Accelerating the Start of Your Outsourced Pharmaceutical Project by Applying Thrust

By Devan Patel and Vidhi Desai

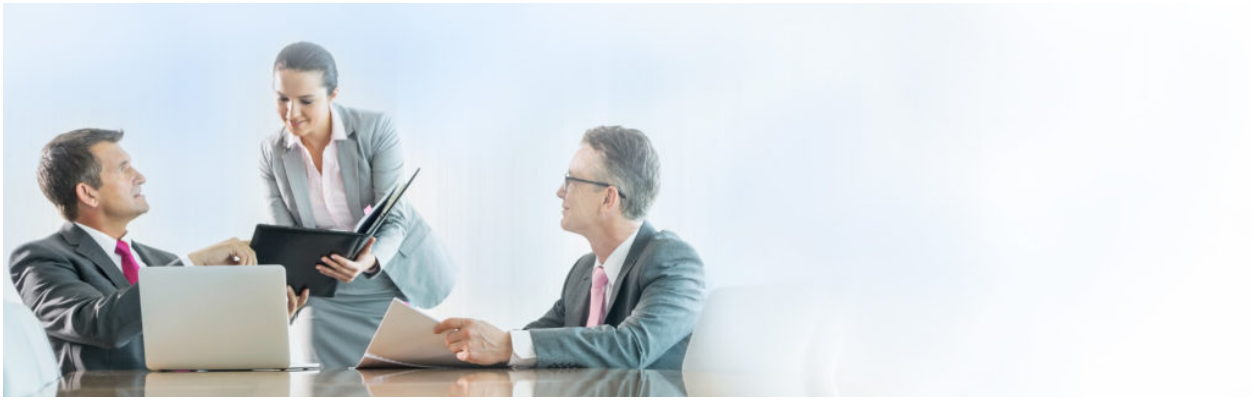
This is the first of two articles exploring best practices to streamline the underappreciated initial stages of a relationship between a drug developer and their CDMO--from the first contact to receiving a proposal.

Who is not struck by the awe and wonder of a rocket launch? Did you ever consider how such a large object can be propelled into the sky with such speed from a standing start? The answer is thrust! The two opposing forces working against each other during launch are the downward weight of the rocket and upward thrust. For success, the push effect of the thrust must be greater than the downward force.

In a way, getting through the initial stages of a complex pharmaceutical project that is being outsourced to a contract development and manufacturing organization (CDMO) is like getting a rocket off the ground.

For many of the drug-developer clients I speak with, they express concern, sometimes frustration, with the time it often takes during the initial stages of working with a CDMO—from the time they first reach out to a CDMO for help, until they receive a proposal. Some have described it as months of silence from when they send a request for proposal (RFP), until they have a proposal in hand. That's a lot of downward pressure, where's the thrust?

When returning to our CDMO roots five years ago, Pii was motivated to streamline the process for pharmaceutical outsourcing, and we examined slowdowns in the entire drug development process and sought ways to use time and resources more effectively and efficiently. We discovered that incorporating a few key practices into the initial stages of a relationship between a drug sponsor and their CDMO can deliver the thrust needed to get projects moving quickly.



Making the Most of the First Meeting

As we set out to streamline the initial steps of an outsourced pharmaceutical project, we were struck by three things drug sponsors shared with us. One, after contacting a CDMO they were subjected to several calls with different people from the same organization, sometimes over a period of weeks, reviewing the same information. Two, they often would not receive an initial indication that the CDMO could take on their project until they received a proposal, which sometimes took months. Three, they had already done some initial vetting of the CDMOs capabilities and were ready to confirm their findings and talk about project specifics and timing. Armed with this information, we felt we could design a better process.

First, we established a one-step follow-up for all customer inquiries intended to schedule the first meeting. Second, we included both a scientific subject matter expert and a technical project manager in the first meeting to address capabilities, capacity, and timing. Third, we established an agenda for the first meeting so that we could offer an initial yes or no on whether we could take on their project, and when they would hear from us next.

One-Step Initial Follow-up

CDMOs and drug developers connect in a variety of ways that are initiated by either organization. Effective digital marketing can deliver valuable experiences for drug developers as they navigate their way toward finding the right CDMO and good marketing departments will help them through this stage of their journey. When the initial stages of their journey are complete, drug developers will contact CDMOs who they think are a fit for their project. This is the signal for a substantive discussion.

At Pii, we've found that a best practice at this point is to schedule a formal meeting between the two organizations with a set agenda--assessing capabilities and timing (ACT) meeting. By the way, the impact of social distancing and ease of video conferencing makes this easy and cost-effective. In the past we put tremendous value on face-to-face meetings, but at this stage, we have discovered that a video conference is effective.

ACT Meeting Outcomes and Attendees

Recall the frustration voiced by drug developers about having the same discussion with several people from the same CDMO over a period of weeks. Why not assemble all the people involved in these initial conversations in a single meeting? Without constraints, this meeting could get bigger than needed and become unwieldy. However, with some well-defined outcomes, attendance can be efficiently right sized.

Drug sponsors find great value in a quick response from the CDMO on whether they can take-on their project or not. However, too quick a response without adequate knowledge of the project is not good either.

We've discovered that focusing the first meeting on CDMO capabilities and capacity, or timing, leads to the best outcome at this stage. To do this, CDMO attendees should

include a scientific expert with a comprehensive understanding of the CDMO's capabilities, a technical project manager with adequate situational awareness of all current and planned CDMO projects, and a business development representative to serve as facilitator.

We are reluctant to direct who should attend from the drug developer organization, but at a minimum, they should be able to speak about the services they need, dosage form specifics, method of delivery, specific stage(s) of development they are in, and in need of support, and timing requirements.

Other ways to facilitate the ACT meeting is by establishing a confidential disclosure agreement (CDA) in advance of the meeting so that the drug developer can complete a project questionnaire or present an RFP to capture critical project information after this initial meeting.

ACT Meeting Deliverables

One consistent frustration from drug sponsors is the amount of time it takes for CDMOs to offer an initial answer on whether they could do the project or not, sometimes waiting for months for an answer.

At a minimum, we think CDMOs should offer the following at the conclusion of an ACT meeting:

- Yes or No on whether the CDMO has the capabilities and timing to take on your project.
- If yes, the drug developer should hear from the CDMO in no more than a week following a formal project review with key department heads and subject matter experts.
- Next contact ought to include a high-level project estimate that includes a general scope of the project, a high-level plan for tech transfer if appropriate, work for any missing actions that have been identified via the Project Questionnaire or RFP, an estimated cost range, and timing.

- Provided the drug sponsor finds the high-level estimate acceptable, they should receive a proposal two weeks later.

When done effectively with the right attendees, the ACT meeting can provide answers to the initial questions drug developers have when they contact a CDMO for support.

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 talk about project specifics and expect an initial answer from the CDMO on whether they can take on the project. The quick scheduling of the ACT meeting with the right attendees can deliver immediate answers to key questions needed by the drug sponsor for effective planning and can deliver the needed thrust to get their project launched.

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 AUTHOR

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Devan Patel is the Senior Director, Project Management at Pharmaceutics International, Inc (Pii).

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 a 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 art form. 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 an 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.