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CASE STUDY

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Cost savings and speed: The untapped value of a single-source solution

In the current drug development pipeline, small and emerging companies are being credited as the drivers of innovation. And although the majority of new drugs in today's pipelines come from these types of companies, there are still significant challenges they must overcome due to limited funding and resources.[1]

These resources include R&D productivity, experienced in-house staff, capacity, and access to advanced technology. To avoid interrupting the flow of these novel drugs into the market, small biopharmaceutical companies must find a competent partner that can help them commercialize their products and/or develop the asset to the phase defined by the company's business model.

There are a growing number of CDMOs in today's market available to assist with all phases of the drug lifecycle and to provide support for any capabilities a company is lacking. However, contracting a partner for each need requires a significant amount of time and resources to negotiate terms and conditions as well as to oversee the project from development to proof of concept (POC) and beyond. Most small companies do not have that kind of bandwidth. This calls for an alternative solution to help small companies achieve success. One option is a single-source solution, a nontraditional approach that aligns all services through one CDMO to accelerate drug development. This eliminates the silos that can often exist in today's outsourcing paradigm, increasing both communication and speed.

In a recent interview,[2] Anil Kane, Executive Director, Global Head of Technical and Scientific Affairs at Thermo Fisher Scientific, describes how this solution can actually benefit pharma companies of all sizes. "Medium and large pharma companies are consolidating to focus on higher-priority products and portfolios and reducing the staff that manages outsourced products and services," he explains. "Thus, the single-vendor concept is becoming increasingly beneficial to medium and large pharma companies, too." Kane adds pharma still questions the effectiveness of integrating drug substance and drug product manufacturing in a single-source solution. However, looking to a company's experience and history can speak volumes about its service and capabilities.

This alignment of the entire drug development process was certainly a concern of one emerging biopharma company as it pursued the commercialization of its highpotency, small molecule drug. The CMC team of less than five people relied on Thermo Fisher's Quick to Care™ solution for the capabilities and standards needed for clinical manufacturing. This approach gave the small biopharma an opportunity to streamline its drug development and expedite the path of idea to reality.

One path, one team, with Quick to Care™

As a very small startup, the company did not have in-house formulation capabilities, nor other capabilities for late-stage development. It was important the company they partnered with had not only manufacturing experience but also the ability to understand regulations and quality requirements. They also wanted project management expertise. “In other partnering scenarios, it is sometimes the experience that you need a large volume of product to get people to listen to you. This can mean even having to show up on-site, which is not an efficient process,” says the company’s current senior director of manufacturing. “We needed someone who would oversee the project and not push it off on us instead. Thermo Fisher presented us with their Quick to Care™ program, which was a new initiative being implemented to provide a better soup-to-nuts experience for customers.”

With Quick to Care™, clients have a dedicated program manager who provides seamless coordination throughout drug development. “One of the first deliverables we were given by our project manager was an overarching timeline across all of the sites. Often in this industry, it is difficult to stick to timelines. However, in this case, the oversight of an independent party helps to keep all individuals on track,” he explains. “Our program manager conducts monthly meetings with members from each site to go over that timeline and make sure each site understands its responsibilities within the project and the deliverables expected from them. As a result, the joint activities between sites have resulted in more efficient solutions to some of our greatest challenges.” The other role their program manager has played, which he says has been an essential benefit, is to be an advocate for them as a client. “If there is a lapse somewhere that is affecting or might affect the overall timeline of the product, our program manager is the single point of contact we go to because they know who to go to and have a discussion with.”

He recalls a time when there was a specific need that was central to the advancement of the molecule and the solution was not available at one of Thermo Fisher’s sites. Without a resolution, it could have potentially been a major stumbling block for the product. “Through direction from the program manager, Thermo Fisher was able to tap into its network and identify a site that could keep the molecule on its critical path,” he explains. “Having someone who knows the players inside the organization and is able to show up on-site or make a phone call to solve these potential setbacks and let people know the importance of the specific deliverable is a key differentiator for us between Thermo Fisher and other CDMO experiences.” Aaron Williams, Program Manager, Quick to Care™, adds, “As program managers, we visit and establish good working relationships with each of our site’s leadership teams. When needs arise with my clients’ molecules, I am able to react quickly to leverage the capability, capacity and expertise of a global network.” Today, the two companies continue to work together using the Quick to Care™ program, and the molecule is continuing to progress through clinical trials.

To determine the benefits of a single supplier, Tufts Center for the Study of Drug Development (CSDD) recently analyzed a sampling of drug development timelines of Thermo Fisher’s Quick to Care™ clients. The results of the analysis determined that these customers reduced their timelines by 9-18 weeks, equating to an average of $36.8 million in development time costs. In an industry where time is money, these savings go well beyond the bottom line. Kane describes the true value of cutting both costs and timelines. “Any delays in bringing a product to market mean lost opportunity from a business perspective and lost benefits to patients,” he says. “By accelerating the development process, a single vendor can deliver better healthcare to patients faster and bring business benefits to the sponsor.”

References

1. 1 New England Journal of Medicine, Drug-Development Challenges for Small Biopharmaceutical Companies — **http://www.nejm.org/doi/full/10.1056/NEJMra1510070#t=article**
2. Drug Discovery Online, New Resource Saves Drug Developers Time and Money — **https://www.drugdiscoveryonline.com/doc/new-resource-saves-drug-developers-time-and-money-0001**

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