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Terumo Blood and Cell Technologies' Peer-Reviewed Publication Shows Hollow Fiber-Based Bioreactors Can Produce 8x Viral Vector-Producing Cells in Four Days

Quantum technology optimized for automated expansion of cell and gene therapy components

LAKEWOOD, Colorado, US, September 7 2023 – Terumo Blood and Cell Technologies (Terumo BCT), a medical technology company, announced the publication of a peer-reviewed manuscript regarding a new protocol for automated expansion of HEK293T cells that are used to produce the viral vectors powering cell and gene therapies. The accepted manuscript, published today in *Biology Methods & Protocols*, demonstrates the flexibility of Terumo BCT's hollow-fiber bioreactor systems for expanding a variety of cells with therapeutic relevance and offers guidance to advanced therapeutics developers and contract manufacturers looking to improve the efficiency of vector and cell production.

Lentiviral, adenoviral and adeno-associated virus vectors are key components of cell and gene therapy manufacturing, commonly used in the burgeoning field to deliver DNA or RNA that modifies a cell's activity—turning a dangerous cell benign or reprogramming a normal cell into a living medicine(1). Between April and June 2023 alone, the Food and Drug Administration approved five new cell and gene therapies, a pace that is expected to rapidly increase in coming years given the results patients have experienced and the estimated 1,000-plus ongoing clinical trials. But the rapid expansion has led to vector production bottlenecks, which slow both clinical scale-up and early-stage development (2).

The publication team was led by Dalip Sethi, Ph.D., Director of Scientific Affairs at Terumo BCT, and also included Mindy M. Miller, Ph.D. and Nathan D. Frank, both of Terumo BCT. The team developed and tested procedures to optimize HEK293T cell expansion under conditions designed to produce cells capable of efficient vector generation. The protocol ensures environmental factors related to glucose consumption, lactate levels and pH are reliably controlled. Pores in the hollow fibers of the Quantum Cell Expansion System's bioreactor allow small molecules in a circulating medium to diffuse consistently across a membrane for optimal growth of the culturing cells. Using the protocol, Sethi's team reliably expanded a starting population of 250 million HEK293T cells to greater than 2 billion cells within 100 hours.

"At Terumo BCT, we are dedicated to enabling the development of cell and gene therapies like the ones that have demonstrated amazing clinical impact. These new protocols demonstrate why the Quantum bioreactor, one of our platforms that supports this field, has been widely adopted for research and GMP-grade cell expansion for over a decade," said Sethi. "We remain committed to ensuring makers of advanced therapies have the tools to flexibly develop, test and adapt their products. Last year, we launched the next-generation Quantum Flex Cell Expansion System, using the same perfusion-based, hollow fiber technology, to allow developers to complete their early process development on the same platform they will use for manufacturing."

Details on the protocol were first presented in a poster at the 2023 International Society for Cell & Gene Therapy annual meeting.

For more information about Terumo BCT's hollow fiber perfusion-based Quantum bioreactors, visit <https://www.terumobct.com/quantum>.

(1), (2) Byrne, J. New US CDMO launched to address viral vector supply bottleneck. *BioPharma Reporter*. <https://www.biopharma-reporter.com/Article/2023/02/01/New-US-CDMO-launched-to-address-viral-vector-supply-bottleneck>. 1 February 2023. Accessed 5 Sept. 2023

About Terumo Blood and Cell Technologies Terumo Blood and Cell Technologies is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees worldwide believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers.

Terumo Blood and Cell Technologies' customers include blood centers, hospitals, therapeutic apheresis clinics, cell collection and processing organizations, researchers and private medical practices. Our customers are based in over 130 countries across the globe. We have 750+ granted patents, with more than 150 additionally pending.

We have global headquarters in Lakewood, Colorado, U.S.A., along with five regional headquarters, seven manufacturing sites and six innovation and development centers across the globe. Terumo Blood and Cell Technologies is a subsidiary of Terumo Corporation (TSE: 4543), a global leader in medical technology.