GORE® STA-PURE®
Flexible Freeze Container

Trends in Cold Chain Storage for Biologics

Packaging is critical, as biotechnology products become more valuable and require colder storage.

By Joe Cintavey, product specialist, Gore PharmBIO Products

It is an exciting time for the biologics industry as new vaccines, monoclonal antibodies, mRNA therapies (or RNA therapies) and cell and gene therapies rapidly move into clinical use. These drugs are helping fight COVID-19 and providing completely new treatment options for diseases like cancer.

The growing biologics market is bringing with it an increasing need for a temperaturecontrolled supply chain, or cold chain storage. Because biologics are isolated from living organisms or can themselves be living organisms, cold storage is typically required to maintain the stability of these biologics during storage and distribution. In 2017, just under half of the top 50 drugs required cold chain handling. These temperature sensitive drugs generated sales of $1.22 billion, 1.5 times the value of drugs that aren't temperature sensitive.[1] By 2024, it is estimated that there will be more than 400 new drugs and vaccines with cold storage handling requirements.

Within the biologics category, cell and gene therapies are receiving a lot of interest and investment due to their therapeutic potential. Today, there are approximately 8 gene therapies[2] being used around the globe and more than a thousand product candidates[3] are in clinical trials worldwide. As many new companies enter this market, they aren't always aware of the risk for product loss during cold chain handling. Because of the high value and colder storage requirements of gene therapy products, it is especially critical to select a bag or packaging solution that maintains its integrity even at extreme temperatures.

The benefits of bags

For gene therapy products, more companies are selecting single-use bags with aseptic connectors as their packaging of choice. Although bottles are an option, they must be filled under a hood to assure sterility. Once the bottle is taken out of the hood and frozen, the sterile barrier between the screw top and the bottle could be comprised as temperature changes cause the different materials to expand and contract. Bags with aseptic connectors can be filled without a hood because they can provide the necessary integrity even during freezing.

How cold can it go?

There are many bags and storage solutions available for bulk drug substances and products, many of which claim they are rated for cold temperatures. However, just because a material does not break down at -80°C doesn't mean that it is robust at these temperatures. In fact, an estimated 3-5 percent of containers fail during cold chain handling based on discussions with biopharmaceutical manufacturers. For gene therapy, this type of failure could be devastating not only in terms of lost investment but also because of the patients who will be affected.

Plastics known as fluoropolymers are ideal for cold chain storage applications because they remain strong and flexible over a wide temperature range. Because these polymers have a wider temperature range, they don't become brittle like most other packaging options. Thus, bags made from fluoropolymers are

more resistant to cracks, breaks, or leaks even if accidently dropped. Fluoropolymers are also very chemically inert, which minimizes the risk of drug interaction or contamination. Non-fluoropolymer materials commonly used in other disposable packaging contain additives and processing aides that may impact the overall stability and efficacy of the drug.

A flexible solution

When it comes to cold chain storage, Gore understands how fluoropolymers as single-use materials can be affected by use within the cold chain. Not all fluoropolymers will perform the same, and we drew on our extensive expertise and experience with the fluoropolymer polytetrafluoroethylene (PTFE) to develop the GORE® STA-PURE® Flexible Freeze Container bag for bioprocessing intermediates storage and transportation. By combining a high strength PTFE composite film with a patented bag design, we created robust containers that can withstand frozen handling, maintain integrity after multiple freeze/thaw cycles, and have a low extractables profile.

For companies making gene therapy products, Gore can not only help minimize the risk of losing valuable products but also provide validation data representative of use in the cold chain application. Partnering with Gore provides access to years of materials science expertise with a proven track record of improving the processing and delivery of pharmaceutical products and a commitment to regulatory compliance.

To learn more, visit https://www.gore.com/products/gore-sta-pure-flexible-freeze-container.

References:

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3. Alliance for Regenerative Medicine, 'Record Financing Drives Sector Growth', *Alliance for Regenerative Medicine* [website], https://alliancerm.org/sector-report/q3-2020-trend-talk/, (accessed Feb 2021).

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.

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PB11043-R2-ARC-US-MAR22