

Clinical trial solutions

Packaging and labeling support for a global cell therapy program

Executive summary

A late-stage cell therapy developer needed packaging and labeling support that could withstand two temperature modalities. The company needed shipping to the US, Canada, and Australia, with further support needed to expand to additional global sites in the EU and South Korea, and they needed a reliable partner they could trust in managing cold chain logistics and in coordinating global shipments while navigating aggressive just-in-time (JIT) requirements. One therapy came in unlabeled vials that needed to be stored at refrigerated temperatures, while another therapy required cryogenic storage (LN₂). Thermo Fisher Scientific was able to tailor a custom labeling and packaging solution with white glove courier service that met aggressive JIT timelines. The cell therapy developer was able to successfully run its clinical trials on schedule with high reliability, allowing the developer to expand the trial to other global sites.

The challenge

A cell therapy developer needed packaging and labeling support for clinical trials in the US, Canada and Australia, with further support needed as they planned to expand to the EU and South Korea. The developer's portfolio of drugs spanned refrigerated and cryogenic storage, each with different label content and handling controls. The company was also under strict timelines. They needed a reliable and experienced partner that could navigate these fluctuating challenges without supervision.

Thermo Fisher Scientific was able to provide a tailored labeling and packaging solution specific to their needs. Thermo Fisher worked with international depots to assist in shipments to global clinical sites. They created single panel labels in-house, attached the labels to the naked vials, placed the vials into labeled cartons, stored at the desired temperatures (refrigerated or cryogenic), and shipped to the clinical trial sites. Thermo Fisher also coordinated global logistics, engaging partner depots to improve responsiveness for distant sites, and offered an optional white glove courier service with tracking and high-care delivery when requested. They also executed rapid turnaround times for the process: one day for label printing, one day for QA review, and only three days for approval and printing.

The outcome

The cell therapy developer executed its clinical trials on schedule, advanced into new global sites without disrupting the existing supply, and gained a reputable partnership as they go from lab to clinic. The working relationship strengthened as the developer trusted Thermo Fisher to recommend fit-for-purpose processes, rather than having to micromanage individual steps, which reduced friction and accelerated decisions.

Why it matters

This case study demonstrates how a purpose-built packaging and labeling solution, an experienced team with global reach, and coordinated global logistics can convert a complex, multi-temperature labeling and packaging challenge into smooth operation of clinical trials. In practice, that means choosing the right partner can help cell and gene therapy developers to expand and scale with confidence.

Learn more at patheon.com/clinicaltrials