

Innovation, Tech and Collaboration: How Advanced Material Solutions Make These Trends Realities

The demands for flexible, scalable, cost effective manufacturing are prompting the cell and gene therapy manufacturers and CDMOs to implement techniques such as single-use technology for manufacturing their exciting therapies. From a materials perspective, however, this approach raises some challenges that require help from industry to minimize the risk of product loss or contamination.

Advanced fluoropolymer materials can make a substantive difference in addressing these challenges.

Market drivers and new technology

What's creating the demand for reduced cost, scalability and improved flexibility? On the one hand, there is the complexity of manufacturing mRNA, viral vector or other new therapies, and the introduction of newer manufacturing technologies that might seem attractive. On the other hand, there are the opposing demands in manufacturing of low volume specialized therapies (such as personalized CGT and orphan drugs) and high volume/low cost products (such as vaccines).

To meet demand, cell and gene therapy manufacturers and CDMOs require that quality and regulatory requirements be met, despite relatively new processes and the development of more complex mRNA therapies.

As mentioned at the outset, addressing cost, scalability and flexibility demands in cell and gene therapy is driving wide interest in single-use technologies. The adoption of this technology has been limited in some applications and could be improved with a consideration to more diverse and advanced materials for processing components.

The manufacturing trend toward single-use technologies has both benefits and challenges. The benefits include flexibility and mobility, reduced costs (particularly with regard to cleaning and utility costs), reduced capital expense, faster speed to market, and reduced down-time. But traditionally, single-use products are susceptible to mechanical and chemical stresses, and consumables costs can be prohibitive.

Materials-based solutions to materials-based challenges

Overcoming the problems of materials-based limitations in manufacturing trends like single-use technology, not surprisingly, requires materials-based solutions. One materials-based solution that can address the challenges is the use of fluoropolymers, particularly a polymer such as polytetrafluoroethylene (PTFE). This substance has favorable chemical properties. It is bio and chemically inert, with a low coefficient of friction. It is chemically stable and non-particulating, with low extractables and high levels of purity.

Polymers such as PTFE, when combined with unique materials engineering capabilities, can lead to advanced materials, with structures that can be manipulated to control physical properties, and combined with other materials to create functionality for particular uses. Advanced materials can improve cold chain handling, storage and transport, especially with single-use products. The high cold-flex durability of a PTFE fluoropolymer composite film can maintain mechanical integrity at extremely low temperatures, where other materials may become brittle and lead to container breakage or leakage.

The need for collaboration

These types of advanced material solutions to certain challenges of single-use technologies offer real innovation for cell and gene therapy manufacturing. But such innovation requires partnerships and relationships at the intersection of four complementary business and regulatory arenas: manufacturing, industry associations, regulatory bodies and suppliers.

Manufacturers develop best practice standard operating procedures and create hybrid operations. Industry associations develop industry-specific best practices for both standardization as well as research and development. Regulatory bodies provide guidance and mandate changes, and suppliers have both technology and equipment expertise as well as specific material solutions. Truly effective innovation is not possible if any of these above relationships is omitted or disregarded.

As a reliable supplier, 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.

Cell and gene therapy is at a threshold – a threshold in which emerging technologies can help realize the vision of the industry and create operational efficiencies that provide real benefits. 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>.

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.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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