

University of Chicago School of Medicine achieves first-ever automated 3-in-1 TCR-T manufacturing on Terumo Blood and Cell Technologies Quantum Flex Bioreactor

Streamlined activation, transduction and expansion on a single closed, GMP-compliant platform could accelerate development of next-generation T cell therapies.

Lakewood, Colorado — November 18, 2025 — Terumo Blood and Cell Technologies (Terumo BCT), a global leader in cell and gene therapy technologies, today announced an advancement in T cell therapy manufacturing in a collaboration with Richard Koya, M.D., Ph.D., and his team at University of Chicago. For the first time, researchers have successfully completed all three critical steps in T cell receptor (TCR) T cell therapy (TCR-T) manufacturing — activation, transduction and expansion — using a single Quantum Flex™ Cell Expansion System small bioreactor.

This end-to-end automated process offers a comprehensive alternative to fragmented, manual workflows with a closed, GMP-friendly workflow that promises to accelerate processing timelines, improve consistency and reduce costs for autologous T cell-based therapies.

In the study, 10 million peripheral blood mononuclear cells (PBMCs) were activated, transduced with a gamma retroviral vector and expanded on Quantum Flex to up to 9 billion cells in 10 days while maintaining high viability. These results highlight the Quantum Flex platform's robustness, scalability and suitability for clinical and commercial workflows.

"The ability to automate TCR-T cell processing end-to-end on a single bioreactor is a foundational advance in the evolution of cell therapy manufacturing," said Dr. Koya, Professor of Medicine and Director of cGMP Vector Development and Production at the University of Chicago's Cancer Center.

"It opens the door to faster, more consistent manufacturing for therapies that could benefit patients with solid tumors and other hard-to-treat diseases," added Dr. Thinle Chodon, M.D., Ph.D., Co-Director of the Cellular and Tissue Based Processing cGMP Core Facility at the University of Chicago and co-investigator of the study.

"With Quantum Flex, we are building on our proven 3-in-1 CAR-T protocol to show the platform's flexibility and applicability across multiple T cell modalities," said Mindy Miller, Ph.D., Head of Scientific Development for Cell Therapy at Terumo BCT. "Industry analysts, including the Alliance for Regenerative Medicine, note that developers are prioritizing proven, adaptable platforms that can support multiple cell types and scales, like the Quantum Flex."

The announcement follows earlier results published by Terumo BCT in *Cytotherapy* demonstrating a similar integrated 3-in-1 workflow for CAR-T cells in partnership with Eureka Biotechnology. Now, with this TCR-T milestone, Quantum Flex shows versatility for both research and clinical production.

Dr. Koya will present the full dataset at the upcoming Advanced Therapies 2025 conference, November 18-19 in Philadelphia.

Why automated 3-in-1 TCR-T matters

The Alliance for Regenerative Medicine reports more than 2,000 active cell and gene therapy clinical trials worldwide, yet manufacturing capacity and consistency remain major barriers to patient access.^{1,2} Advanced manufacturing strategies — automation, closed systems and proven, adaptable platforms — are increasingly recognized as critical to overcoming these challenges.²

At the same time, the FDA's recent removal of certain risk evaluation and mitigation strategies (REMS) requirements for CAR-T therapies³ signals broader delivery in more treatment centers, creating urgency for scalable, reliable solutions. The Quantum Flex 3-in-1 workflow meets this need by integrating

activation, transduction and expansion in a single closed system, reducing reliance on highly skilled manual labor and improving reproducibility.

[1] Alliance for Regenerative Medicine (ARM). Q2 2025 Sector Snapshot. July 2025. <https://alliancerm.org/wp-content/uploads/2025/09/20250715-ARM-Sector-Snapshot-Q2-2025.pdf>

[2] ARM. Advanced Manufacturing Strategies to Increase the Reach of Cell and Gene Therapies: Takeaways From a Scientific Workshop. October 2024. https://alliancerm.org/wp-content/uploads/2025/09/Advanced-Manufacturing-Whitepaper-2024_Preview.pdf

[3] U.S. Food and Drug Administration. FDA eliminates risk evaluation and mitigation strategies (REMS) for autologous chimeric antigen receptor CAR T cell immunotherapies. June 27, 2025. <https://www.fda.gov/news-events/press-announcements/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>

Quantum Flex™ is either a registered trademark or trademark of Terumo BCT, Inc. in the United States and/or other countries. See TerumoBCT.com/Trademarks for details.

Dr. Richard Koya serves as a paid consultant to Terumo BCT. Dr. Mindy Miller is employed by Terumo BCT. Both individuals' affiliations may be relevant to the interpretation of the scientific information presented.

About Terumo BCT

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 160 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 four regional headquarters, eight 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.