

Cell therapy

Streamlining your cell therapy workflow: exploring the benefits of larger bioprocess container sizes

Keywords

Bioprocess container, BPC, cell therapy, scale-up, autologous, T cell media, media, contamination

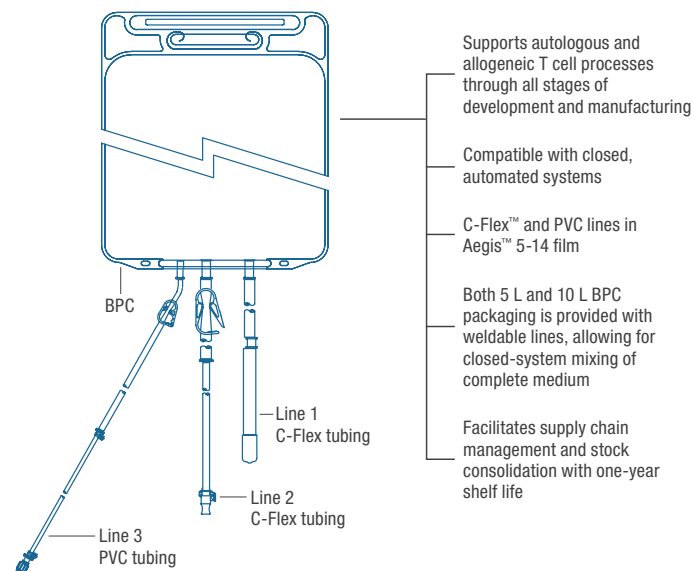
Cell therapy has the potential to help many patients with cancer or autoimmune diseases. As with other modalities within the biopharmaceutical space, cell therapy developers must overcome challenges in timelines, costs, and efficacy. Delivering young and healthy T cells capable of long-term persistence is crucial in cell therapy, but the manufacturing process can involve multiple touchpoints, increasing the risk of contamination. To streamline this process, it can be valuable to examine how the apparatus used may influence the efficacy of the drug produced.

Bioprocess containers (BPCs) are ready-to-use, single-use, flexible container systems for liquid products such as media. They can be readily integrated into a variety of high-performance processes to help maintain sterility during the production of biologics. Larger sizes and increased flexibility in BPC design can help optimize their benefits and increase productivity, helping to address some of the challenges associated with cell therapy manufacturing.

BPC line expansion and the family of CTS OpTmizer media

Designed for the development of both autologous and allogeneic T cell therapies, the family of Gibco™ CTS™ OpTmizer™ serum-free media (SFM) was designed to help optimize cell therapy production and scale-up. The media support rapid T cell expansion and high-density T cell cultures, helping to accelerate workflows and improve productivity. To further enhance these benefits, the CTS OpTmizer SFM family is now available in an increased offering of flexible BPC pack sizes (Figure 1). With a BPC consisting of Thermo Scientific™ Aegis™ 5-14 film with C-Flex™ and polyvinyl chloride (PVC) lines, the new 5 L and 10 L packaging is compatible with a range of workflows and closed, automated systems.

Basal Medium BPC



Supplement BPC

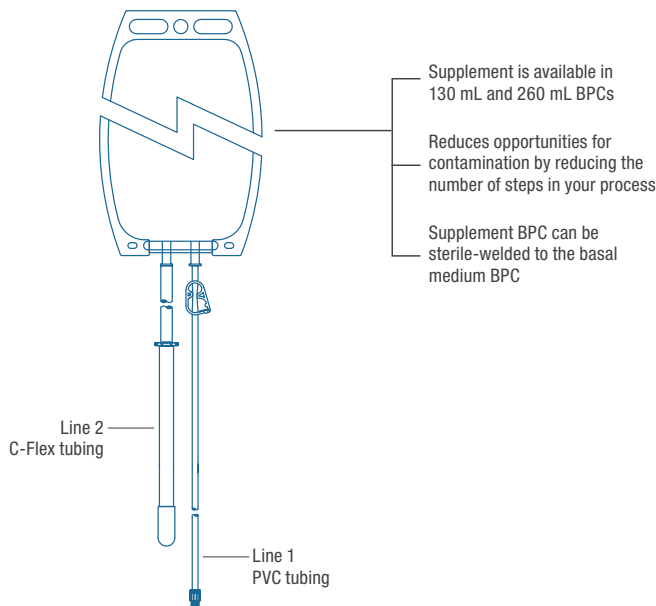


Figure 1. Features of the BPCs containing CTS OpTmizer basal medium or supplement.

Here we outline the benefits of increased BPC pack size options, as well as updated features such as sterile weldability, for both Gibco™ CTS™ OpTmizer™ T Cell Expansion SFM (No Phenol Red) and Gibco™ CTS™ OpTmizer™ Pro SFM.

Accelerating timelines

In an industry as time-sensitive as cell therapy, rapid timelines are crucial. Manufacturing cell therapies that involve harnessing patients' own cells requires strict timelines, with a general guidance of cell collection, gene editing, and transplantation within 21 days [1]. Therefore, cell therapy developers must aim to streamline the process wherever possible.

Using larger BPC pack sizes can help to achieve this goal. Preparation of CTS OpTmizer T Cell Expansion SFM and CTS OpTmizer Pro SFM involves adding a supplement to the selected cell culture medium to support T cell growth. When producing larger quantities of media, using smaller BPCs involves several repetitions of connecting and disconnecting packs, as well as manual addition of the supplement via spiking, often followed by use of a transfer assembly. For the production of 5 L of medium, using 1 L BPCs would require this process to be repeated 5 times. However, using the new, larger 5 L BPC significantly cuts down the process time, with only one pack required to produce 5 L of medium. The updated format of the new pack sizes also allows the supplement and the medium to be connected via aseptic welding of the lines—negating the need for spiking and transfer, thus reducing manual handling time and further streamlining the process.

Overall, these aspects enable a potential time saving of 66% for CTS OpTmizer Pro SFM (Figure 2) and 90% for CTS OpTmizer T Cell Expansion SFM (No Phenol Red) (Figure 3). This accelerates manufacturing, helping to efficiently produce a patient-ready therapeutic product.

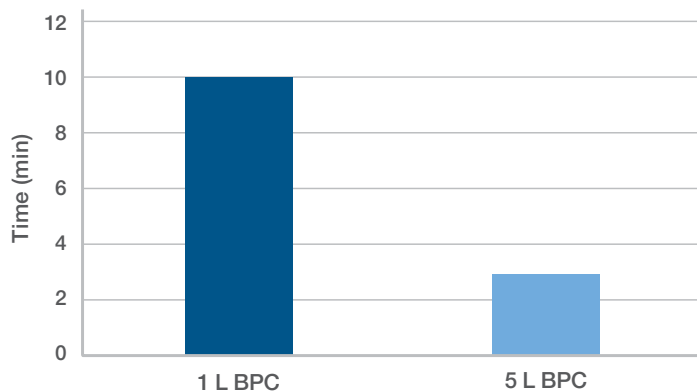


Figure 2. The time taken to prepare 5 L of CTS OpTmizer Pro SFM was reduced from 10 minutes to 3 minutes when using a 5 L BPC compared to a 1 L BPC.

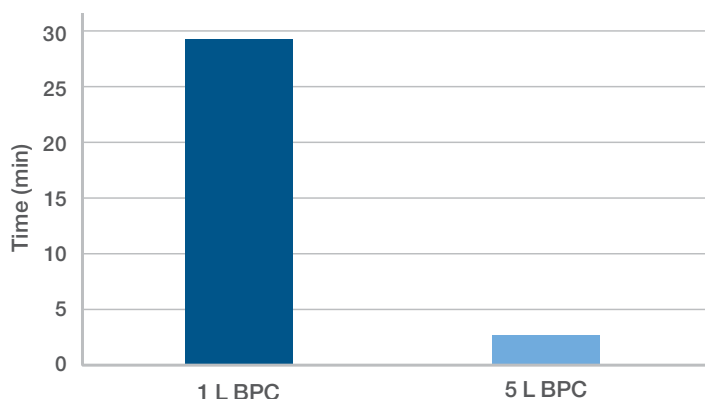


Figure 3. The time taken to prepare 5 L of CTS OpTmizer T Cell Expansion SFM (No Phenol Red) was reduced from 29 minutes to 3 minutes when using a 5 L BPC compared to a 1 L BPC.

Prioritizing safety

Manufacturing autologous cell therapies is a delicate process. A constant supply of healthy T cells from patients is not always possible, so developers often have limited opportunities to attempt to create a safe and efficacious therapeutic. Contamination during the manufacturing process threatens the integrity and safety of the drug and can ultimately prevent the production of a much-needed treatment.

Not only does minimizing the number of manual steps within the cell therapy manufacturing process save time, but it also reduces the risk of contamination. With the new 5 L and 10 L BPC sizes, manual steps such as spiking can be avoided, thanks to aseptic welding, protecting the sterility and safety of the final product. Removing the need to manually spike the supplement can help to streamline production and reduce opportunities for the introduction of impurities. This benefit is then amplified because using larger volumes cuts down on the need for repetitions and therefore minimizes supplement additions altogether.

Cutting costs

An already costly process, long throughput times and delays can result in a much more expensive cell therapy workflow, with some CAR T cell therapies costing patients anywhere from \$300,000 to \$500,000 per dose [2]. Minimizing costs is important for making a therapy economically viable and will help support the journey to commercialization.

The new larger BPCs can help improve cost efficiency. The current 1 L pack sizes require multiple intermediate vessels and extra materials in order to produce 5 L of media. With the option to aseptically weld, the updated 5 L and 10 L pack sizes do not have this issue and as a result minimize this need—and cost—for extra materials and resources. One example of this is the reduction of transfer bottles needed in the process as a result of using a larger BPC, saving almost \$360 per 5 L of medium produced (Table 1). Here, the number of transfer bottles required per 5 L of CTS OpTmizer Pro SFM produced was decreased from 5 to 1 when using the new 5 L BPC pack size. Consequently, the cost of transfer bottles required to produce 5 L of media also went down, from \$448.05 to \$89.61.

Table 1. Transfer bottle cost savings.

CTS OpTmizer Pro SFM	Number of transfer bottles required per 5 L	Cost of transfer bottles per 5 L
1 L BPC	5	\$448.05
5 L BPC	1	\$89.61

Efficient scale-up

The data presented clearly demonstrate the new efficiencies offered by the updated BPC pack sizes. By reducing the number of steps involved and using aseptic welding, the new 5 L and 10 L BPC pack sizes can help developers overcome challenges related to time, cost, and contamination. Optimizing T cell processes throughout development and manufacturing, this updated line of BPCs has the potential to support safe and efficacious transformative therapies for those who need them most.

Learn more about the new CTS OpTmizer BPC line expansion and how you can seamlessly scale up your cell therapy workflow with Gibco™ products [here](#).

References

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