Pharma Intelligence

Why Should Biopharma Consider An End-to-End CDMO Partnership?

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BY VLADAS BUMELIS, PROF.

Timelines for drug development and manufacturing have become shorter, with processes that previously took two years – for example moving from cell bank construction to GMP manufacturing – decreasing to 18 months or even a year in some scenarios. This has led to heightened expectations from biopharma companies looking to fast-track their path to commercialization. One way to accelerate project progress is through an end-to-end partnership with a trusted contract development and manufacturing organization (CDMO). This not only streamlines processes but can improve the quality of delivery, due to minimized risk during tech transfer, improved understanding of the asset, and reduced project management requirements for the sponsor.

Mitigating Risks Of Tech Transfer And Transport

The drug development process is notoriously difficult to navigate, with a fraction of assets making it to full commercialization. Part of the role of a CDMO is to mitigate risk and put clients in the best possible position to succeed. Tech transfer and the movement of materials between different providers and locations can be one of the most challenging processes. There is potential for delays due to shipment requirements that are contingent on different stakeholders, and also risks regarding the asset itself, such as contamination in transit. In particular, COVID-19 highlighted the complications of global supply chains and what can go wrong if transport and travel is restricted.

An end-to-end partnership with one CDMO lessens the scale of such transfers. Often, the product can remain within a single facility if the provider has all the necessary equipment and technology in one site, removing the need for significant transits entirely. On the other hand, where movement between sites is necessary – for example the cell line to the drug substance manufacturing site, or the drug substance to the drug product manufacturing site – it is handled by one single entity with one point of contact, so a sponsor can always gain insight on the location and progress of their asset. The ideal situation from this perspective is if different activities are all performed at the same site under one roof. Therefore, while some biopharma companies may believe that by utilizing different providers for cell line development, drug substance and drug product, they are mitigating risk, the opposite is the case. Outsourcing partnerships are not like the stock market; diversification is not necessarily beneficial.

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Maintaining Flexibility, Quality And Efficient Project Management

Moreover, an end-to-end partnership enables the CDMO to provide much more flexibility to their biopharma clients. For example, if one stage of development takes longer than anticipated, there is less risk of missing out on a future production slot, as might be the case if this were being managed by another provider. Instead, the end-to-end CDMO is able to communicate the delay to the relevant team and make changes to facilitate a later slot without stalling progress any further for the client. This alignment ensures the project can proceed with maximum efficiency.

There are further benefits to working with one provider from a project management perspective. Especially for early-phase clients, those who are responsible for keeping track of CDMO relationships and project progress are often wearing multiple hats, spreading their time over multiple activities. Only having to manage one partnership is a much more efficient use of time, and it is up to the CDMO to keep track of the project internally and ensure the main point of contact is updated at all times.

Having just one partner own the project throughout development also enables the CDMO to gain an in-depth understanding of the asset. From a quality standpoint, this enables the experts to provide a much more consultative service that guides the sponsor on the best processes for their product. It also means that from the very start, the development path is crafted with the end goal of scale-up in mind. Alternatively, when working with multiple CDMOs this may be limited to looking to the end of that particular stage, which doesn't always complement the approach of the partner responsible for the next step. This removal of silos ensures that the project can run as efficiently as possible and the potential for surprises along the way is minimized.

What Is Truly End-to-End?

End-to-end is a popular term among CDMOs, but the offering can differ depending on the provider. This begs the question: what is a true end-to-end service?

Ultimately, on paper the pre-requisite of an end-to-end partnership is that one CDMO is responsible for early development through to full-scale production. However, within some CDMOs silos can still exist even internally, due to size and the locations of different facilities. Here there is still an element of risk during transfer of the asset, and the benefits of end-to-end agreements cannot be fully realized. There is also the risk when moving between teams internally that one does not necessarily get the "A team", meaning the most experienced, for every step due to availability at that stage, despite what may have initially been promised.

At Northway Biotech, while there are two sites available for development and GMP manufacturing (one in Vilnius, Lithuania and another in Boston, Massachusetts), both have nearly identical facilities. Normally, all activities from cell line development via process development and drug substance manufacturing until fill and finish activities are executed at one site in Europe or the US. Movement between the two is only considered where it will benefit the project from an efficiency standpoint for the client. For example, if availability for a particular process arises sooner at one site than another, it may be more effective to pivot to this location. This means there are all the benefits of having options available for project progression, without the potential silos.

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While there are clear benefits to an end-to-end partnership, it is also very important that sponsors assess the CDMOs they are considering for this to make sure they are a technical fit for the project. Picking the wrong partner for these arrangements could have negative consequences to the future of an asset.

When To Start Deliberating End-to-End Partnerships

As the name suggests, the earlier a CDMO is consulted for end-to-end partnerships, the better. Not only does it enable those working on the project to gain a more in-depth understanding of the asset and its requirements, but there can be detrimental consequences to working with a different CDMO and switching part way through, or after, process development. As an example, the initial CDMO may develop a process in a certain way using specific equipment, and then upon moving to a new partner this may not be available. This results in a necessary change in process that may trigger alterations to the product itself that were not anticipated. Additionally, this could raise questions with regulators regarding comparability, which could significantly delay commercialization.

Nevertheless, some early-phase clients with limited finances may not feel entirely comfortable committing to an end-to-end partnership with a CDMO straight away. In these instances, the sponsor might decide to start with one service, such as cell line development. Once they have experienced the nuances of the CDMO's approach and are satisfied, at this stage they can sign on for the rest of the development

journey. If taking this approach, it is very important that sponsors choose a partner that has the capacity to support their end-to-end requirements.

An end-to-end partnership ensures that from the start of a project, the CDMO has the end goal in mind and is continually striving to make the process as efficient and effective as possible for clients. While it may be daunting for early-phase clients, the benefits attributed to these arrangements can far outweigh any risks. Northway Biotech has built business acumen that combines flexibility with a full-service offering, to ensure that it can guide customers through the entire development process and optimize the success prospects of assets.

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