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Meeting milestones and patient needs through expedited delivery of phase I materials

Reneo Pharmaceuticals, a clinical stage pharmaceutical company, focuses on the development of therapies for patients suffering from genetic mitochondrial disease.

Many of Reneo's patients struggle with day-to-day activities, such as opening a jar or walking across the room. These genetic disorders are mainly present from birth and may be a cause of infant death. Therefore, the company's aim is to significantly improve these patients' quality of life by improving how their mitochondria work, preserving muscle function, and preventing muscle injury.¹ A key factor in doing this is securing rapid delivery of its product to the patients in need, which required a partner that could provide both product development and clinical packaging services. Reneo found this partner in Thermo Fisher Scientific, which had recently acquired Patheon. Experts from two different sites were able to team up and offer both elements in one proposal and under one contract using Thermo Fisher's Quick to Clinic™ for Oral Solid Dose program.

Flexibility and speed with quick to clinic™ for oral solid dose

The pressure of delivering safe and effective drugs to patients whose quality of life depends on it is compounded by the need to do so in a timely manner. Drug manufacturers must find ways to expedite early testing, in order to make informed proof of concept decisions and complete their regulatory submissions. Recognizing this need in the industry, Thermo Fisher Scientific combined the clinical services expertise at its Horsham, U.K., site with the drug development expertise at Milton Park, U.K., site to create a program that would help customers meet their early milestones. "When Patheon came into the Thermo Fisher family, we went immediately to Milton Park and looked at what we could do together to bring something new and something better to the industry," says Ceri Thayer, General Manager, Horsham UK. She explains that, in those discussions, the team realized that, by bringing the manufacturing together with the packaging, it eliminates the need to contract with different parties and go out to different suppliers, ultimately taking time out of that process.

Now, with Quick to Clinic for Oral Solid Dose, Thermo Fisher Scientific can deliver oral solid dose product to the Phase I clinic in as little as 14 weeks from API supply, including one-month stability data. “The Quick to Clinic for solid oral dose is an evolution and, in fact, it’s two complementary skills,” says Helen Underwood, Director of Strategic Customer Development at Horsham U.K. “We have scientific excellence coming from our Milton Park facility, and [in Horsham] we have operational excellence where we’re really focusing on the delivery. And what we’ve been able to do is compress the timelines, so we have early access and can obtain information that we need for that seamless delivery of the trial product.”

Quick to Clinic for Oral Solid Dose begins when the customer is able to provide Thermo Fisher with their API. They can then formulate a product for the customer and move that to clinical manufacturing at Milton Park before moving on to Horsham for labeling and packaging. The program involves developing phase-appropriate formulations for oral solid dose forms, which can be capsules or also powder in bottles, and then delivering the end-to-end solution in 14 weeks. This saves both time and money because the speed at which customers can get to clinic allows them to generate a proof of concept a lot quicker and in a time efficient manner.

Streamlining delivery through a single vendor

Working with one vendor through Quick to Clinic for Oral Solid Dose eliminates having multiple quality agreements and master service agreements, while adding efficiency by using a single contact. From a quality perspective, there is also a seamless ability to contact one site for discussions about quality and delivery and facilitating that through both facilities simultaneously. Helen Barker, Senior Director, Head of Pharmaceutical Development at Reneo explains that, in addition to this added efficiency, there were several reasons they ended up making the decision to work with Thermo Fisher. “The first one was speed, as it is absolutely critical for our patients that we have a rapid development program and Thermo Fisher Scientific offered us that,” she explains. “The second reason is the fabulous interaction we now have between Milton Park and Horsham, where we have the development piece at Milton Park followed by a seamless integration into the Horsham activities with Thermo Fisher Clinical Services, which then offers as a springboard into our global portfolio of clinical programs.”

Barker says the most important thing in the Quick to Clinic for Oral Solid Dose program, though, that she has experienced is the planning and collaboration between the two sites. “What I’ve seen, so far, is seamless and transparent planning between the site project managers, which keeps us all informed and on track.” The relationship between the project management team at Milton Park and Horsham is set up in a way that they are working together from the beginning. This certifies both teams are on board with the progress after the project begins and that any issues are ironed out as quickly as possible to be able to deliver the client’s materials on time. The focus remains on the details of the milestones, how each is going to be met, and how the teams will ensure delivery so that customers can be confident their needs will be met. “Working with a CDMO is more about a partnership than a customer-supplier relationship,” continues Barker. “And I feel that’s what we have between Reneo and Thermo Fisher Scientific.” Thayer says the core of the Quick to Clinic for Oral Solid Dose program is dedicated to one overall goal. “Everything we do here is about delivering quicker for our customers to get their drug to market quicker, so patients can have their medicines that will hopefully make them better faster. That’s my family, that’s your family.”

References

1. Reneo Pharmaceuticals – <https://reneopharma.com/>