

# GMP Cytokines

## for T Cell and NK Cell Manufacturing

GMP cytokines are critical raw materials for T cell and NK cell therapy manufacturing. Variability in lot-to-lot consistency can impact product reproducibility and increase risk of product failure, while inability to secure clinical-trial size lots of cytokine can sideline manufacturing and clinical trial progress. There is now an option for GMP cytokines to help alleviate these risks.

**All the GMP cytokine you want** — Now you can secure large clinical-trial size lots of highly consistent GMP cytokines (IL-2, IL-7, IL-15, and IL-21). This helps de-risk your cell manufacturing process by securing reagent supply and improving cell quality consistency across therapeutic doses.

**In the format you need** — With options to purchase as single vials, multiple vials, bulk protein, or in custom-filled vials by mass or activity, you will be confident that your GMP cytokines are process optimized.

**Same protein from RUO to GMP** — The same master cell line and manufacturing process is used for GMP and research-grade cytokines, helping you minimize risk and comparability testing during translation.

Bio-Techne GMP-grade cytokines are ideal for the ScaleReady platform because of their consistency, flexibility, quality, and scalability. These features support our goal to seamlessly scale-up immune cell therapy manufacturing.



GMP Protein	Source	Animal-free	DMF Filed	Format	Sizes	Catalog #	Research-grade Catalog #
rhIL-2	E. coli	Yes	Yes	Standard	10 µg	202-GMP-010	202-IL
					50 µg	202-GMP-050	
					1 mg	202-GMP-01M	
				Custom fill**	Schedule a consultation*		
rhIL-7	E. coli	Yes	Yes	Standard	25 µg	BT-007-GMP-025	BT-007-AFL
					1 mg	BT-007-GMP-01M	
				Custom fill**	Schedule a consultation*		
rhIL-15	E. coli	Yes	Yes	Standard	25 µg	BT-015-GMP-025	BT-015-AFL
					1 mg	BT-015-GMP-01M	
				Custom fill**	Schedule a consultation*		
rhIL-21	E. coli	Yes	Yes	Standard	25 µg	8879-GMP-025	8879-IL
					1 mg	8879-GMP-01M	
				Custom fill**	Schedule a consultation*		

Bio-Techne manufactures GMP proteins for many cell therapy and regenerative medicine applications. Inquire with your ScaleReady representative to learn more.

\* Contact [info@scaleready.com](mailto:info@scaleready.com)

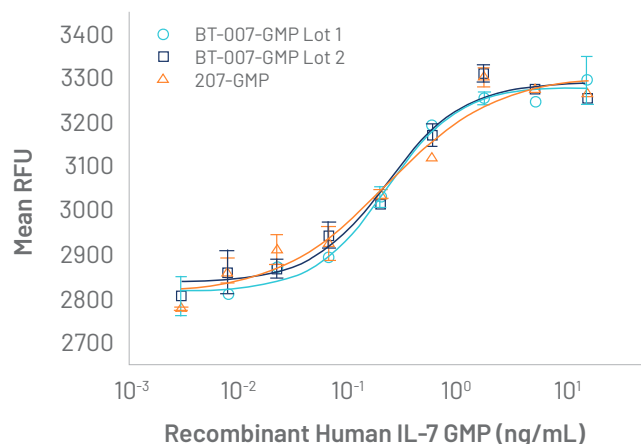
\*\* Options to fill by mass, activity, lyophilized, and liquid-frozen.



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

## Consistent Bioactivity for Reproducible Manufacturing

Ensure quality and consistency across manufacturing lots and clinical trial sites. With low lot-to-lot variability and high bioactivity, you can be confident in Bio Techne's animal-free GMP cytokines to support product reproducibility and lower manufacturing risk.



**GMP-grade Recombinant Human IL-7 stimulates proliferation of PHA-activated human peripheral blood lymphocytes.** Comparison of two lots of GMP IL-7 (Catalog # BT-007-GMP) manufactured in the new GMP facility to the legacy GMP IL-7 (Catalog # 207-GMP). Bioassay data for two lots of the new GMP IL-7 are nearly identical to the legacy GMP IL-7 with ED50 values within the margin of error.

## Quality that Scales through Clinical Trials.

Our GMP cytokines can now be produced at a game-changing scale within Bio-Techne's new dedicated animal-free GMP facility. This state-of-the-art facility has large volume bioreactors for scalable GMP cytokine production and is backed by experienced manufacturing, quality, and regulatory teams. The facility is equipped with space for future increased demand in GMP lot-sizes, including larger lot size and facility throughput.

Rigorous master cell lot control and lot-to-lot bioactivity testing uniquely elevates the performance and consistency of our GMP cytokines to meet the long-term manufacturing requirements of the cell therapy industry.

## GMP Manufacturing Capabilities

- Entire facility dedicated to producing GMP and research-grade proteins for cell therapy manufacturing.
- Animal-free facility – No animal components are allowed in the facility.
- Capacity – 61,000 sq. ft. to meet your supply requirements now and in the future.
- ISO 5/7/8 cleanrooms for entire production process.



## Certifications And Regulatory Guidelines

- USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- USP Chapter <92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing
- Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Products



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

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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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