MAGic™
BioProcessing

CASE

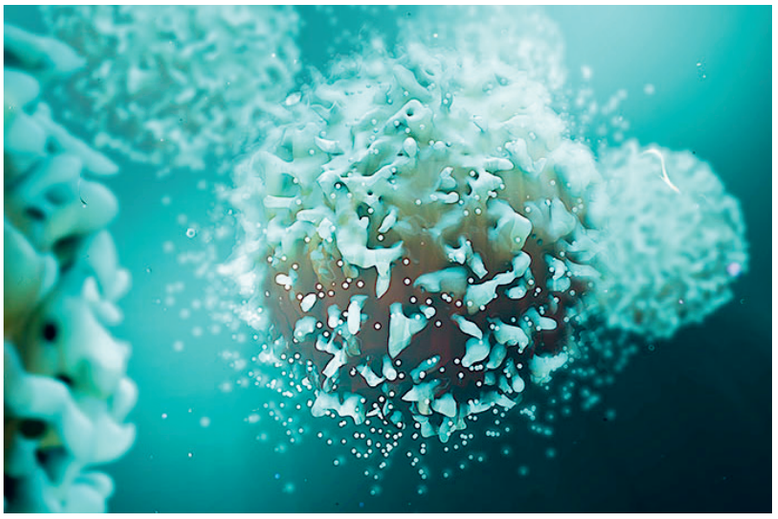
# Enabling off-the-shelf cell therapy products

The focus on personalized medicine – and especially the rising incidence of chronic and infectious disease – has driven the cell and gene therapy market to a point where where there is talk about a revolution.

The global size of the cell therapy technologies market was estimated to $4.2 billion in 2023 and is projected at a CAGR of 13.3% to reach $7.8 billion in 2028. (MarketsandMarkets, 2023a) Similarly, the global gene therapy market, valued at $9.0 billion in 2023, is expected to grow at a CAGR of 21.4% to reach $23.9 billion by 2028 (MarketsandMarkets, 2023b). While survey results vary, they all share one common prediction: market growth is expected to be massive.

The promise of cell and gene therapies is at risk due to high production costs, often exceeding $1 million per treatment, that largely arise from their complex manufacturing process (Nature Editorial, 2023), Genetic Engineering & Biotechnology News, 2023). Unless significant advancements in production methods are achieved, these revolutionary treatments will remain inaccessible to a vast majority of patients. Thus, it is imperative to introduce process innovation and new technology, to ensure the continued development and widespread implementation of cell and gene therapies. Innovation to improve large-scale workflows can help overcome these manufacturing challenges (Zynda, n.d.). Otherwise, the revolution may stall, hindering their potential to transform healthcare and treat various diseases (Nature Editorial, 2023), Genetic Engineering & Biotechnology News, 2023).

Allogeneic therapies may offer a promising way forward. These therapies involve collecting cells from healthy donors, modifying them to target specific diseases, expanding them, and storing them in a centralized cell bank. Thus, potentially revolutionizing patient access to treatments by allowing a single batch to treat multiple patients, improving scalability, and the ability to reach over the counter. The benefits of such large-scale batch production include pre-prepared and cryopreserved cells for timely administration, crucial for critically ill patients. While this approach introduces several benefits, there is still a great need for scalable new technology and process innovation before it can provide a more efficient off-the-shelf solution for cell therapy. Magnetic separation can offer such a process-innovating, scalable technology in cell therapy manufacturing of allogeneic therapies.



Magnetic separation methods – previously limited by poorly scalable iron oxide-based particles – have already proven a viable, safe and gentle alternative to flow cytometry-based isolation, offering a quick and gentle way to handle samples for laboratories that do not have access to a flow cytometer; the only drawbacks being scalability and the requirement of a secondary quantification method i.e. cell count (refs 6,7 in article 13) mot (Thakur et al., 2015; Jariyal et al., 2019) September 2024).

**MAG-SP** is the world's first truly scalable magnetic separation platform that utilizes metallic iron-based super-paramagnetic agarose beads to effectively collect stem cells and purify the cell therapeutic product in a gentle and highly scalable manner. MAG-SP enables the cost-effective scale-up of the cell manufacturing process to help realize the promise of off-the-shelf cell therapy products without risk of internalization.

## Learn more!

Would you like to know more about our **MAG-SP platform,** our magnetic seperator, **MAGic™ Accio,** and our magnetic beads? Do you have your own custom solution you would like to investigate with us? **Visit www.magicbioprocessing.com**

## REFERENCES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