Contract Service Providers: Part of Your Process!

Build and maintain winning, trusted, long-lasting partnerships from start to finish. *This is the first of a four-part series of articles addressing best practices for a successful relationship with your service partners.*

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The use of contract services across the entire biopharmaceutical drug development and approval process has exploded since the 1980s, significantly expanding biopharma companies' capabilities, and often allowing them to focus their energies on critical drug development while CMOs take care of other functions. Today, most small, emerging, as well as many established larger firms rely heavily on external contract service support for each stage of the product development, clinical trial, material manufacture, and approval/launch process. These external providers include CROs, Contract Labs, CMOs, CDMOs, as well as contract staffing and consulting, and the result is that smaller, more nimble startups can focus on drug discovery and R&D with a smaller staff, competing more effectively with larger organizations.

The decisions to determine your contract provider strategy will depend on your company's current operational strategy, core capabilities, staffing levels, funding, and equipment access, as well as your corporate culture and ability to support an indirect supplier ecosystem that often spans multiple locations and countries. Beyond traditional brick and mortar facility and equipment needs, you may also seek help with staff augmentation, and/or consulting to support time management, competing priorities, material supplies and logistics, and reliable leadership in all the development areas.

Due to the nature of these relationships and the importance of their contribution to your company's success, we consider them Service Partners.

In this 4-part in-depth series, Tunnell will provide a road map on how to prepare for, collaborate, educate, monitor, and reward or terminate these critical relationships inside and outside of your organization. For this series, we recognize there are several stages to a successful relationship with your Service Partners, and for the purpose of this series, we will simply identify them as Before, During, and After. The following is a brief outline of each part of this series.

Part 1: Before – Partner selection
This phase includes negotiation of contracts, which should include leverage, contingency, accountability and relationship management, and the QA agreement responsibilities. There are many key factors to consider when choosing your Service Partner and they extend far beyond the financial considerations. These include the site capabilities, experience, quality culture, capacity, and transparent and consistent communication. However, in parallel to selection, there must be a fully supported due diligence of the service provider to validate their claims capabilities and experience. It takes a seasoned CMC expert to ask the right questions and look under the hood.

Part 2: During – Delivery
The delivery phase includes an analysis of your responsibilities, how you build and maintain a productive level of collaboration and shop floor relationships, clear articulation of the WHY, incentives for performance or disincentives if required, and educating the CDMO on your process and understanding theirs. During the delivery phase, both parties will face any unexpected challenges that will require balancing a level of urgency while maintaining respect and patience for the process of addressing and resolving the issue. When you consider your CMO or service provider as a true partner, resolving these challenging issues will be more effective.

Part 3: During – Quality and Regulatory Management
When considering quality and regulatory management issues, you may face multiple challenges, not the least of which is the CDMO's understanding of compliance and regulations relative to your particular need. Other quality challenges may include issues related to handling deviations, storage, stability reviews, and updating the regulatory filings. Many emerging companies will defer some of these requirements to the Service Partner to execute. However, as a Product Sponsor, the quality and regulatory oversight sit squarely with your team. Some may think this is inherently redundant, however that is not the case. Building a quality culture is not just for your Service Partner, it is also for your own company and having complete oversight is an FDA requirement.

Part 4: After
Once the contracts have been signed and the work has begun, the contract and the relationship will still need constant attention. Is the CDMO compliant with the contract terms on a continuing basis, and how will it be monitored? Besides contract compliance, "soft" issues such as simply keeping the relationship productive and "warm" is essential and may include recognition and rewards. Also, provisions for contract termination must be taken into account should the product fail or fall short, or if the agreed term has ended.

PART 1: BEFORE

The "Before" stage of the contract scenario may be the most fraught, as you are considering business relationships that will influence the success of your company for years to come. In some cases where no prior relationship existed—and in which you may have very limited knowledge of the candidate—serious due diligence is in order to make sure the candidate is not only fully capable of filling the contract, but that they are able to do so while maintaining a positive working relationship and fitting in with your own culture and expectations.

Beginning with the decision to outsource, the "Before" stage includes the selection process and associated due diligence, defining precisely what you are outsourcing and what you expect to be delivered and when, and negotiation of a Shared Services Agreement and Quality Agreement. Tunnell has supported many emerging and small to mid-size companies in selecting their Service Partners. We have supported all stages of the decision process to find the appropriate stage and size CDMOs to meet their needs. A few articles on this subject that Tunnell has published include: "Betting the House—CDMO Selection for Emerging Pharma" by David Stowe and Greg Anthos, and "What's Essential and What's Not for Early-Stage Biopharma Companies" by Jonathan Horn, Bob Johnson, and Scott Myers.

During the negotiation process, it is critically important to remember that you will be working with many of these people after the contracts are signed. Maintaining healthy relationships and holding respect for those at the table will set the stage for a stable foundation of trust after the contract ink has dried. This trusting culture will also help foster ideas for how to incentivize and reward good performance as well as how to correct for poor performance.

These discussions should be part of the negotiation and if possible, precisely defined and documented into the agreements. Having the end in mind is a critical consideration during the negotiation process. Thinking about your Service Partners as part of your team, even before the deal is finished, will help foster the culture required for success. All too often, the urgency to meet clinical milestones or other time sensitive critical tasks will lead to hasty decisions or concessions that avoid or delay the difficult discussions around performance and culture. Instead, this time pressure will push one side or the other into

accepting terms that may result in trouble later in securing the capacity or meeting the objectives in the promised timeline.

Having a seasoned CDMO expert to navigate you though the many challenges that will inevitably come to pass and building provisions to ensure these scenarios are considered and managed will save possibly millions of dollars, preserve critical timelines, and increase the likelihood of a positive outcome, while also preventing unintended consequences, loss of trust, and missed performance expectations.

Additional questions to consider during the CMO selection process include:

- What is the company culture? Will you and your provider align and share similar values and working styles?
- What are the consequences of delays? How can you build some safeguards to ensure you can minimize the possibility of failure or potential missteps, while recovering from those missteps should they occur?
- Do you have deep operationally experienced folks helping to negotiate the contract who understand the process, the stakes involved, and the expected outcome?
- Do you have clear exit strategies in the event of a product termination or failure?
- How would you like to make sure that the CMO mid-level and shop floor team is kept informed, is trained, and is valued?
- What can you bring to the CMO that will help them feel connected to your program?

The biopharmaceutical industry is more competitive than ever, and companies need to rely on their CMO relationships to succeed in this fast-paced environment. Smaller and emerging companies especially can increase their chance of success with the right sourcing process and long-term supplier relationships. **CP**

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