ADARE® PHARMA SOLUTIONS

MEETING AN AGGRESSIVE GO-TO-CLINIC TIMELINE

When a large CDMO couldn't give a mid-size pharma company the proper attention, Adare stepped in to get their project to the clinic quickly

The Challenge

A mid-sized pharma company was working with a very large CDMO to enter clinical trials for a potentially life-changing medication that may slow the progression of common neurodegenerative disorders.

However, the large CDMO lacked resourcefulness and delayed production of the clinical trial batches for months. The company's go-to-clinic timelines were already aggressive, and this delay from their CDMO jeopardized their market commitments for the start of Phase 2 and 3 clinical trials.

The pharma company reached out to Adare to see if we could help them where their current CDMO had failed. After intensely reviewing the project's history, progress, and objectives, we were confident we could produce the Clinical Trial batches within the necessary timeframe.

The Solution

Knowing that the window for success was very short, Adare convened a group of experts to evaluate existing conditions, including the inventory and procurement of raw materials, and developed a streamlined plan for execution of scale-up and manufacture of the drug.

Adare's expertise, preparation, and resources allowed us to begin production in a very short period of time. Within three months of project initiation, we had supplied both the engineering batch and the contracted supply of phase 2 clinical trial materials our customer desperately needed.

Impressed with Adare's ability to meet a challenging timeline, the customer asked us to continue supporting their clinical trials in several ways:

Additional CTM Batches

Initially, Adare was only contracted to fill the customer's immediate need for clinical trial supplies. However, their clinical trial had many more participants than they'd projected thanks to very successful patient recruitment.

Adare, able to quickly adapt to a customer's changing needs, began producing the additional batches needed to supply the clinical trial's expanded patient population.

"In three weeks, we got more accomplished with Adare than I did in over four months with a very large CDMO."

Senior Vice President, Regulatory Operations

Mid-sized Pharma Company

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Formulations For Different Strengths

The pharma company was also initiating a separate clinical trial that would measure the same drug's efficacy on a different indication, a neurodegenerative disorder affecting the elderly. They requested that Adare produce batches for that trial as well.

However, this additional indication required different strengths from the original trial supplies, but Adare's development experts were able to efficiently create new formulations for these strengths and provide batches for this additional trial as well.

Randomized Labeling

Due to long lead times at the pharma company's clinical depot, randomized labeling of the product was creating another bottleneck for the trials. After a request from the customer, Adare stepped in to fill this gap by providing randomized labeling on the batches we were producing.

Randomized labeling must be impeccable; therefore, numerous highly stringent SOPs and precautions were put into place to ensure 100% compliance. These included a comprehensive quality assurance process led by a QA specialist who was present at all times during the labeling process.

Stability Issue

The previous CDMO had developed the formulation that was transferred to us for the initial batches. However, as the product entered stability testing, an issue with their formulation was discovered: a color change over time.

Adare scientists were able to trace the cause to one of the excipients used in the original CDMO's formulation and devised a strategy to eliminate this issue.

The Outcome

By partnering with Adare, the pharma company was able to provide its clinical trials with the supplies needed to be conducted successfully.

Within three months of initiating work, Adare met the company's timelines and supplied the phase 2 clinical trial materials requested. Adare continues to supply the ongoing clinical trials, having delivered close to ten CTM batches since the beginning of the project. Our development team also successfully created a formulation needed for different strengths of the drug in the company's second clinical trial.

Our QA and packaging experts provided flawless randomized labeling, and the customer has asked us to continue this work for all additional batches. A potential solution to the color-change issue caused by the previous CDMO's formulation has been developed and will be implemented when production begins on phase 3 registration batches.

The customer has been very pleased with Adare's ability to supply their clinical trials despite the compressed timelines caused in part by their previous CDMO's lack of attention to a mid-sized pharma company's needs. The company's Senior Vice President of Regulatory Operations says: "In three weeks, we got more accomplished with Adare than I did in over four months with a very large CDMO."

TRANSFORMING DRUG DELIVERY. TRANSFORMING LIVES.

Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, customized release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare has developed and manufactures more than 65 products sold by customers worldwide.

Connect with our experts today: BusDev@adareps.com

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