Decision Timeline: Considerations in Selecting an Outsourced Solution

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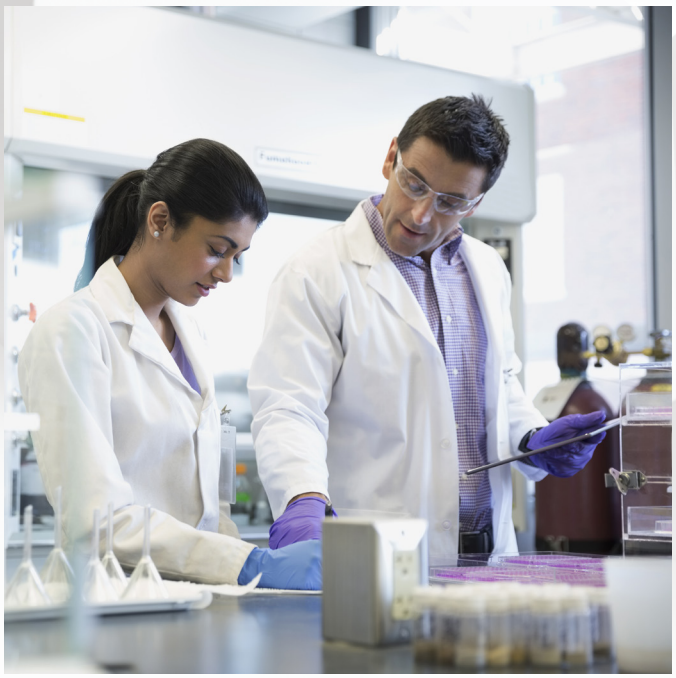

The traditional business model for in-house pharmaceutical manufacturing is nearly a thing of the past.

More companies are turning to outsourcing to achieve flexibility and efficiency in a highly competitive market. According to a recent report by business intelligence provider Visiongain, the global contract biopharmaceutical manufacturing market is predicted to reach $79.24 billion in 2019.

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This is a substantial increase from $54.54 billion in 2013.[1] Nevertheless, this does not mean an outsourcing strategy is necessary for every project. A thorough evaluation of a manufacturer's capabilities and true cost structure must be completed early to determine if its goals can be achieved in-house. More importantly, this decision must be made early to allow enough time to initiate an outsourcing partnership.

Expertise and capacity: Do you have what it takes?

The drug development process begins with discovery, where most companies rely on in-house scientists to create the chemical or biologic process. However, a small company may choose to outsource this stage virtually. Either way, most of the focus at this point is getting the molecule to the clinic with little consideration for future scalability or its commercial supply. It is in Phase II clinical development when manufacturers often consider more advanced formulation development.

For those companies that have been working virtually to develop a product and formulation, Phase II can be the ceiling for scalability with existing partners. Typically, smaller scale virtual providers are not capable of scaling up or may not have commercial good manufacturing practice (GMP) compliance. It is at this stage when small companies must start to consider outsourcing for registration and commercial supply for their project. For larger pharma companies, the traditional perception is that, because they have the necessary capabilities in-house, it is best to keep manufacturing there. Yet, given the complexity of new products, past manufacturing capabilities and technical know-how may not be adequate, and outside options should be considered. CDMOs may have a strategic advantage based on their exposure to a variety of projects with multiple types of processes, and that type of experience can translate to a higher level of knowledge in both operations and development.

Capacity is also a factor at this stage, as a company must ensure it has the space to manufacture its product. Demand forecasting for the future commercial product and, in particular, launch forecast accuracy are often significantly wrong. In fact, over 60 percent of drug forecasts over- or underestimate peak revenues by more than 40 percent.[2] These inaccurate forecasts have damaging and costly impacts. When demand is overestimated, a decision to manufacture in-house results in expensive, unused facility capacity for both drug substance and drug product. When demand is underestimated, the manufacturer faces a race against the clock to quickly produce lifesaving medications that must still be of the highest quality. This takes place while facing lost sales.

In addition to standard capacity needs, it is important to consider any specific or unique technologies needed for the product. New and emerging technologies, including sterile single-use processes, biologics perfusion, HME or continuous manufacturing, create exciting possibilities for improved development and commercial efficiency and flexibility. As these technologies are not as widespread, they can be difficult to apply internally for just a single project or product. A manufacturer must consider if it wants to invest in the equipment and expertise needed for these technological approaches; or if it wants to defer to a CDMO with greater experience and a variety of projects to stabilize the expertise.

Timeline considerations after partner selection

Companies that ultimately decide to outsource often underestimate the time required once the decision has been made. The supplier selection process, including requests for proposals (RFPs), evaluation of capable suppliers, and final selection, takes considerable time and is often managed by groups far removed from the technology experts. This step can take up six months to complete, time which becomes critical at start-up. A quality audit should be part of a CDMO evaluation, which, depending on availability of internal and/or external quality experts, could require a waiting period of up to three months.

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After selection, a kickoff and onboarding process with the selected partner is necessary, including the commitment of stakeholders. It is not uncommon at this point for research and operations personnel to become engaged after not having participated in the initial selection of the partner. They often bring new questions and new needs that can complicate the deal and delay the project. A company can prevent this kind of delay by ensuring all appropriate parties are involved from the beginning rather than handing off to Procurement or Supply Chain to manage exclusively. Finally, the deal terms and conditions and scope for the project will be formalized in a master service agreement (MSA). Even in a scenario where there is an attempt to expedite this process, it is best to anticipate a three- to six-month waiting period to complete this part of the process. New stakeholders from legal, finance and supply chain are often involved here for the first time, and the process of each trying to protect the interests of their company can affect the original need and timeline. It is common for companies to not fully understand their own negotiation and approval processes, leading to rework and delays, depending on the size of the companies and number of people involved.

Making a decision between keeping a project in-house versus outsourcing is not an easy one, especially with so much at stake. If a company has the expertise, technology, and experience necessary to work with today's most innovative drugs, it may have a case to stay in-house. However, if it does not have those capabilities, evaluation of an outsourcing solution will provide the optimum long-term solution. By working back from your desired launch date and including the steps above in your development and manufacturing timeline, you will be able to better manage the process in order to meet your goals.

1 Visiongain, *Pharmaceutical Contract Manufacturing World Market to Reach $79.24BN in 2019* – https://www.visiongain.com/Press_Release/761/%E2%80%9CPharmaceutical-Contract-Manufacturing-World-Market-To-Reach-79-24bn-In-2019%E2%80%9D-New-Visiongain-Study-Predicts

2 Patheon, *Implications of Inaccurate Forecasting on Biologics Drug Substance Manufacturing – White Paper* - https://www.patheon.com/en-us/Ideas-in-Action/Material-Details/59/Implications-of-Inaccurate-Forecasting-on- Biologics-Drug-Substance-Manufacturing---White-Paper

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