PHARMACEUTICAL ONLINE

Guest Column | March 18, 2022

Betting The House: CDMO Selection For Emerging Pharma

By David Stowe and Greg Anthos, Tunnell Consulting

Successfully completing an NDA and securing approval for a drug is a significant accomplishment for an emerging company and a major milestone in its young life. All the emotion from long days, FDA reviews, tight deadlines, clinical studies, and numerous patient and investor meetings is finally realized when the company can sell its new drug and improve lives.

An essential step in a company's evolution is the selection of a contract development manufacturing organization (CDMO) to develop and manufacture its drug. How an emerging company selects a CDMO to produce materials for clinical trials and commercial production is like the high stakes of "***betting the house***" at a pivotal point in a card game. A good gambler knows how to assess the risks and odds to know when it is best to "bet the house." In a similar manner, selecting the right CDMO can lead to successful clinical trials and rapid commercial growth, while making the wrong selection can seriously impact the future of a company. Given that "luck" is often defined as the intersection of preparation and opportunity, proper preparation is essential to this process.

Improving the odds of selecting the right CDMO for your organization requires an evaluation of market analysis, manufacturing and quality assessment, financial discussion, and several other key factors. Teams of people, both present and future, will be brought together to meet stringent regulations and address several drug manufacturing and compliance issues in a collaborative environment. Both the sponsor and the CDMO need to know they can build strong relationships between the people in the two organizations to address complex issues while meeting tight deadlines.

For this critical decision, emerging companies may be limited in the necessary business, technical, and negotiation skills and/or time needed to assess options. Often, as an emerging company enters this phase, several important questions arise, such as:

- What gaps are in our drug development technology process? Where can we use a partner to help us successfully manufacture our drug?
- Does the CDMO have the capacity and technology to meet our drug manufacturing requirements?
- What is the CDMO's track record with the FDA and other regulatory authorities?
- What criteria should we use to evaluate CDMOs?
- How are successful partnerships structured from a legal, financial, and regulatory perspective?
- What risks should we consider as we evaluate CDMO options?
- How do we structure sourcing and quality agreements to ensure source of supply and regulatory compliance?
- How do I get the best price from a CDMO to manufacture our product?

Fortunately, these questions and others can be addressed through a well-managed sourcing process that minimizes risk and improves the odds of a successful partnership. While it may appear to be a time-consuming process, a well-organized sourcing process builds trust between the sponsor and the CDMO, thereby minimizing the risk of failure. Each step provides the sponsor team with a better understanding of a CDMO's technical, quality, financial, and management capabilities to meet their goals.

A strategic CDMO sourcing framework starts with a long-term perspective between the sponsor and CDMO and can be structured in four steps:

I. Timeline definition from drug development through commercialization phases
II. Alignment on CDMO relationship framework
III. Development of a request for proposal (RFP)
IV. Execution of supply and quality agreements

Managing this four-step process can be conducted in a few months or several months based on resources (internal and external) as well as market conditions.

To understand how this process relates to your specific company needs, each step is outlined below.

Timeline Definition

An emerging company's success is defined by how they manage their development timeline and complete critical milestones. Several timeline management factors include:

- The stage of drug development: early-stage or late-stage clinical trials
- Planned submission period for FDA/governing authorities for study review and approval
- Expected commercial launch timing

During this step, a sponsor will be able to refine their approval time window, technology development needs, and potential sales volume. All these factors are important when identifying CDMOs and making initial assessments. For example, some CDMOs may have the cell and gene therapy technology knowledge that is critical to producing a drug while others may have capacity to grow or have capacity limits to producing certain drugs. Therefore, based on the sponsor's drug technology platform and the CDMO's capabilities, it will be important to clarify the overall timeline and milestones to align expectations and build a strong relationship.

Alignment On CDMO Relationship Framework

From a long-term perspective, it is important to develop a complementary approach to skills, capabilities, and cultures between the sponsor and CDMO. Over the duration of a multiyear agreement, both parties will experience tight timelines and complicated issues requiring a strong working relationship. Some aspects to consider include:

- Depth of staff technical capabilities
- Maturity of process development
- FDA compliance and quality experience
- Relevant therapeutic experience and knowledge
- Responsiveness, problem solving capabilities, and general interest in the product

From these aspects, it is possible to define detailed technical and business requirements needed for an RFP.

- Drug profile
- Drug substance manufacturing
- Volume
- Packaging requirements
- Data sharing and/or IT system interface requirements
- Capacity requirements
- Inspection audit history (FDA/EMEA and other regulatory agencies)

Documenting these details will provide the sponsor with information to start evaluating the CDMO marketplace and identifying a short list of target CDMOs. At this point, a sponsor can start contacting CDMOs to understand their interest in working with them. While not yet the formal RFP phase, this process can help a sponsor take a prospective number of suppliers from a dozen down to three to five that are very interested and meet most of the essential criteria.

Request For Proposal

The development of a comprehensive RFP includes input from multiple functions and requires diligence to ensure accuracy across important criteria such as: production requirements/specifications, regulatory requirements, and evaluation criteria. While there may be a temptation to cut corners and expedite this process, it is very important to take time and collect all the relevant information and develop a comprehensive RFP process. A poorly designed RFP creates a disincentive for suppliers to participate in the RFP process and further creates confusion when proposals are submitted.

While emerging companies vary in staff size and capability, it is important to get input for the RFP from different functions, such as clinical operations, quality, technical operations, finance, and marketing. Colleagues from these functions will provide important evaluation criteria for two important sections of an RFP: technical/service and financial. Within each of these sections, a company will need to define which criteria are essential and can be defined in a "yes/no" or "go/no-go" framework.

For example, criteria for technical/service can include:

- Quality system
- Production capacity
- Regulatory track record
- Warehouse and storage capability
- Analytical processes and release testing
- Technical product support

To develop and assess these criteria, an emerging company may need outside support given their resource constraints. For example, you may determine that the first three items are critical criteria where you need support and know that your internal team can manage the remaining items.

Once the RFP criteria are defined, the composition of the actual RFP becomes more of an administrative process requiring diligence from the team to ensure proper documentation and clarity in the proposal request. With an RFP and a targeted group of CDMOs, a sponsor can issue the RFP, solicit proposals, and evaluate options.

This process allows time to review written responses and conduct supplier oral presentations to identify several aspects needed for a collaborative relationship. Sponsor teams often find this approach provides an easier way to negotiate by taking the time to evaluate offers and ask questions to ensure a good fit and strong partnership.

Execute Supply And Quality Agreements

Once a final CDMO is selected, the analysis and proposal should be shared with the executive team and/or the board depending on the governance structure given the significant financial and risk impact on your company.

After internal review and agreement, there are a few critical follow-up steps that need to take place. These include quality audit, sourcing and quality agreement development, equipment order, and engineering studies and validation batch production.

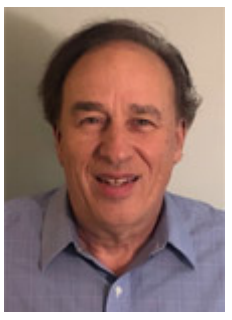
While each of these four steps needs to be developed for a specific sponsor's situation, the overall focus for any CDMO selection should follow a spirit of long-term relationship development. This mindset will allow the sponsor the opportunity to grow their partnership with a CDMO not only with one product but also future products.

Improving The Odds For Successful Drug Development

In a competitive and regulatory intensive market, companies cannot afford poorly performing relationships with their CDMOs. Just as a skilled card player knows how to improve their odds and manage through several challenges, emerging pharma companies can greatly improve their ability to successfully complete clinical trials and launch new drugs by using a simple but effective sourcing process and building strong long-term supplier relationships.

About The Authors:

Dave Stowe is senior procurement adviser at Tunnell Consulting, with global experience in the life sciences industry, including pharmaceuticals, biopharma, medical devices, medical diagnostics, and healthcare. He can be reached at david.stowe@tunnellconsulting.com.



Greg Anthos is a principal and operational excellence leader at Tunnell Consulting. He has more than 30 years of experience in the life sciences industry, including over a decade of consulting experience in all business functions, with significant expertise in engineering, organizational transformation, and supply chain. He can be reached at greg.anthos@tunnellconsulting.com.