GORE® STA-PURE®
Flexible Freeze Container

Biopharmaceutical Advancements and Considerations in Packaging Solutions

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Due to the worldwide response to COVID-19-related R&D; increased development of novel therapeutics; and the expansion of cell and gene therapy innovations, biopharma manufacturers are seeing significant manufacturing momentum. The statistics are impressive:

- Biopharmaceuticals are a large market that is growing at a steady rate: In 2020, the global market was valued at $291 billion and by 2030, it's expected to increase to nearly $1 trillion.[1]
- Gene and cell therapies are showing tremendous promise and there are currently more than 1000 cell and gene therapy clinical trials in progress worldwide.[2]

Emerging cell and gene therapies and other more established therapeutics have immense potential for patients in need of life-saving treatments, and as solutions are developed and manufactured, a reliable supply chain is critical for both drug substance and drug product transport. Specifically, storing and safely distributing these materials to ensure quality is essential for ultimately improving patient outcomes. Drug substance transportation, as part of the complete journey to the manufacture of final products, can be compromised without reliable cold storage strategies but managing and maintaining a proper cold chain in pharmaceutical manufacturing is often complicated. There are many factors that manufacturers must consider when transporting substances, including packaging durability, ensuring that products are not damaged during transportation, and maintaining optimal temperature to make sure they don't degrade. Packaging should be a primary focus, as it is critical given the sensitive nature of the substances it holds.

There is no easy way around the extreme conditions bulk drug substances are subjected to when getting from point A to point B. Logistic solutions like RFID tags and temperature sensors have become more common to track and monitor products in transit but starting with an effective packaging solution should come first.

And while there are numerous categories of packaging utilized throughout the supply chain, as outlined below, one of the most effective ways that manufacturers can successfully address these needs is to carefully evaluate and select the most durable primary packaging that protects their valuable drug product.

Primary, secondary, and tertiary packaging

The pharmaceutical packaging industry continues to innovate, but a constant is that packaging systems must remain functional through thermal and mechanical stress as materials are being transported between different manufacturing facilities and, in some cases, being stored long-term.

In modern cold chain logistics, manufacturers must make careful decisions to ensure substances maintain product stability and minimize substance loss. All packaging solutions, including primary, secondary, and tertiary, must meet user and regulatory requirements for Good Manufacturing Practices (cGMP) and consideration must be given for safety as well as material/packaging quality. It's essential for manufacturers and their suppliers to have a well-established packaging design and development plan for biopharmaceutical products and start by choosing the most effective primary packaging options, the first and most important line of defense for substance integrity.

For bulk drug substances and process intermediaries, the safe handling and storing between downstream and fill and finish can pose challenges that well-designed primary packaging can address. Primary packaging is the packaging that comes in direct contact with the material itself and should be inert and cause no alteration in the chemical makeup of the substance. The purpose of this type of packaging is to contain, protect and preserve it from contamination as it travels through the manufacturing supply chain. At this phase, examples include single use bags, used to reduce the chance of contamination. As processes advance from drug substance to drug product transportation, primary packaging doesn't just protect the contents from contamination; it is often involved in the dispensing, dosing, and using of the final drug product it contains. Examples include ampoules, vials, blister packs, bottles, and single-use bags. The type of primary packaging used for each therapeutic product depends on the stability requirements.

Secondary packaging is used outside primary packaging and does not come in direct contact with the drug substance. It is often used to keep similar bulk substances together, maintain the integrity of the primary packaging and sometimes identify the bulk substance with labels. Secondary packaging is frequently made up of multiple components such as outer cartons, trays or cardboard boxes.

The final step is tertiary packaging, also called bulk or transit packaging; this packaging is used to group larger quantities of drug substance to transport them from point A to point B. During this stage, the materials are being handled as distribution units; therefore, this packaging makes it easier to transport large and heavy loads safely and securely. Examples of tertiary packaging include shipping containers and stretch-wrapped pallets containing large quantities of secondary packaging to enable efficient product shipping.

Rethinking a primary packaging approach

As discussed, storage and handling of bottles and bags present potential contamination risks and challenges with safe transport. Process intermediates and bulk drug substances are regularly frozen, stored, and shipped at temperatures down to -80C to maximize stability and eliminate mechanical agitation through the processing chain. However, these freeze-thaw processes present considerable risks to products stored in traditional single-use plastic storage bags and containers. The extreme and varied conditions involved in the process require durable and innovative containers to ensure product integrity by minimizing any potential risk of contamination or risk of damage during transportation.

Traditionally, polymer-film-based single-use bags have been used, but they are often 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.

GORE PharmBIO is addressing these industry issues with our Flexible Freeze Containers, developed to circumvent the vulnerabilities of single-use plastic containers commonly used in biopharmaceutical manufacturing. Using a highly durable proprietary composite film, polytetrafluoroethylene (ePTFE) material, Flexible Freeze Containers were designed specifically for bulk pharmaceutical cold chain applications. Benefits for storage of biopharmaceutical intermediates include:

- High purity and low extractable profile, minimizing the risk of drug interaction or contamination
- Proven strength and durability that resists cracks, leaks or breaks if accidentally dropped, and maintains integrity through multiple freeze-thaw cycles or long term storage.
- Flexibility in configuration: containers are available in a range of sizes from 50 mL to 12 L and are suitable for both plate and blast freezers.
- Secure and protective design that maintains closed conditions throughout handling and has an optional outer hard-shell carrier to protect tubing.

The effect of innovative primary packaging on secondary packaging

As manufacturers develop more advanced therapeutics, especially cell and gene therapies, solutions that support reliable cold chains will become central. Biopharmaceuticals culminate in complex design decisions requiring substantial research, resources, and time investment.

Oftentimes, manufacturers will misguidedly look to improve end-user training and secondary packaging before first evaluating the most durable primary solutions to prevent product loss. Many recognize the critical aspect and value, both in cost and to patients, of container integrity. The key takeaway for manufacturers is that by choosing the most durable and innovative primary packaging, they can eliminate potential issues that might occur through subsequent phases of supply chain transportation.

About Gore

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. For the pharmaceutical and biopharmaceutical industry, Gore is helping those in drug discovery and manufacturing compete in this increasingly regulated landscape with reliable solutions for purifying, transferring, storing, filtering, processing, and packaging. These solutions include durable, multi-use process components and single-use products that enable researchers and manufacturers to control costs through process improvements.

References:

1. https://www.statista.com/statistics/1293077/global-biopharmaceuticals-market-size/
2. https://www.visionresearchreports.com/cell-and-gene-therapy-clinical-trials-market/38278

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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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