

Satisfying Aggressive Timelines With A Simplified Supply Chain For Drug Delivery



The new business model of the biopharmaceutical industry that focuses on the unmet needs of smaller patient populations has diversified today's pipelines and brought new hope to patient care.

In its own pursuit to improve the quality of life for patients in need, Kaleido Biosciences, a clinical-stage healthcare company, has focused its efforts on Microbiome Metabolic Therapies (MMT™) to help address a variety of diseases and conditions. Their lead candidate, KB195, is intended to treat urea cycle disorder (UCD), which affects a small population of patients who inherit this serious, rare and life-threatening disease.¹ To bring KB195 to patients, Kaleido needed an IND filed by the end of its first year. And as a small company, it lacked the resources

to accomplish this on its own, so it had to consider an alternative yet efficient route to meet its aggressive timeline.

Kaleido approached Thermo Fisher asking for very individual approaches to their drug substance, drug product, and clinical trial packaging needs. These fragmented needs are what often drive smaller companies to work with multiple suppliers, stretching resources thin and ultimately adding considerable risk and time to the critical path of their molecule. Stephen Sofen, Senior Vice President of Technical Operations at Kaleido, explains, “In my past experience, I’d always gone with virtual supply chains from a collection of niche or boutique suppliers, but it requires a significant amount of effort on the part of a company like Kaleido to coordinate the activities of each of those entities.”

Increased efficiency through unified program management

Thermo Fisher was able to meet Kaleido’s needs using its Quick to Care™ program, a customizable integrated solution that combines drug substance and drug product development, clinical manufacturing, early demand planning, and clinical trial supply execution. By offering multiple services in one package, Quick to Care gives customers an opportunity to improve efficiency in delivery and, as a result, bring drugs to patients faster.



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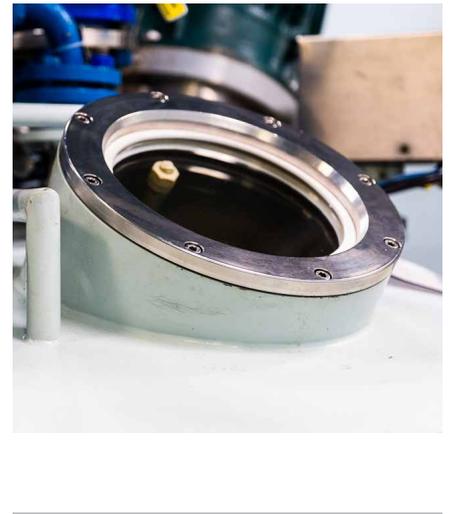
Kim Hocknell, Senior Director of External Manufacturing at Kaleido, adds, “Being a small company with limited resources, the Quick to Care program was a strong fit for us, because it allowed us to be able to manufacture across multiple sites while having the core program manager help us communicate and maintain relationships across the site to make sure that all the activities were completed

under a tight timeline. One thing the Thermo Fisher team was very good at was understanding what our milestone was but also projecting what our next milestones would be.”

The unified program management of the Quick to Care program focuses on end-to-end oversight of a project’s most crucial details, from API manufacturing to clinical distribution. “My job is really to manage those timelines, identify risks in the supply chain, and help to mitigate those risks before they occur,” explains Doug Ahrens, Program Manager for the Quick to Care Team. “I’m also looking to shorten the timelines for the customer, so trying to get them to clinic as quickly as possible.” In the end, the goal is to simplify the client’s life and make the process as easy as possible, which is facilitated by simplifying their supply chain and providing a competitive advantage of extensive scientific and technical insight.

The ability to work within one team through every step of the process is especially important for smaller companies that may have concerns about working with a larger CDMO, such as getting enough attention and meeting timelines. However, as Hocknell explains, the opposite happened with Thermo Fisher. “As we came in, we received a warm welcome from the team and built a huge partnership from day one,” she says. “Given our timelines, it was critical to be able to move this process forward as quickly as we can. As we were going into our production runs, Thermo Fisher was very welcoming to have our experts come in and watch the process as it was running. We have now generated over four metric tons of material to support our clinical trials and have our first clinical product packaged and ready to support our first patient coming into our Phase II trial.”

Overall, Sofen says the partnership has been a tremendous success, based on meeting its deadline for KB195 and subsequent activities. Kaleido has already begun a second project at Thermo Fisher, again using the entire network as a one-stop shop. Hocknell adds about the future of the partnership, “As we move forward, we’re looking to build our partnership with the Thermo Fisher Scientific team and continue to enhance our current program by scaling up some of the activities in addition to transitioning to our pivotal process over the next couple of years.”



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