



Client Oriented Project Management

By Devan Patel, Senior Director, Project Management

Outsourcing in the pharmaceutical industry is vital in delivering capabilities and capacity for biopharma companies as they face increased competition fueled by innovation and rooted in a better understanding of patients and their needs. The industry has recognized for some time the value of contract development and manufacturing organizations (CDMOs) to reliably deliver drug substances and products.

Several years ago, the global pharmaceutical outsourcing market was valued at over \$70billion with an expected annual growth rate of 6.6%¹. We estimate that on any given day, hundreds, if not thousands, of outsourcing projects are being carried out.

When surveyed, biopharma companies typically cite CDMO selection criteria that falls under the heading of capabilities and capacity. Does the CDMO have the technical know how I need, and can they do the work on my timeline? However, project management operations serves as the conductor that advances projects unimpeded. With the significant amount of outsourcing being done by the pharmaceutical industry, we believe project management has earned the right to be a critical factor in CDMO selection and deserves some exploration and understanding.

Over our 26-year history and having successfully completed over 400 development projects, Pii has developed and refined project management operations to ensure outcomes are achieved and client expectations are exceeded. We have found that excellent project management has seven distinct features.

Seven Features of World Class Project Management



One project-lifecycle manager.

Our experience tells us that changing project managers is highly disruptive for a project, contributing to confusion, potentially causing delays, and sometimes even project failure. Rather, we've learned the value of assigning a single project manager for the entire lifecycle of the project, this best serves the

client's needs and best leads to project success.



Project manager professionalism.

For contract development and manufacturing organizations (CDMOs), projects have a defined beginning and end and are therefore temporary, but project managers should not be. Ad hoc assignments of personnel to project manager roles is not a best practice. Project management teams ought to be comprised of professionals who find project management to be their life's work. CDMOs should continuously improve their project management operations through ongoing development of their project managers, both with formal education and training, and with company internal development programs.



An agent for the client.

What we've learned over time is that project managers should serve as agents for the client. First, they must take the time to fully understand the project from the client's perspective including project-specific nuances. All clients want their projects completed on their timeline, but project managers should understand the negative impact of not meeting the timeline. E.g. missing a critical timeline milestone will lead to the loss of 50% of the client's expecting funding. Understanding how distinctive aspects of the project may negatively impact the client enables the CDMO to exceed expectations.



Experience, Skills and Collaboration.

A CDMO client should have access to the best talent, experience, and skills of the CDMO, best aligned with the project's needs. Great project managers will not only gain a full understanding of the client's project, they know their own organizations, and will facilitate assembling the best team for the client's outcomes. With more situational understanding than anyone else on the team, the project manager can facilitate collaboration across the CDMO's functional areas. E.g. rather than pursuing a formulation recommended during concept development, a simpler formulation could be less costly and developed faster. See the Pii case study: [Creating a New Dosage Form from an Approved Drug for a New Rare Disease Indication](#). This will link to the [Cure HHT case study](#).



Client-centered communications.

To work efficiently on multiple projects simultaneously, CDMOs must have effective internal communications systems, but so do their clients and often those systems are not the same. Great CDMO project management operations adapt how they communicate and share data to methods that are preferred by the clients. The project manager serves as chief interpreter, ensuring and timing that best supports the client's critical decision-making.



Strategic project managers.

We mentioned earlier about the need for project managers to understand the nuances of projects with client's perspective. However, they should also bring additional experience and skill to the partnership, and a focus on the overall objective: a long view to the project. At Pii, the relationship between the project manager and the client begins before a contract or quality agreement is signed. Great project managers will ask questions that the client has not considered that can avert problems, advance the work more quickly, and anticipate what FDA will want to see in filings. The project manager facilitates on-boarding, sets-up the kick-off meeting, ensure key technical aspects of the project is clear, and communicates strategies within the scope of work.



Executive involvement.

Finally, great project management operations have the visibility of senior decision-makers at the CDMO. At Pii we have two weekly meetings that review client projects in which the senior executives participate. The first is an R&D review, focused on the technology challenges related to our client's work and ways to overcome them. The second is projects review meeting focused on milestones and client deliverables. Having our senior leadership team enables us to exercise agility in decision making on behalf of our clients.

We've heard the project management role described as be similar to herding cats or pushing a wet noodle across sandpaper. At Pii we see it differently. Superb project management provides project continuity, serves as the client's agent, facilitates collaboration across functional areas, maintains a strategic view while working to help advance daily outcomes, adapts the CDMO's communications for the

client's needs, and has the trust of the CDMO's senior leadership to exercise agility on behalf of the client.



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

Devan Patel joined Pii in 2012 as a member of the Project Management team and he now leads that 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.

Pharmaceuticals International, Inc. (Pii) is a contract development and manufacturing organization (CDMO) located in Hunt Valley, Maryland. Pii is on a growth trajectory and anticipates a need for additional project managers. If you are passionate about project management and have an interest in joining the team, please visit the [career section of the webpage](#). The experienced scientists, engineers, and staff at Pii pride themselves on solving difficult problems, it is part of their DNA. In addition to manufacturing complex parenteral drugs, Pii has a wealth of analytical testing, formulation development, and manufacturing capabilities across a variety of dosage forms. Its Hunt Valley campus has four aseptic suites with lyophilization capabilities.

1. ["Outsourced Pharmaceutical Manufacturing Grows To \\$76 Billion"](#) by Louis Garguilo, Chief Editor, [Outsourced Pharma](#).