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How Single-use Cryopreservation Solutions Enable Biopharmaceutical Manufacturing

By Ian Burdick, MBA, Director of Business Strategy, Biopharma, Solesis; and Evan Hagen, Business Development Manager, Charter Medical LLC

Cryopreservation plays a fundamental role in biopharmaceutical operations, allowing researchers and advanced therapy manufacturers to preserve biological specimens for extended periods of time. This technique involves freezing cells and other biological fluids to temperatures that dip down to between -135°C to -196°C (liquid nitrogen temperatures), effectively halting biological activity while maintaining cell integrity and performance. Today, cryopreservation is used to advance therapeutic breakthroughs or to preserve and deliver cell and gene therapies to hospitals or clinical sites, who then administer these therapies to patients.

As we look at the four common applications of cryopreservation, we'll also explore the science behind selecting the appropriate materials to build single-use solutions such as bags and tubing that enable cryogenic storage for cell and gene applications.

Selecting the Right Single-use Materials for Cryogenic Conditions

Perhaps the most significant challenge in cryopreservation is choosing single-use materials that can withstand extreme temperatures. Because cryogenic environments are harsh by nature, the materials used in these applications must be able to withstand considerable stress. For example, polymers like polyolefin and polyethylene are well-suited for these low-temperature conditions, as they can maintain their durability in such environments. On the other hand, a material like polyvinyl chloride (PVC) can become too brittle in such conditions, leading to issues like cracking, breakage, or delamination.

How Is Cryopreservation Used in Biopharma Manufacturing?

Once biopharma companies establish their manufacturing process, they'll need to consider how they'll use cryopreservation to move their therapies from benchtop to the patient's bedside. The four common ways cryopreservation is used across the biopharmaceutical industry are raw material storage and transportation, sample retention, in working cell banks, and during final fill.

1. Raw Material Storage and Transportation

Cryopreservation is instrumental in the storage and transportation of raw biological materials like blood or living cells. These samples are often collected in hospitals or other clinical facilities, then sent to manufacturing labs or research centers for further analysis or bioprocessing. These materials can then be manipulated, stored, and eventually transported back to a patient. Throughout this process, durable cryopreservation bags play a pivotal role in maintaining the quality and security of these materials throughout their journey. This ensures the samples remain viable and ready for use upon arrival at clinical trial sites or hospitals..

2. Sample Retention

In addition to storing raw biological materials, biopharmaceutical companies often cryogenically store small aliquots of product for extended periods of time. These small quantities – often referred to as Quality samples – can be used for testing and analysis during pharmaceutical development as well as in commercialized processes. These samples are carefully removed from the bulk product to avoid contamination and obtain homogeneous samples that are strong representative samples of the bulk product. Their cryopreserved state provides the user with a controlled and reliable environment for sample retention for later testing or analysis, whether in-house or when transported to another facility.

3. Working Cell Banks

Working cell banks are the backbone of many biopharma manufacturing operations. Cell banks are used to preserve cell samples for days, weeks, months, or years before manufacturers need to thaw them for utilization. This process typically starts in the lab or manufacturing suite where technicians fill standard or customized cryopreservation bags with cell-based fluids. Because they remain in these types of facilities, working cell banks typically require specific design considerations to ensure compatibility with existing biopharma systems. The

materials used in their construction must also be suitable for cryogenic conditions while minimizing the risk of contamination, leachables, or bioreactivity, and allow for low-risk methods of fluid transfer to subsequent steps in the process.

4. Final Fill

In the final stages of manufacturing, biopharma companies fill final product in cryopreservation containers to store therapies. This phase is particularly critical, as cryopreservation bags must not only be able to withstand the rigors of low temperatures and transportation, but they also must adhere to stringent safety standards and regulations. At this stage, if a bag is damaged (e.g., punctured or torn) or is discovered to have particulate contamination, the therapy developer may have to start the manufacturing process over, ultimately delaying patient care.

Meeting Clinical and Regulatory Compliance

When optimizing materials used to construct single-use solutions for cryopreservation needs, biopharma manufacturers must think beyond specific application requirements – such as durability in low temperatures – and take another critical consideration into account: clinical safety.

As previously explored in the article "Choosing Safer Single-use Materials to Enhance Advanced Therapy Manufacturing," biopharma manufacturers should prioritize clinical safety as early as possible in the material selection process. Regulatory bodies – such as the EU's Registration, Evaluation, and Authorization of Chemicals (REACH) – set guidelines and regulations on the use of certain chemicals found in materials used in the construction of single-use solutions due to their health and environmental impacts. One of the chemicals is di(2-ethylhexyl)phthalate (DEHP), a common plasticizer – or phthalate – that is used in some films. Understanding how materials interact with therapies and within a patient's body can help biopharma manufacturers optimize single-use solutions for the safe administration of therapies at clinical trial sites and hospitals worldwide.

Confidently Build Your Single-Use Cryopreservation Solutions

Therapy manufacturers should account for their cryopreservation needs well in advance to avoid issues that can arise throughout the cold chain process. They should consider partnering with an experienced single-use supplier that can offer standard or custom cryopreservation solutions backed by polymer expertise. To start building your single-use cryopreservation solutions, visit https://chartermedical.com/cryopreservation

About The Authors

Ian Burdick is the Director of Business Strategy, Biopharma, for Solesis (Telford, PA), parent company of Charter Medical (Winston-Salem, NC). Ian assesses, plans, and organizes long-term strategic direction and growth strategies for Solesis' Biopharma business. He leverages his 12 years of experience in global sourcing, distribution, and contract manufacturing to bring unique insights into meeting these market needs. Ian has a B.S. from Western Michigan University and an MBA from the University of North Carolina.

Evan Hagen is Business Development Manager at Charter Medical. With 9 years of process development experience in cell therapy manufacturing, bioprocessing, and cryopreservation, Evan regularly pinpoints unique solutions for customers that facilitate process effectiveness and efficiency. Evan has a bachelor's degree in Biomedical Engineering and an MBA, both from Purdue University.

About Charter Medical, LLC

Charter Medical, LLC has more than 30 years' experience developing and providing specialty single-use products for bioprocessing, advanced therapies, and blood management applications, delivering solutions to the biotechnology and pharmaceutical markets.

Our 16,000 square feet of cleanroom space located in Winston-Salem, NC, is ISO 13485:2016 certified and FDA registered, with a focus on designing and supplying single-use solutions for cell growth, frozen storage, and biological fluid handling. Custom product design services are available for clients who need specialized single-use products for biomanufacturing. Our team of engineers will work with you to develop the best solution for your specific requirements.

Charter Medical is committed to providing quality products and services with an experienced staff dedicated to exceeding customer expectations from product development to delivery and implementation.

At Charter Medical, we work closely with our sister companies, Polyzen, SanaVita Medical, and Secant Group, to provide essential products and services to life science companies. Through integrated research and development activities, we are helping to bring new technologies and therapies to market.

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