HOW CDMO PROJECT MANAGEMENT MAKES OR BREAKS A DEVELOPMENT PROJECT

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An adept CDMO PM team is flexible, relentless, and communicative, in addition to possessing deep experience and expertise.

By Rose Rhomberg and Vladas Algirdas Bumelis, Prof., Northway Biotech

Every biopharmaceutical company that hires a CDMO partner invests time, money, and faith in that organization to shepherd its project through development to commercialization. However, pre-hire analysis of a CDMO's development systems, manufacturing equipment, and personnel resources can overlook the person at the center of any collaboration: the project manager (PM).

Concentrating on the "how" of a CDMO's capabilities is important, but it is equally critical to explore the "who." Advanced technology and innovative development systems are only as effective as the people coordinating which levers are pulled and when. Accordingly, examining a CDMO's project management – both its structure and its personnel – is a vital component of securing a partner that is experienced, knowledgeable, and flexible enough to see a project through to completion within an ambitious timeline.

ASK THE HARD QUESTIONS UP FRONT

Key inquiries regarding project management include the PM's workload and individual expertise, management support for that individual, subject matter expert (SME) involvement, and communications strategy.

PM Workload – It is important to know, within a CDMO, how many PMs they have versus active projects (i.e., the ratio of PMs to projects). For example, if each PM is managing four projects, that is much more practical than each PM overseeing 10 projects.

PM Expertise – A PM also needs to have some scientific background or experience relevant to project management of a particular contract. It is advantageous for a CDMO to utilize internal resources, if possible, because those people already understand the organization's systems and philosophy, versus outside resources who need time to become acclimated to a new environment and a novel workflow.

Regardless of whether a CDMO leverages internal or external resources, preestablished criteria should be met, and the effectiveness of those individuals should be confirmed through regular conversations with the client. Continually monitoring the pulse of client feedback is a crucial component of CDMO success.

Management Support – How much help is the PM able to leverage when things get chaotic or priority items demand their time? Additionally, is an established structure in place that ensures each

PM's clients receive proper attention when the PM must triage responsibilities?

Adept CDMOs will employ an individual to oversee their PM team, ensuring adequate response to such challenges. For example, PMs may welcome client teams onsite to collaborate on day-to-day activities. But, if a PM is managing three or four clients simultaneously and needs to spend a few days with a particular customer onsite, other important tasks should not be delayed. So, a clear structure must be established – when someone is occupied with a client, on holiday, or otherwise unavailable – allowing another individual to take over activities in the interim.

Additionally, biopharma companies should inquire with potential CDMO partners about their business development (BD) representatives' knowledge of – and involvement in – projects under their care. Do the BDs "hand off" each project to the PM and step back, or do they remain involved at some level to ensure each project is executed in the best interest of the customer?

SME Involvement – Much like management support, this element comprises the extent to which SMEs are involved in day-to-day project operations with the client, as well as the amount of flexibility those individuals can exercise to meet client needs. Do the SMEs typically route information to the PM, who then shares that information with the client, or is there direct communication between the SMEs and client? Is there flexibility in that dynamic, should circumstances demand it?

Typically, in a regular program, it is best to route everything through the PM. This single point of contact is vital when up to two dozen people from the CDMO, and another half-dozen on the client end, are involved in a project. With that many individuals, operating across various tasks, a project can easily disintegrate into chaos absent an established structure. So, defining that person on both sides up front is key, particularly when project strategy changes on the fly.

For example, a titer is not what was expected. The client may need to add another batch, or they may opt to increase the current batch's scale. All available data must be gathered to inform a quick decision. Additionally, if the project plan has to be updated, a process must be defined for that task. An adept PM is at the center of all of this activity.

But, in a fast-track program, time may prevent immediate consultation of the PM. In such a scenario, the client must know whether SMEs are empowered to make some decisions and contact the client directly – not circumventing the PM, but including them in the email or call.

Obviously, best practice dictates the PM be part of every communication, but pragmatically speaking, times will arise when a PM is dealing with another critical matter. The organization must be able to continue moving forward in real time, without having all players available at all times, while still communicating effectively with clients so the latter can make informed, timely decisions.

Communication Strategy & Tools – Communication strategy depends largely on the client's demand. Some biopharmas prefer to hold bi-weekly meetings because they cannot dedicate the resources to support more frequent meetings or the project is not time-sensitive. In other scenarios, including critical and fast-tracked projects, clients seek daily phone calls to address any issues.

Clients working against the clock may want meetings within 30 minutes of an issue presenting itself, challenging the CDMO to gather its PM and SMEs to attend the meeting on short notice. Moreover, even though the PM is the primary point of contact, it is useful for a biopharma client to understand which individuals in the organization (i.e., the CDMO) are going to support them – upstream, downstream, formulation, analytical – so they understand who's who, especially on calls that include many people.

Another critical dimension of communication is the tools the PM uses to communicate effectively and minimize back-and-forth. Given project pacing and the condensed nature of these communications, 15 deliverables might result from a 30-minute call. So, it is vital to take detailed notes – stipulating each

deliverable, who is responsible for it, its promised timeframe — because things could be forgotten quickly or overlooked. The format also should be conducive to accessing and reviewing that information quickly.

PM RESPONSIBILITIES AND DELIVERABLES

In coordinating all these moving parts, a CDMO's PM must constantly track five key areas of concern: available personnel, equipment, raw materials, outsourced activities, and shipping. Personnel available to provide answers to client queries and fill in while the PM is otherwise engaged, as well as support PM functions, have been discussed above. Equipment concerns comprise what equipment a CDMO offers and which units/lines are available at any given time.

Raw material challenges are becoming increasingly common in biopharma manufacturing. Resins that formerly took one month to procure now can take up to 30 weeks, meaning CDMOs may be asked to stockpile materials with short shelf lives. So, supply chain management — and ensuring materials are used within an appropriate timeframe — is a vital PM skill, as the PM is tasked with identifying long lead time items early so they can be ordered as soon as possible.

Even with the right equipment and personnel in place, work cannot begin in earnest if materials are delayed or unavailable. Thus, initial discussion with a CDMO should not ignore procurement of essentials in favor of details like equipment or protocol. In situations where a material is difficult to procure, a PM's creativity can help to overcome the issue. For example, one liter of the material may not be available, but 500 ml is available from another vendor. It may be double the cost, but it allows the client's project to move forward, saving money in the end. The PM's skill in seeking out different suppliers or material quantities also depends on the CDMO maintaining relationships with multiple vendors.

In this same vein, a PM should maintain an adaptable material sampling plan. Consider that a certain amount of material is necessary to conduct toxicity studies, analytical testing, and viral clearance studies. The PM must determine where that material is being drawn from and how much is being used.

For example, a production team encountering titer issues will need an adept PM to minimize cost and timeline impact. Say the production team expected a titer of 1g/L, but instead is getting just 0.4g/L. Now, not enough material is available for viral clearance, meaning another run might be added or the study must be rescheduled — multiple elements requiring the PM's immediate attention.

This example also highlights the importance of a PM's insight into **outsourced activities**. CDMOs that maintain relationships with several viral clearance study houses have access to multiple options when the schedule is disrupted, rather than stalling the project. In addition to the steep fees a canceled viral study is likely to incur, the viral clearance study house may be working with a compressed schedule; if you miss your slot, they might not have another available for months. So, PM visibility and coordination relevant to outsourced activities is as important as anything occurring internally.

Finally, **shipping** must be on a PM's mind throughout development. The process can be complex, requiring the involvement of multiple brokers and delivery companies, all of whom must receive appropriate paperwork up front to expedite delivery. For example, if the broker is not aware it is about to receive a shipment, the delivery could sit for a day or two, or the broker might lack information necessary to facilitate release.

If the product is a dangerous good, certain labeling is required, and only certified personnel may be permitted to handle it. Biopharma companies vetting CDMO partners should inquire how a CDMO's PMs maintain preparedness for such scenarios, ensuring all those boxes are checked at the end of a project so shipping occurs quickly and problem-free.

In addition to maintaining visibility on these five focus areas, the PM must be able to communicate up-to-date information to the client regarding their status, a goal generally achieved through a GANTT

chart and a project plan. The GANTT chart should be a part of every proposal a biopharma client receives, acting as a "view from 10,000 feet." For example, the chart may lay out 10 project stages, stipulating two months to complete one stage, four months for the next, etc.

The GANTT chart provides an at-a-glance overview of the program's schedule and extent but does not include details about raw material ordering, shipping, an analytical method that requires qualification before its use in the cGMP run, etc. Providing that more granular detail is the role of the project plan. However, a project plan is only as good as the data entered and the commitment to a high level of detail.

In our experience, PMs must work diligently to understand their clients' demands regarding the level of detail they want to see: some clients want to know every minute facet of a project, while others prefer a more hands-off approach. PMs need to have clarity on how each client wants that information delivered, as well as updates when things change

FINAL THOUGHTS

The experience and expertise of a CDMO's PM team and, by extension, the CDMO itself, is as critical a consideration as the organization's equipment, reputation, and processes. Embracing this dynamic, Northway Biotech strives to provide our clients with project management that is flexible and relentless, as well as dedicated to clear, constant communication.

Flexibility is vital to any biopharma company seeking to fast-track a project – a group that includes nearly all organizations developing a COVID-related product. Compressing timelines by several orders of magnitude requires an innovative mindset and the capability to pivot one's thinking and project plan at a moment's notice. Many CDMOs operate with set processes – at which they are very good, because project steps are confirmed and move forward in a logical way – but that progress can be slow. Thus, balanced flexibility is a valuable trait, enabling the PM to maintain control and adequately manage communication without a project descending into chaos when things go amiss.

Relentlessness comprises both hardworking diligence and the presence of mind to delegate less-critical tasks when a matter takes priority. Employees should be able to go on holiday, fall sick, or step away to address a personal matter without disrupting the 24/7 cycle of client service. Northway Biotech facilitates this by ensuring SMEs and PMs have trained colleagues ahead of time, introducing them to roles they may be asked to temporarily fill.

Accordingly, if someone is unable to be present, we know right away who is filling in, and that they will have the necessary information and expertise to do so. To achieve modern development timelines, it is not enough to be committed and hardworking; organizations must be dedicated to intuitive teamwork that allows us to maintain the unyielding pace of the biopharma industry across months and years.

Finally, communication can be the PM capability that makes or breaks a CDMO's relationship with its clients. Every customer – deservedly so – wants to be top priority, to command the most attention, and demands a PM who can provide timely solutions to problems and responds to questions quickly. A PM who not only delivers data, but delivers it in proper context, along paths that allow the client to understand its impact and their options, is an invaluable commodity. There will always be challenges in this type of environment; a good PM, working within an innovative system, offers the best opportunity to overcome those challenges.

To learn more, contact the authors and visit https://www.northwaybiotech.com/.

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ing previously served in senior management positions at international companies in the biopharma industry such as Teva Pharmaceuticals, Sicor Inc., Biofa, and Biotechna. His illustrious career has been recognized many times. In 2004, Prof. V. Bumelis received the Science Award of Lithuania in recognition of his achievements in the development and production of recombinant proteins, and in 2012, he was named CEO of the year in Lithuania. Vladas can be contacted at vladas.bumelis@northwaybiotech.com.

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ABOUT NORTHWAY BIOTECH

Northway Biotech is a leading CDMO supporting customers worldwide. Its highly experienced, professional team executes projects at any stage, from cell line construction and process development to cGMP manufacturing of biopharmaceutical products. The company's wide-ranging expertise and vertically integrated service offering translate to the ability to rapidly execute multiple projects from its state-of-the-art GMP facilities while ensuring full process and product compliance at all stages of research, development, and commercial manufacturing. Northway Biotech is a privately-owned company founded in 2004 and located in Vilnius, Lithuania; London, UK; and Waltham, MA (US).

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