

ELEVATING CLINICAL TRIALS SUCCESS: CCT SOLUTIONS & SERVICES FOR CELL AND GENE CLINICAL TRANSPORTATION

SITUATION:

A biotechnology company specializing in Cell and Gene therapies was progressing into Stage 1 clinical trials for a unique Allogeneic therapy. They approached Cold Chain Technologies (CCT) with three distinct needs in the realm of Thermal Design and Qualification, Easy to use & Monitor Tracking abilities and On-demand ordering.

The product specific requirements were as follows:

- Provide a shipper that can maintain temperatures between 2°C to 8°C for 72 hours.
- Utilize the shipper to pre-condition the payload in transit.
- Maintain temperature and duration for up to one hour inspection event.
- Track samples in real time with temperature and GPS location.

NEED:

The key objective was to ensure timely delivery of the therapy from the manufacturer to the clinic within a 48-hour timeframe.

To achieve this, the shipping process involved conditioning the payload in transit to preserve its integrity while in transit. Furthermore, once the payload reached its destination, a thorough physical inspection needed to be conducted to confirm both the absence of leaks during transit and the integrity of the chain of custody. The "open" event could not impact the duration of the shipper, as storage at the clinical site was limited and the therapy was stored within the shipper until dosing the patient. It was also integral for the company to be able to track each therapy in real time with temperature and GPS location.

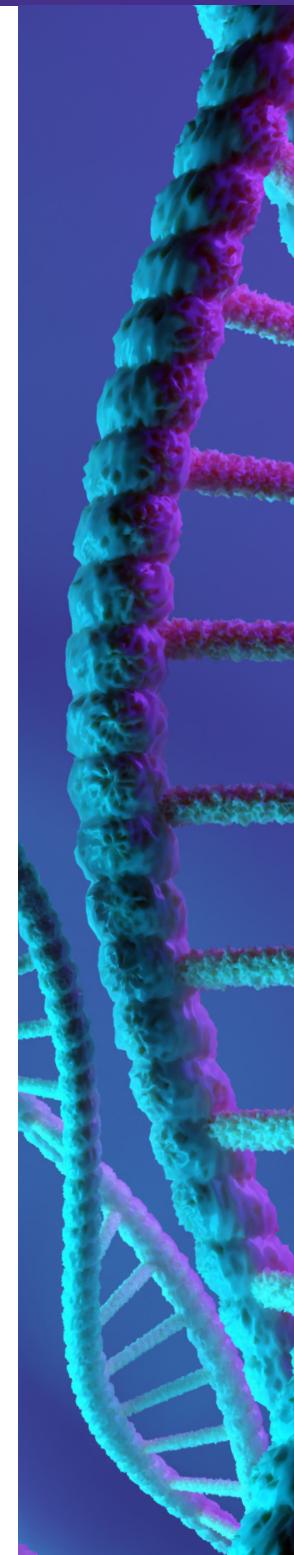
SOLUTION:

CCT played a crucial role in assisting the biotech company by supporting the thermal qualification and modeling for their specific therapy. CCT utilized their dedicated Cell & Gene Therapy portfolio of Single Use VIP based shippers with shape stable PCM. The product was qualified to support the pre-conditioning of the payload from 2°C to 8°C and maintain that temperature during the entire journey. CCT was able to give full visibility into each shipment by utilizing CCT Smart Solutions™. This platform goes beyond just visibility and tracking and allows companies to Plan, Ship, Track and Optimize Solutions. One of the applications in CCT Smart Solutions allowed the customer the ability to place On-demand ordering service to their clinical trial sites.

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Pictured: CCT TheraShield™



Below are the steps of the partnership between CCT and the biotech company.

1. Initial Assessment and Planning

CCT began by conducting a comprehensive design, qualification and modeling of the product's temperature sensitivity, duration of transportation and the potential impact of brief temperature deviations.

2. Designing the Shipper

CCT's team of experts collaborated with the biotech company to qualify an existing VIP based shipper utilizing shape stable PCM, that could maintain temperatures within the 2°C to 8°C range.

The system was calibrated to maintain the desired temperature range and continue to maintain that temperature range, even after a 20-minute open event.

3. Data Logging and Monitoring

Data loggers, which are temperature and location monitoring devices, were integrated into the shipper. These loggers continuously recorded temperature data during transit, providing real-time information on the product's condition and location.

4. Tracing and Compliance

The data loggers played a critical role in ensuring the product's temperature compliance throughout the entire shipping journey. Any temperature deviations, including those during the 30 to 60-minute open event, could immediately be documented and addressed.

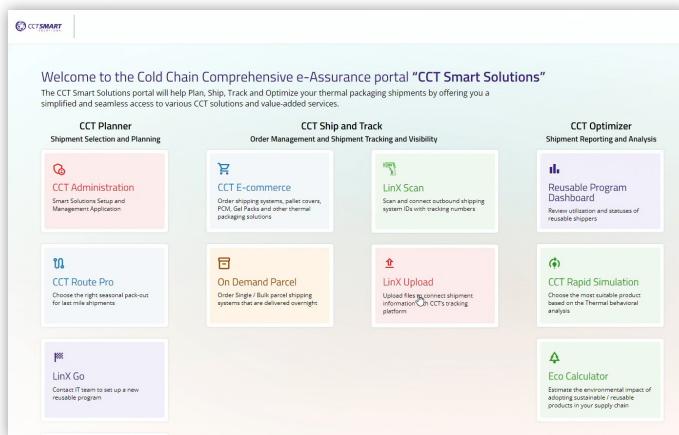
Alerts and notifications were set up to notify relevant parties if temperature parameters were breached.

5. Real-Team ordering

The implementation of real-time ordering streamlined the process and allowed for quick response to unexpected changes in patient availability, reduced risk of errors and improved overall efficiency.

6. Visibility

CCT provided the customer with full visibility of the shipments via the CCT Smart Solutions portal. As a result, the customer was able to accomplish all the tasks from ordering, monitoring etc on one portal.



Pictured: CCT Smart Solutions™ portal

CONCLUSION:

The collaboration between CCT and the Biotech company has played a pivotal role in facilitating the commencement of a Phase 1 trial. CCT's expertise in managing cold chain logistics, ensuring thermal design integrity, enhancing digital visibility, and enabling real-time ordering has not only streamlined operations but also laid a strong foundation for the success of this therapy in clinical trials. The partnership exemplifies the importance of synergy between industry stakeholders in advancing the field of cell and gene therapies.