Accelerating the Start of Your Outsourced Pharmaceutical Project—the Role of the Project Technical Review

By Devan Patel and Vidhi Desai

This is the second of two articles exploring best practices to streamline the underappreciated initial stages of a relationship between a drug developer and their CDMO--from first contact to receiving a proposal.

When Pii returned to its contract development and manufacturing (CDMO) roots five years ago, we set out to streamline the process for pharmaceutical outsourcing. We examined slowdowns in the drug development process and sought ways to use time and resources more effectively and efficiently.

Drug sponsors had shared their concerns with us regarding the time it took to get their projects started. They bemoaned not hearing from service providers after their initial contact and before receiving a proposal, with weeks and sometimes months passing with no communications. We thought the process could be better!

In our first article of this two-part series, we introduced the ACT meeting—assessing capabilities and timing. When done well with the right people and a clear agenda, this first meeting between the drug developer and the CDMO can provide answers to the critical questions both parties need to begin more detailed project planning.

The next significant slowdown we discovered was the time it often takes for a drug sponsors to receive a proposal after having issued a request for proposal (RFP) to the CDMO, and we developed some practices to make sure time is not wasted, the drug sponsor hears from the CDMO with meaningful information, and the project can begin as soon as feasible.

ACT Meeting Next Steps

When the ACT meeting is concluded, drug sponsors should receive the following, as a minimum, from the CDMO:

- Yes or No on whether the CDMO has the capabilities and timing to take on your project.
- If yes, the CDMO ought to inform the drug sponsor of the next steps they will take.
- And finally, the drug sponsor should know when they will next hear from the CDMO.

Projects can vary greatly and so can their complexity and proposals must be done with meticulous care and attention to detail. Therefore, proposals for more complex projects may take more time. However, as critical information becomes known before the formal proposal is delivered, sharing it with the drug sponsor can be valuable in keeping the project on pace.

We've found that a project technical review meeting with key CDMO subject matter experts following the ACT meeting is especially beneficial in beginning projects as soon as possible and establishing a rapport between the CDMO and drug sponsor based on transparency and trust.

Project Technical Review (PTR)

A project technical review (PTR) by all CDMO key department heads and subject matter experts helps bridge the gap between the ACT meeting and the formal proposal from the CDMO. It also can significantly reduce any concern or frustration felt by the drug sponsor by not hearing from the CDMO. At Pii, two PTRs are scheduled each week and all projects that have been discussed in ACT meetings since the last PTR are reviewed.

Attendees include key leaders with situational awareness of current and planned projects and who have supervisory authority over specific CDMO resources that will be needed for the project. Key leaders from research and development, analytical services, quality assurance, manufacturing science technology (MST), project management, and business development attend each review and are expected to have familiarized themselves with information gained from the ACT meeting. Additionally, key senior leaders should attend--those who have the authority to establish resource priorities and authorize or redirect resources as needed.

The PTR is conducted as a structured, yet open, candid discussion of a potential project. Discussion points include pre-proposal scientific review, anticipated challenges, CDMO organizational development, identifying missing information, timeline development, and potential time saving activities. At the end of the review, the senior CDMO leaders will be able to issue proposal planning guidance, and interim information of value to the drug sponsor will be available.

PTR Deliverables

At the conclusion of the PTR, the CDMO will be able to share the following with the drug sponsor:

- High-level estimate for the project tied to the RFP, scope of work, and proposal.
- An estimate for when the proposal will be delivered.
- Cost Estimate
- Anything missing from the body of information regarding the project or other documents such as safety information of the drug, analytical queries, or formulation & process development questions.
- Timing—when the project could begin.
- Identify anything that might slow down the project.

This interim step offers transparency and builds trust between the CDMO and drug sponsor and enables the drug sponsor to effectively continue their own planning. For example, if the project is intended to manufacture clinical batch supply, the drug sponsor can realistically plan for the clinical trial.

Summary

The initial stages of a relationship between drug sponsor and CDMO often does not get the attention it deserves, and valuable time is lost, delaying projects, and delaying delivery of therapeutics to the patients who need them.

When a drug sponsor contacts a CDMO, we've found they are ready to discuss their project (ACT Meeting), and before the proposal is completed, an exchange of information derived from a project technical review (PTR) can be extremely valuable. An effective PTR followed by timely communications with the drug sponsor can help build trust between the CDMO and drug sponsor, can get projects started as soon as feasible, and can keep them on schedule.

ABOUT Pii

Pharmaceutics International, Inc. (Pii) is a US-based contract development and manufacturing organization (CDMO) located in Hunt Valley, Maryland. The experienced scientists, engineers, and staff at Pii pride themselves on adroitly employing a phase appropriate method of drug development for the prudent use of their client's resources as they solve challenging problems. In addition to offering end-to-end development services, Pii manufactures a variety of dosage forms to include complex parenteral drugs and has a wealth of analytical testing capabilities. Its Hunt Valley campus has four aseptic suites with lyophilization capabilities. Our talented professionals stand ready to help!

ABOUT THE AUTHORS

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Devan Patel joined Pii in 2012 as a member of the Project Management team.

Devan has held roles of increasing responsibility in Project Management leading key development and commercial programs for Pii for both the orals and injectables. With his leadership, Pii has built a world-class Project Management Organization (PMO) consistently characterized by superb customer experience. Over the years, Devan has used his knowledge and technical skills to play a vital role for the Operations team, managing key initiatives for the Parenteral/Sterile business unit, including managing the overall scheduling and planning of all Aseptic Operations. His collaborative style when working with cross-functional teams across Pii's business units and ability to anticipate problems before they occur as raised the role of project management to an artform. Devan delivers a positive, outcomes-focused experience for our client-partners, from initial contact through successful completion of each project.

Devan earned his Bachelors in Cell Biology and Molecular Genetics from the University of Maryland and a M.B.A. from Johns Hopkins University.

Vidhi Desai
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Vidhi Desai is the Sales and Marketing Assistant and responsible for facilitating all initial contact between drug developers and Pii, and streamlining the initial stages of every potential drug developer project that comes to the Pii team.

Prior to joining Pii, Vidhi was a Formulation Scientist and Associate Manager at Tergus Pharma. She was also a Teaching Assistant in the Biology Department and Pharmaceutical Analysis Lab, an Assistant Analyst, and a Research Assistant, all at Campbell University.

Vidhi earned a Masters in Pharmaceutical Sciences from Campbell University, a Masters in Pharmacy Quality Assurance from Ganput University, and a Bachelors of Pharmacy from B.S. Patel College of Pharmacy.