

# Revolutionizing Cell Therapy Manufacturing

ScaleReady Portfolio Overview

[scaleready.com](https://scaleready.com)



Don't let the success of your cell therapy catch you off-guard. ScaleReady has thoughtfully designed a portfolio that is robust, flexes for scale, and solves the cost and logistical burdens that can side-line a company as clinical trials progress and patient demand escalates.

We've anticipated where the industry needs to be and we're the only solution for cost-effective, practical scale-up and scale-out of cell and gene therapy manufacturing.

The ScaleReady Portfolio Delivers:

- Efficient and practical cell therapy manufacturing
- High-volume parallel patient processing
- Small cleanroom footprint
- Reduced capital equipment investments

## Closed-system Bioreactors that Scale

### **G-Rex Bioreactors**

The G-Rex Bioreactor is the only cell expansion technology that can linearly scale up from 10 million to 100 billion cells. Providing predictable and scalable cell expansion, the G-Rex enables your process to accommodate the cell volume demands for preclinical through commercial scale manufacturing.

- Design maximizes cell expansion per device
- Cell expansion reproducibly scales from small to large processes
- All-in-one closed system design
- Sterile, single-use disposable format



## Quality-driven Ancillary Materials

### GMP Cytokines

Our animal-free GMP cytokines can fit any process at any scale. Available as standard lyophilized proteins, formulated as closed-system ready in a bag, or custom vialled and packaged to your process specifications.

- High lot-to-lot consistency for simplified batch bridging
- Supported by quality and regulatory documentation
- Equivalent bioactivity between R&D Systems research-grade and GMP cytokines
- RUO and GMP-grade IL-2, IL-7 and IL-15 are available from the new animal-free GMP facility in St. Paul, MN. GMP rhIL-21 also available



### ExCellerate™ Media

ExCellerate Media support the expansion of immune cell therapeutics. Our rich serum-free and xeno-free base media maximize cell growth and purity while reducing the need for serum replacements. Formulations available for T cells and NK cells.

- Provides robust cell expansion and phenotypes
- Eliminates need for human serum or serum replacements
- Supported by quality and regulatory documentation

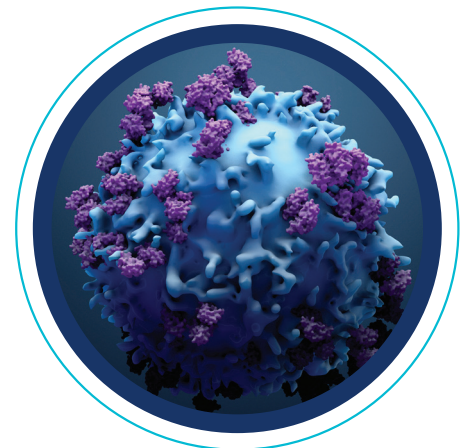


## Non-Viral Gene Editing

### TcBuster Non-viral Genetic Engineering

Efficient and sustainable gene editing for cell therapy manufacturing is now at your fingertips. TcBuster technology and services solve the supply chain and timeline bottlenecks facing viral vector-based editing, while maintaining high efficiency.

- Eliminates challenges of manufacturing lentiviral vectors
- Stabilizes supply chain using a consistent manufacturing process
- Improves gene integration and efficient multigene transfer
- Consolidates knock-in and knock-out unit operations



# Cell Processing with Precision

## Lovo® Automated Cell Processing System\*

Lovo is the industry-standard for large volume functionally closed system processing. Its spinning membrane technology can process billions of cells, handle varying cell concentrations, and precisely deliver final product volumes as low as 50 mL.

- Automates immunomagnetic selection cell preparation
- Simplifies fresh or frozen leukapheresis wash
- Enables high supernatant washout\* (up to 99.9999%)
- Delivers high cell recovery and viability in final product volume

\*Based on theoretical wash-out from system estimator.



For Laboratory Use Only

## Cue® Cell Processing System

Exact and responsive, Cue is the definitive instrument for small volume applications including cryopreservation preparation, electroporation preparation, and small-volume culture media exchange.

- Supports final product volumes  $\geq 2$  mL (single product) or  $\geq 10$  mL (multiple products)
- Enables user-defined type and number of final product containers
- Offers optional concentrate/wash steps in the same procedure as final formulate/fill
- Allows for configurable temperature control and mixing



For Laboratory Use Only

The Lovo and Cue Cell Processing Systems are for laboratory use only and may not be used for direct transfusion. Appropriate regulatory clearance is required by the user for clinical use. Refer to the Lovo Cell Processing System Operator's Manual and Cue Cell Processing System User's Guide for a complete list of warnings and precautions associated with the use of these products. For additional information, please visit [scaleready.com](https://scaleready.com).

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Contact us: [info@scaleready.com](mailto: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.

Lovo and Cue are manufactured by Fresenius Kabi. All products are for research use or manufacturing purposes only.

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