

COLD CHAIN HANDLING IN CELL AND GENE THERAPY: Polymer Technology Takes Freeze Containers Beyond the Breaking Point

To say managing cold chain decisions in pharmaceutical manufacturing are complicated is a huge understatement. What storage container can withstand the rigors of cold temperature and transportation? Will it keep product safe during shipping? How will the product temperature be monitored and maintained? How will product location be tracked across the globe?

Certainly, there is no way around the extreme conditions bulk drug substances are subjected to when getting from point A to point B. Although logistics solutions like RFID tags and temperature sensors have become common to track and monitor products in-transit, the single-use storage containers that so many manufacturers rely on are often not up to the challenge of keeping product secure.

Unfortunately, traditional polymer-film-based single use bags are vulnerable to several problems. These containers can become brittle and fragile at low temperatures, which adds to the risk of loss during cold chain handling, transport or storage. In addition, materials commonly used in single use packaging may have issues with extractables and leaching.

More recently, new materials have been considered for single-use cold chain storage containers, to reduce or eliminate issues with durability at cold temperatures. Using a high-purity fluoropolymer known as expanded polytetrafluoroethylene (ePTFE), W. L. Gore & Associates launched the GORE STA-PURE Flexible Freeze Container in 2018. This new breed of highly robust single-use containers is purpose-built for storing and transporting bulk drug substances during cold chain handling, transport, and storage –even after freezing at -86°C.



Such resilience to cold handling conditions in storing and transporting bulk drug substances can be particularly important in the manufacturing process of vaccines, antibody drug conjugates and monoclonal antibodies, among other products. Especially under current circumstances – in which we will likely see a greater uptick in vaccine development, with greater need for more bulk drug substances – cold chain handling will become more important than ever.

It's vital to the industry to have reliable storage containers that can go past the breaking point of traditional methods of transport and storage. For example, frozen impact durability testing includes freezing the product in a freezer at -86°C and dropping onto a concrete floor from a height of 36 inches.

[See Flexible Freeze Container Bag Drop Video.](#)

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE STA-PURE Flexible Freeze Container, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

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