive and mutually beneficial. Partnerships between drug sponsors and contract manufacturers that begin and end amicably can be rewarding and profitable. When the partnership is a good match on both ends, the success rate is higher than if either party were to develop the drug on their own.