Fortrea

Short-run, small window drug manufacture at the clinical research unit (CRU).

Save time and money with cGMP manufacture

A small biopharmaceutical client was developing a higher-dose version of an existing treatment to block symptoms of opioid withdrawal. Since the drug had been on the market for some time, no current testing data were available. When the FDA placed a clinical hold on the IND submission to request animal studies to address a toxicology question, the sponsor came to Fortrea. This client needed a high-quality, low-cost solution with fast turnaround along with special preparation and custom containers for long-term stability testing. A customized, short run at the Fortrea cGMP-compliant clinical pharmacy met the need.

KEY TAKEAWAY

Fortrea cGMP manufacture, matching CDMO quality, saved 40-60% in cost and several months on the timeline. The sponsor was able to conduct testing quickly, have the FDA hold removed and proceed to its first-in-human (FIH) clinical trial.

Understanding the challenge

- cGMP drug manufacturing for reliable, high-quality data
- Special processing using unique containers
- Fast turnaround with cost efficiency

Solution: custom cGMP drug manufacture at the CRU

The Fortrea team understands regulatory requirements and routinely helps clients address FDA issues. The agency had placed a clinical hold on the sponsor's drug at the proposed dosage because of a concern regarding potential toxicity. Therefore, a batch of the drug was required for an animal toxicology study at a third-party laboratory. The client asked the Fortrea cGMP pharmacy to manufacture the drug inside a unique apparatus using nitrogen bags to minimize moisture, with sterile preparation. The sponsor also needed two batches customized for drug product amount and type, packaged in unique vessels, for long-term stability testing at two Fortrea-qualified vendors which provide analytical and microbiological testing.

Within one week, Fortrea prepared and shipped 1,200 units according to specifications. This type of complex project would typically take eight to twelve weeks at a contract development and manufacturing organization (CDMO).

Alternatives to standard approaches exist in the realm of clinical trial material manufacturing. Custom cGMP solutions run in small batches increase cost efficiency—using less active pharmaceutical ingredient (API) than a large run with a smaller price tag than a CDMO contract—while providing flexibility and fast turnaround. Whether you need to overcome an obstacle quickly or save time and money with high-quality data during development, consider cGMP manufacture for your Phase I testing.

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