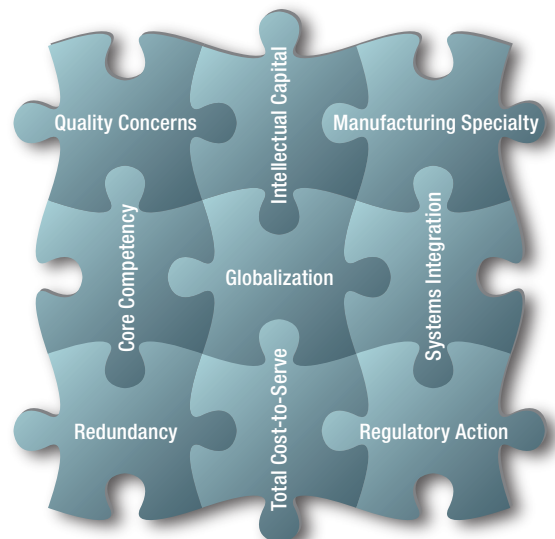


Contract Manufacturing Partnerships

Identifying the “Best Mix” of the Right Partners

As the Life Sciences industry continues to become increasingly competitive, it has never been more important for companies to focus on what they do well, and outsource where it makes sense. For many firms, the use of contract manufacturing organizations (CMO) provides a perfect business opportunity to focus on their own strengths and let other companies make up the difference. Since the Life Sciences industry brings a unique set of constraints and requirements, it's critical to approach outsourcing relationships very carefully. How many firms should I contract with? How should I select them? And once I have selected them, how do I ensure my reputation is maintained with a quality product, delivered on time, and economically?

Life Sciences companies have struggled to answer these questions and find the right balance for decades. Some firms have gone to one extreme and tried to manage all functions in-house, missing out on the many advantages that can be gained from partnering with a CMO. On the other extreme are firms that try to manage dozens of relationships with different partners, thus wasting time, energy, and money. Instead, firms should shoot for the “best mix” and form strategic, targeted partnerships with carefully selected CMOs. They should look beyond just manufacturing capabilities and include the overall supply chain strategy to create a governance process that addresses the entire network.



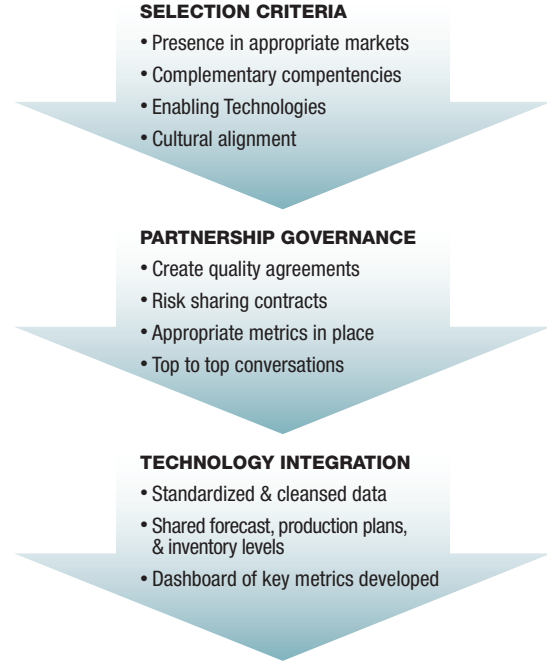
Finding the ‘Best Mix’

Finding the “best mix” of CMOs to work with comes down to balancing growth potential, financial impact, and market risk versus the safeguards built in through the organization, process, and technologies. Vigilance around the process of selecting, product transfer, and management of CMO relationships will help Life Sciences companies avoid working with too many CMOs and thus optimize the effort required to manage each relationship. Life Sciences companies that work with too many partners lose influence with each CMO as a result of dividing up the contract work. At the best mix level, partnerships with CMOs support strategic company objectives, and the management and relationship is high-performing and yields expected results, ultimately creating an environment where the Life Sciences company’s requests become priority for the CMO.

Finding the “best mix” can be summed up into three simple steps:

- 1) Carefully selecting partners;
- 2) Transferring knowledge successfully; and
- 3) Managing the relationship effectively.

| | Selection Considerations | Knowledge Transfer | Relationship Management |
|------------------------------|---|---|---|
| Life Sciences company | <ul style="list-style-type: none"> • Financial stability • Complement core competencies • Willingness to adjust schedule for special request | <ul style="list-style-type: none"> • Focused group responsible • Technology / IT standards developed | <ul style="list-style-type: none"> • Agreed-to KPIs • Visibility into product manufacturing runs • Treated as extension of company |
| CMO | <ul style="list-style-type: none"> • Length of contract • Alignment to manufacturing excellence capabilities • Cultural alignment | <ul style="list-style-type: none"> • Standard process established for knowledge and technology transfer • Regulatory assistance | <ul style="list-style-type: none"> • Agreed-to KPIs • Visibility into LS company scheduling • Quality controls |



To find the best mix, firms must first build a strategy around the types of relationships needed and the risk tolerance level related to those relationships. Three key considerations the company must keep in mind when developing the strategy include:

- Perhaps most importantly, how the company will align quality processes and systems standards to ensure an **acceptable level of product quality**, since failure to do so could lead to regulatory action and loss of credibility with the public.
- **Protection of intellectual capital** is particularly important for CMOs operating in developing countries where regulations are not as well defined. However this must be carefully evaluated with the growth potential in those markets and how to best gain market share.
- **Total cost to serve.** Is the goal to lower total cost or is it acceptable for cost to remain the same or even increase slightly with the realization of other benefits?

The strategy can then guide the way to finding the “best mix” of strategic partnerships.

Choosing the right CMOs and establishing the “Best Mix” of partnerships

Carefully select partners based on strategic selection criteria

Creating appropriate selection criteria will ensure that the right partners are selected. First, an organization must assess each CMO’s presence or planned presence in markets where growth potential is greatest. A firm can limit the number of partnerships required to enter new markets by seeking out CMOs that have already, or are planning to, enter those same markets. This will help identify those few, strategic mutually beneficial partnerships a firm requires, instead of utilizing a unique CMO for each new market a firm wishes to penetrate.

Life Sciences companies should also evaluate CMOs for complementary core competencies. For instance, contracting with a CMO to do lyophilization of product does not make sense if that is a differentiator for the Life Sciences company itself. In addition, firms should always consider a CMO’s technology capabilities. In the 21st century, best mix CMO partners have cutting edge technology solutions. Advanced technology enhances the firm’s ability to integrate with multiple CMOs and seamlessly transmit information between the organizations. In addition to technology, evaluation criteria must include “table stakes” items, such as the quality of the CMOs’ standards, willingness to adhere to the Life Sciences company’s standards, and the security measures taken to ensure confidentiality.

An important step often ignored is the cultural alignment of the companies. This becomes especially critical when managing multiple relationships. Strategic partnerships are expected to be long-term, high-value relationships. This will likely mean significant interaction between employees of the various organizations. Thus, the more culturally aligned the organizations are, the more likely strong relationships will be developed. When determining cultural fit with each CMO, incorporate criteria into the selection process similar to that used in recruiting. If the CMO would not fit in as a person at the company, it should not be a part of the best mix network.

Creating the partnership governance process

After successfully choosing the right CMOs, look to quickly move these relationships from the infancy stage to true partnerships by establishing quality agreements and minimum performance expectations. The key to this step is that it should not

be done for each CMO individually. Instead, the Life Sciences company must think of their entire CMO structure as a single unit and then create the governance standards accordingly. Representatives from each CMO should be involved in the creation of agreed-upon metrics and standards. This will ensure that each party is striving towards mutually accepted and achievable goals. By thinking of the entire network of contract manufacturers as one, operational control and visibility into the CMOs’ manufacturing processes are increased. Building on this network idea, the partnership governance process should be mutually beneficial for all members involved. Be creative with contracts, and consider gain-sharing and pain-sharing goals, where profits are shared under thriving conditions and losses are split equally when incurred. Performance-based contracts encourage success by properly incenting the desired behavior, discouraging undesirable behaviors, and fostering trust between each party.

Having a thoughtfully prepared governance contract is not enough to ensure success. Each company needs commitment from the top-levels of their organization. This commitment not only helps to ensure success but also demonstrates the importance of the relationship to employees in each organization. Representatives from each CMO should be included in any significant long-term planning that takes place that impacts, or can be influenced by, the contract manufacturers. These two actions help to align the companies in action and behavior which will help to reach mutually set goals.

No matter how well the contract is written and adhered to, without the proper measurements of success in place it will be impossible to gauge the effectiveness of the new structure. Understanding how each CMO performs against key metrics is important, but must be executed in a manner that emphasizes partnership and does not create the feeling or perception of a vendor relationship. At the “best mix” level, the Life Sciences company and the CMOs work together to achieve the targeted quality and operational efficiencies for the Life Sciences company. In this scenario, the CMO structure is viewed, and treated, as an extension of the business, not as a contractor network that needs to be managed. Creating this level of openness and communication throughout the network is essential to achieving true partnerships, as well as results, and is critical to achieving the best mix.

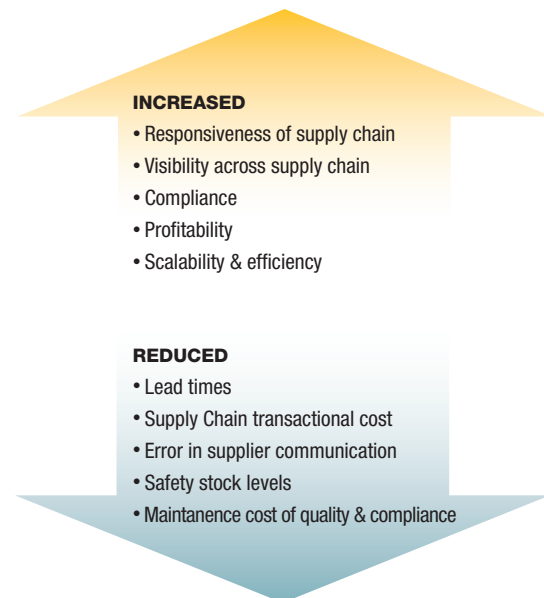
Integrating technologies for collaborative information sharing

The right mix of CMOs has been selected and a strong governance contract has set the stage for high-performing partnerships, with the entire network treated as a single entity. The final step is to establish the information sharing foundation with integrated systems and processes, which will help drive better decision making for the Life Sciences company and the CMO network. First, some basic components need to be addressed, such as how data is to be cleansed and creation of standardized security measures so that company-specific information is not shared with competitors. In addition, decisions must be made as to how data will be passed between the Life Sciences organization and each CMO, as well as between the CMOs themselves. This decision may be especially difficult but is vital for the success of the CMO network.

After these decisions have been made and components are put in place, or at least understood, company leaders can look at how the shared information can give them a strategic advantage. Evaluate how the information captured at each CMO can be incorporated into the company's overall Business Intelligence strategy. Or possibly use the expertise of the CMOs to understand what measurements they feel best demonstrate how not only the manufacturing process is going but also the overall health of the entire enterprise. The major benefit to a full integration is the availability of real-time data that enables employees in all companies to make quick, informed decisions based on mutually agreed upon metrics and KPIs. Reports and dashboards should be created to show the metrics that were developed early in the partnership; this information needs to be displayed real-time to assess performance across the value chain. In addition, by increasing the available information, demand and supply chain predicting technologies have a better picture and will generate more valuable data.

Realize the benefits from the 'Best Mix'

Using the steps outlined in this paper, Life Sciences organizations can identify and create a network of contract manufacturers at the "best mix" level. Once the optimal CMO structure is in place, firms will no longer struggle to manage many disparate relationships, nor will they miss out on the benefits and expertise that contract manufacturing organizations can provide. By ensuring decisions align with overall company objectives related to market expansion, profitability, and supply chain, Life Sciences companies can expect benefits across the company. Additionally, these organizations will be best positioned to meet the economic, regulatory, and value chain challenges of the future. If the process of selecting and developing these partnerships has not already occurred, it needs to start at once. Failure to do so will leave firms watching from the sidelines as the competition gains a competitive advantage from recognizing the benefits that the best mix of strategic partnership can provide.



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