PCT CELL THERAPY SERVICES

CASE STUDY

TITLE: Packaging and delivery design for a cell therapy product requiring durability for transit at constant near-freezing temperature range and an innovative product delivery mechanism for optimal patient dosing.

CLIENT: A development stage biotechnology company developing novel cell therapeutics to treat cardiovascular disease.

OPPORTUNITY:

- Cell therapy products must be processed by PCT and returned to clinical site within 72 hours of initial autologous biological material harvest for final patient infusion.
- Protective case must protect products from possible rough handling situations in transit under varying conditions.
- Temperature of shipment must maintain a constant internal temperature range of 1-10° C for 24 hours.
- Case and protective housing system must protect product container (two syringes) against leakage in transit.
- Product container must allow for maximal infusion of cells to patient.

SOLUTION:

- PCT has established relationships with a dedicated network of commercial carriers that have specialized business lines in shipping medical products, allowing for safe and reliable turnaround times for Client's products.
- PCT designed a protective container for Client's final product to be used for shipment from PCT to the clinical site. As shipping logistics often include ground and air transportation, the container is designed to withstand possible rough handling situations.
- Product container (two syringes) is placed in the protective case. The case is overwrapped with two sterile pouches and is placed in an insulated (Thermosafe) shipper with frozen gel packs on either side which help maintain the required temperature range (1-10° C). A temperature study conducted by PCT verified that the required internal temperature of the protective case can be maintained for 24 hours.
    - PCT codified these steps into standard operating procedures and in addition to Operational Qualification under extremes of external temperature conditions, validated the entire shipping process in the context of real-time continuous temperature monitoring and needle-to-needle Process Qualification.
- The specially designed, double-syringe mechanism is protected by an innovative locking mechanism that "locks" the plungers of the syringes and prevents the syringes from leaking.
- PCT created a diversionary mechanism at the point of connection that, after product syringe is emptied into catheter, allows for a flushing solution to enter into the product

syringe, ensuring that the entire cellular product is emptied into the catheter. This mechanism allows for maximum product dose to reach the patient.

CONCLUSION:

The protective shipping container and product dosing mechanism designed by PCT has proved reliable and effective throughout Client's Phase 1 trial and remains unchanged for the ongoing Phase 2 trial.

PCT is a Client-focused contract development manufacturing organization (CDMO) supporting the development and commercialization of cell therapy and regenerative medicine products through specialized services tailored to address the unique scientific, technical, manufacturing, Quality, regulatory and financial challenges of our diverse Client base. Our services include cGMP-compliant manufacturing, storage and distribution of clinical products, cell and tissue collection, processing and storage, process and product development, engineering and innovation, regulatory consulting, facility design, validation, and due diligence evaluations.

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