Pharma Intelligence

Are Milestone-Based Approaches The Future Of Biopharma And CDMO Partnerships?

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The drug development process can be incredibly costly, especially for small and mid-sized biopharma companies that rely heavily on external funding in order to progress through the stages to commercialization. These companies are also heavily reliant on the facilities and knowledge of contract development and manufacturing organizations (CDMOs) due to their smaller workforces and the high costs of acquiring these attributes in-house. Any spend on outsourcing partnerships must therefore be used as efficiently as possible.

In most CDMO agreements, biopharma sponsors will sign on for one part of the development and manufacturing process or the full scope of work for a particular project. The former gives the flexibility to make alterations to the program approach along the way but can result in lengthy delays due to high demand for production slots. The latter ensures that sponsors can move through the development process efficiently but involves committing to a timeline and approach that may prove to be suboptimal following results from earlier stages.

According to Northway Biotech, a milestone-based approach to CDMO partnerships offers a balance between these two scenarios, without the compromises that each may bring. In this approach, set points in the development process are established whereby

payments can be spread out over the milestone in order to ease financial commitments and the next steps of the project can be reviewed.

Choosing Appropriate Milestones

In a typical milestone-based agreement there are two or three milestones, according to Professor Vladas Bumelis, CEO of Northway Biotech. "The setting of these milestones is customized. One we have implemented at the project start for the first milestone is all activities way through to master cell bank (MCB) production, then, when the client is ready for scale up, cGMP drug substance is the second milestone, and cGMP drug product is the third." he states. This bespoke approach ensures that no matter what the project is, or the funding the biopharma sponsor has, an agreement can be reached that suits their needs.

With regard to how the project is structured and movement between milestones, there needs to be an additional lever in place within the statement of work to indicate to both the client and CDMO how this will occur from a payment perspective. "One way that we've structured it before is that when the client initiates the payment for the first stage of the second milestone, that tells both parties that we can move forward to the next milestone," says Bumelis.

This is also when any decisions or deviations from the original project plan must be made in order to capitalize on the timeline benefits of a milestone approach. Supply chain shortages during the COVID-19 pandemic highlighted the importance of this, as raw materials often need to be ordered far in advance, which can delay progress, even if all parties are aligned on what the next step will be from a technical perspective.

Flexibility And Efficiency Benefits

Flexibility in payment models and approaches to drug development is indicative of the milestone-based approach and offers significant benefits to biopharma developers with high-stakes projects. One of the key advantages is the fact that at each milestone, depending on the outcomes of the previous task, there is the ability to make critical "go or no-go" decisions. For example, if early in the development of a product the titer proves to be a challenge, it may not be feasible to proceed with the asset and cell lines may want to be revisited. Rather than be committed to a full development program with the CDMO partner in its current state, the sponsor would have the opportunity to make the decision on whether or not they want to move forward and continue to spend funds on the project.

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Additionally, milestones can be used as a gating mechanism for important strategic decisions to ensure every element of the project is optimized to its fullest potential. At the onset of the project, a biopharma company might be extremely risk-averse and may initially plan the

development and manufacturing process with this in mind. However, as Bumelis illustrates, "If milestone A ended up taking an extra two months, that would then push everything back. So, we might decide to take more risk where we weren't previously and, for example, skip an engineering run because we still have to get to our end goal by a certain date."

Despite the flexibility advantages, in a milestone-based agreement biopharma sponsors can still reap the timeline benefits of having a full proposal set. By provisionally signing up for the total spectrum of services, they can ensure production slots are available for their project. When split into multiple proposals there is inevitably a gap between activities if one stage takes longer than anticipated, and for the customer this time results in costs. "If you end up having a three-month delay, that actually could translate into a year delay because of slot availability. They fill up quickly, making it difficult to add another project to the production schedule. While a three-month gap isn't so big of a deal, a year is very detrimental."

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Advantages For Small And Mid-Sized Biopharma

In Northway Biotech's experience, milestone-based CDMO partnerships are particularly appealing to small and mid-sized biopharma companies, as they usually have finite resources and therefore must make every decision count. The ability to maintain flexibility while also meeting timelines is key for investors, whose funding is contingent on project progress.

Moreover, Bumelis notes there are further benefits to sponsors working on biologics. "We are talking about living organisms, where there is a lot more unpredictability. It's not like small molecule chemistry where you know that if you include a certain amount of reagent, you will have a certain amount of product at the end. Again, the flexibility of revisiting the development strategy at milestones enables sponsors to react to any such unforeseen issues before they become too costly." A milestone-based approach is key to Northway Biotech's offering as it continually strives to offer as tailored a service as possible to its biopharma clients.

Assessing CDMOs For Milestone Approaches

As previously mentioned, most outsourced manufacturing service agreements are either for a certain stage of the development process or for the full end-to-end process, without milestones. The availability of a milestone-based approach ultimately comes down to the business model of the CDMO and its facilities.

As one of the main benefits of these partnerships is flexibility, the CDMO must be able to provide alternative offerings in case of a pivot during the project. "We have all the quality systems and services in place that large CDMOs can offer, but also we have the flexibility of being a flat organization with direct access

to management," comments Bumelis.

Firstly, they must have capacity to support early-stage manufacturing through to drug product. The CDMO partner must also have the breadth of equipment to support different approaches should these decisions be made at a milestone. As an example, Bumelis states, "Northway is very focused on reinvesting revenues into our facilities and bringing in new technologies. Being forward-thinking, our facility in Vilnius, Lithuania, utilizes modular technology. This has already been expanded since initial implementation to increase capacity and in case of need it can be further increased."

"Project management is also a critical element of a milestone approach, so that sponsors have all the information they need to make the right strategic decision when milestones are on the horizon. "

He continues, "For us, we can offer the flexibility because Northway realized that there could soon be a crunch in production slot availability, thus we added more bioreactors to increase capacity to help our clients with offering these milestone approaches to them."

As well as sites and equipment, in order to facilitate a flexible, milestone-based approach, the CDMO must take a consultative attitude to its partnerships with biopharma customers. Bumelis notes, "It's a matter of being client-oriented and providing tailored customer care. We consider how we can get a client's project completed according to their needs, whether it's the timing or available funding. We want to deliver something correct, on time, and of course in a financially efficient manner."

Project management is also a critical element of a milestone approach, so that sponsors have all the information they need to make the right strategic decision when milestones are on the horizon. Bumelis acknowledges that there is a high administrative burden on the part of the CDMO when managing a milestone-based project. "Clients should be able to reach out to their point of contact when needed, making open lines of communication crucial to project success."

The Future Of CDMO Partnerships

The benefits of milestone-based partnerships are clear for biopharma companies that need to make their outsourcing decisions and spend count. However, there are a number of prerequisites that enable a CDMO to provide this offering and deliver successfully for clients to maximize the advantages. In order to flexibly accommodate client needs as milestones are reached, the CDMO must also operate flexibly internally. Northway Biotech has prioritized this in its business model with the proximity between business development and senior leadership. "Business development reports directly into me, so if we need to make a decision for a customer, we are able to do so in a quick and efficient manner," asserts Bumelis. By acting swiftly and with expertise, CDMOs can ensure the full benefit of a milestone-based approach is realized, and projects utilize the best technology, processes and facilities possible for an asset's development.

Vladas Algirdas Bumelis, Prof.

Vladas Algirdas Bumelis, Prof., is the Founder and CEO of Northway Biotech. He holds PhDs in both chemistry and biotechnology from Vilnius University and is a full member of the Lithuanian Academy of Sciences. Prof. V. Bumelis has extensive experience in the pharmaceutical and biotech industries, having 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, while in 2012, he was named CEO of the year in Lithuania.

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About Northway Biotech

Northway Biotech is a leading contract development and manufacturing organization (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, United Kingdom; and in Waltham, Mass., U.S.

Learn more at www.northwaybiotech.com