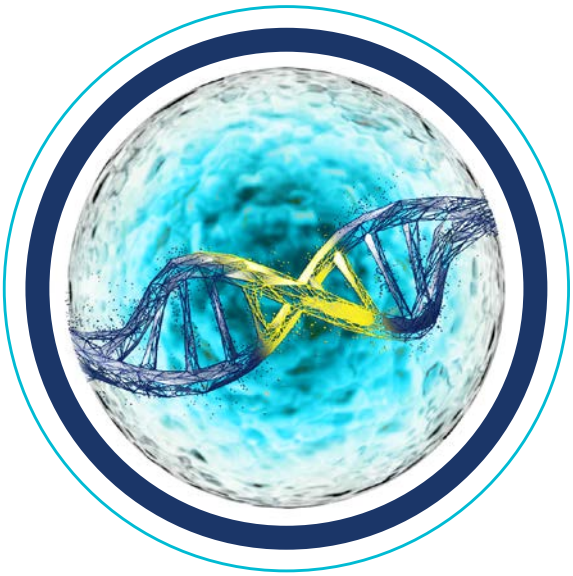
TcBuster™ Non-viral Genetic Engineering

for Cell and Gene Therapy Manufacturing



Efficient and scalable gene editing for cell therapy manufacturing is now at your fingertips. TcBuster non-viral genetic engineering technology and services solve the supply chain and timeline bottlenecks facing viral vector-based editing, while maintaining high efficiency insertion and a low-risk profile.

TcBuster is a commercially available non-viral, transposon-based gene transfer system. Proven to insert CAR and TCR constructs reliably and cost-effectively into T cells and NK cells, TcBuster is the future of genetically engineered autologous and allogeneic cell therapies.

CAR and TCR Gene Transfer without the Viral Baggage

TcBuster addresses the cost, scalability, supply chain, and integration challenges of retroviral and lentiviral vectors, as demonstrated in the table below. Manufacturing of TcBuster plasmids is inherently faster and less variable than retro and lentiviral production.

	TcBuster	Lentivirus
Cost	$	$$$
Manufacturing Timeline	8-14 weeks	11-20 weeks
Lot Consistency	Repeatable	Lot-to-lot variability
Manufacturing Capacity	Robust and scalable	Susceptible to supply shortage
Cargo Size	>11 kb	< 9kb
Gene Transfer Capacity	Multiple genes	One gene
Mediates Stable Gene Transfer	Yes	Yes
Delivery Method	Electroporation or Reagent-based Transfection	Transduction
Integration Risk Profile	Low Random; No site preference	Medium Random; Preferences for exons, transcriptional start sites
Immunogenicity	No	Yes
Clinical Use	Yes	Yes

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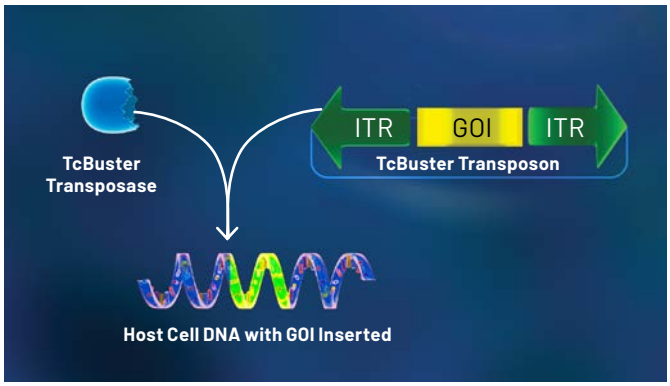
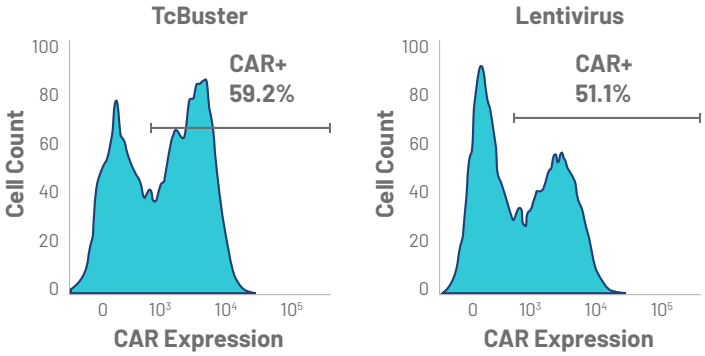
How TcBuster Works

TcBuster integrates your gene of interest (GOI) into host cell DNA using the highly efficient Red Flour Beetle transposase and specifically-designed transposons. Transposon systems have the safest insertion profile of any commercial gene delivery, with limited off-target effects and stable, reliable gene expression.



Highly Efficient Integration

Optimized protocols can result in TcBuster transposition yielding similar or higher efficiencies compared to lentivirus transduction.



Comparable Efficiency Compared to Lentvirus. CAR expression was evaluated by flow cytometry, showing similar rates of efficiency between TcBuster transposition (59.2%) versus lentivirus (51.1%).

Scalable to Support Therapeutic Manufacturing

TcBuster gene edited cells are compatible with cell expansion in closed-system G-Rex bioreactors. Optimized transposition and expansion protocols will support research and therapeutic scales.

Small Scale G-Rex6M	Mid Scale G-Rex100M	Large Scale G-Rex500M
		
40% transposition 25-fold expansion Yield: 2.5×10^8	51.3% transposition 50-fold expansion Yield: 4×10^9	40.9% transposition 38-fold expansion Yield: 15×10^9

Transposition and Expansion Rates of TcBuster-edited Cells in G-Rex Bioreactors. Increasing numbers of cells ($1x10^7$, $8x10^7$, and $40x10^7$) were electroporated to introduce TcBuster, then seeded into small, mid-, and large-scale G-Rex bioreactors, respectively, for expansion. TcBuster successfully transposed cells with >30% efficiency and resulted in 25-, 50-, and 38-fold expansion in the G-Rex.

TcBuster Service Options

From proof-of-concept studies and process optimization to cGMP cell line manufacturing or technology licensing, we have you covered. We've partnered with Bio-Techne's process development and CDMO team to make sure TcBuster integrates seamlessly into your clinical manufacturing process.

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Contact us: info@scaleready.com

ScaleReady is a Joint Venture formed by Bio-Techne, Fresenius Kabi, and Wilson Wolf. Combining selected offerings from the three partners, the ScaleReady manufacturing platform combines tools and technologies for cell culture, cell activation and expansion, gene editing, and cell processing.

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