

SPEED. FLEXIBILITY. CONTROL.

A GMP Pharmacy Case Study

A mid-sized drug manufacturer was in Phase I clinical trials for a molecule designed to treat adenoviral infection. Their contract manufacturing organization (CMO) predicted a delay in drug production leading to a three- to six-month delay in study start-up. The client inquired if Covance could manufacture the drug on time and manage the clinical trial with their supplied active pharmaceutical ingredient (API). This sponsor needed fast turnaround to get the study on track and on budget, with cGMP quality plus flexibility to adjust the formulation if needed.

Understanding the Challenge

- ▶ cGMP quality for patient safety
- ▶ Fast turnaround to meet study timelines
- ▶ Flexibility for adaptive trial design
- ▶ Control over costs and decision-making

Game-Changing Solution: cGMP Manufacturing and Clinical Trial on One Campus

Covance proposed that our cGMP Pharmacy manufacture a small quantity of the client's formulation for the Phase I clinical trial. Their auditors were assured of quality and oversight by reviewing our documented cGMP process. On-site manufacturing ensured drug quality and patient safety plus fast delivery – a concern when some formulations may be stable for only minutes or hours.

With the pharmacy and trial site located on one campus, our team could quickly deliver doses from manufacture to clinic. A large CMO would add distance and shipping time between manufacture of the product and delivery to the clinic. Covance removed the time and distance gap between pharmacy and trial site for fast turnaround.

The client also gained flexibility to adjust their formulation on the fly based on observed trial results. A CMO could only deliver one formulation and one dosage, with the expectation of a large run. Our adaptive trial design provided for formula or dosage adjustment in response to trial indications – with less waste of API.

With cGMP manufacturing, the client gained control and cost savings during the trial. Instead of one large CMO run of one formulation, Covance delivered cost-efficiency for small runs, with the ability to change or halt the process without delay or material loss.

Phase I cGMP manufacturing may save 25-50 percent on drug production costs – significant when total manufacturing costs are 20-40 percent of drug development, with much invested during early clinical development.

The client met their study timeline, with quality cGMP drugs produced in small runs for flexible formulation, expedient regulatory review, controlled costs and informed decision-making.

Covance Inc., headquartered in Princeton, NJ, USA is the drug development business of Laboratory Corporation of America Holdings (LabCorp). COVANCE is a registered trademark and the marketing name for Covance Inc. and its subsidiaries around the world.

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