Ensuring the integrity of your product

The healthcare industry is currently benefitting from groundbreaking developments in new areas of medicine, such as cell and gene therapies. By partnering with an experienced clinical supplies management provider like **Clinigen**, sponsors can ensure the integrity of their temperature-sensitive products throughout the cold chain.

The properties of next-generation therapies differ from traditional medicinal products in that they require a specific approach to clinical trial supplies management, most notably in regards to mitigating the risk of temperature excursions. However, you can preserve your product throughout each stage of the clinical supply chain with the right cold-chain clinical supplies management methods.

Supporting cell and gene therapies entails specific frozen cold-chain and storage capabilities alongside stringent SOPs for clinical trial supplies management processes. As the medicinal products used for such trials tend to have lower stability, preserving the integrity of the sensitive materials is crucial to the success of a trial.

The storage and distribution of cell and gene therapies call for ultra-low temperature capabilities. Different temperatures and methods are required depending on the therapy: typically -180°C for cell therapies (cryogenic storage) and -80°C for gene therapy. Choosing a storage and distribution partner with the compulsory authorisations and capabilities to support these requirements is critical. At a minimum, a provider should have vast freezer capacity at a variety of ultra-frozen temperatures and be equipped with liquid nitrogen tanks.

In addition, sponsors should prioritise partners with their own facilities for clinical trials in key geographic areas. Geographic coverage drives cost efficiency, facilitates efficient supply planning and aids flexibility.

Packaging and labelling under frozen conditions

Maintaining ultra-low frozen temperatures throughout the packaging and labelling process requires specialised technologies due to the logistical constraints of such conditions (for example, label adherence is to be considered). A solution which may be offered is to package and label Investigational Medicinal Products (IMPs) over dry ice.

When dealing with low-stability products, the required temperatures must be maintained at all stages.

Secondly, advanced technology may be utilised to ensure that ultra-low temperature conditions can be met during handling. For example, when a cryo box is removed from a liquid nitrogen tank, the extreme temperature may be maintained thanks to LN2 vapour-based cryogenic carriers. These carrier boxes provide a safe, portable and trackable solution for transferring temperature-sensitive biological materials and maintain a maximum temperature of -150°C while the products are outside the liquid nitrogen tank.

Global distribution for low-stability drugs

To safeguard your medicinal product against temperature excursions, ensure your service provider utilises advanced distribution solutions to maintain temperature thresholds throughout shipping and distribution. Validated shipping systems, procedures and technologies, such as temperature-controlled dry shippers, provide safe and efficient global distribution along the entire cold chain.

With over 25 years of experience and sites across Europe, America, Asia Pacific and Africa, Clinigen has the tools and proven qualifications to handle even the most complex projects, from Phase I to Phase IV. Its teams follow rigorous cold chain management practices and utilise 24/7 environmental monitoring and security systems to ensure clinical materials are protected during frozen storage. Acting as its client's advisor at every step of the way, Clinigen tailors its clinical trial supplies management to the particular needs of the trial and oversees the entire study from start to finish. ●

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