

biotechne®

R&D SYSTEMS®

# GMP Cytokines & Growth Factors

For Cell Therapy  
Manufacturing

Ensure a Consistent, Safe, and  
Traceable GMP Protein Supply



# Ensure a *Consistent, Safe, and Traceable* GMP Protein Supply

The complexity of cell and gene therapy manufacturing demands consistency and traceability in every detail, making it crucial to start your process on the right foot. We aim to set you up for success by providing GMP cytokines and growth factors that are consistently reliable and free from variation, ensuring the safety and efficacy of your therapy.

Produced under stringent guidelines, these proteins may be used as ancillary materials in cell therapy manufacturing. They undergo rigorous quality control testing and come with comprehensive documentation, ensuring complete transparency and traceability of their sources and manufacturing processes. Leverage over 40 years of experience in protein manufacturing with R&D Systems™, a Bio-Techne brand. We are committed to delivering consistent quality and safety in every batch.



# Futureproofing Your *Cell Therapy* Programs

To meet the rising demand for GMP-grade proteins, we have invested heavily in our manufacturing capabilities to increase access to high-quality raw materials and ensure a robust supply chain.

Our state-of-the-art, 61,000-square-foot animal-free manufacturing facility in St. Paul, MN, USA, is designed with your needs in mind. It features advanced manufacturing and quality control technologies, supported by our expertise in protein development.

Production takes place in ISO 5/7/8 cleanrooms, adhering to RUO, Medical Device standard (ISO 13485), and Ancillary Material grade GMP standards (USP<1043>, E.Ph 5.2.12), maintaining the highest levels of cleanliness and quality.

Our facility ensures continuous and robust raw material supplies essential for your cell therapy development, supporting your needs through clinical trials and into therapeutic manufacturing.



## Take a Virtual Tour of Our GMP Facility

Scan the QR Code or Visit:

[bio-techne.com/gmp-facility-tour](https://bio-techne.com/gmp-facility-tour)



## Learn More

Scan the QR Code or Visit:

[bio-techne.com/gmp-manufacturing-facility](https://bio-techne.com/gmp-manufacturing-facility)



Bio-Techne has been a world leader in cytokine development dating back to the 1980s with R&D Systems. Our experienced team understands the critical applications served by these proteins. This facility, the people, the processes, and the products were all brought together with this in mind."

**Tony Person**

Vice President, Proteins Business Unit



### Animal-Free

The entire facility is dedicated to animal-free manufacturing, ensuring the highest standards of purity and safety.



### Consistent Quality

Experience lot-to-lot consistency with GMP process capabilities that prioritize patient safety and the success of your therapeutics.



### Scalability

Our facility is optimized for large-scale production, supporting the growing demand for clinical trials and future commercial therapeutics.



### Supply Chain Assurance

We ensure a reliable supply chain through all phases of commercialization. You can reserve entire lots, eliminating the need for time-consuming and costly requalification.



# Seamlessly Transition from *RUO to GMP*

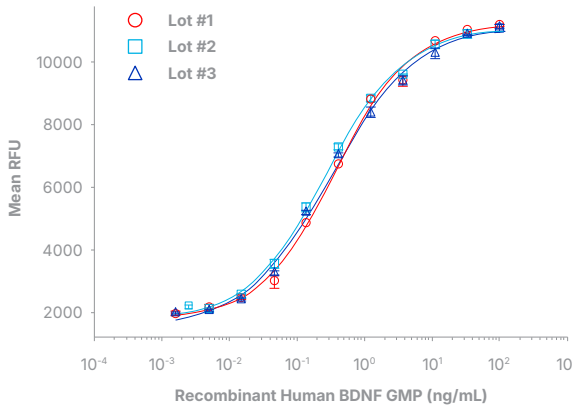
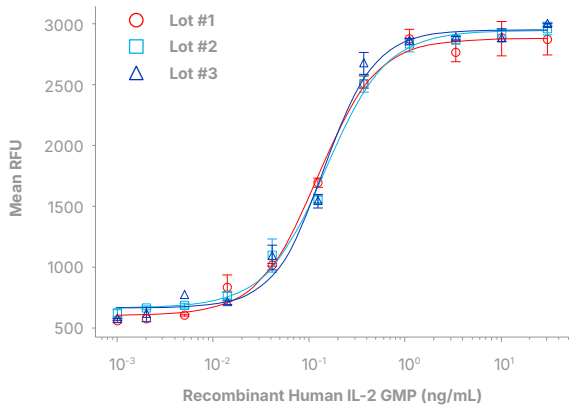
Same Vector, Same Protein, Same Process, Same Results

Experience a seamless transition from RUO to GMP with animal-free RUO and GMP-grades of *E. coli*-sourced proteins. Maintaining identical sequences, sources, formulations, activities, purities, manufacturing sites, personnel, and vial types across protein grades ensures consistent performance and process continuity as you advance toward clinical applications.

## Equivalent Bioactivity from Lot-to-Lot

Over the years, we have developed a robust quality management system and precise protocols for manufacturing recombinant proteins known for their industry-leading bioactivity, purity, and consistency.

Each new lot undergoes stringent quality control, including evaluation in a standardized bioassay and comparison against a master lot to ensure assay consistency. Lot-specific activity details are provided in each product's certificate of analysis (CoA), with additional lot-to-lot sample data available upon request.

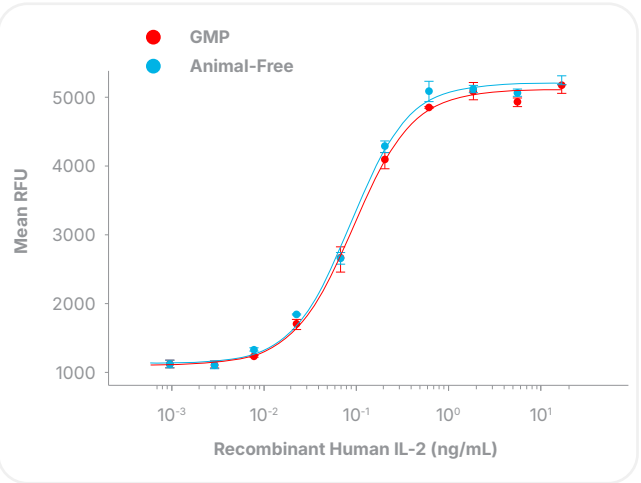
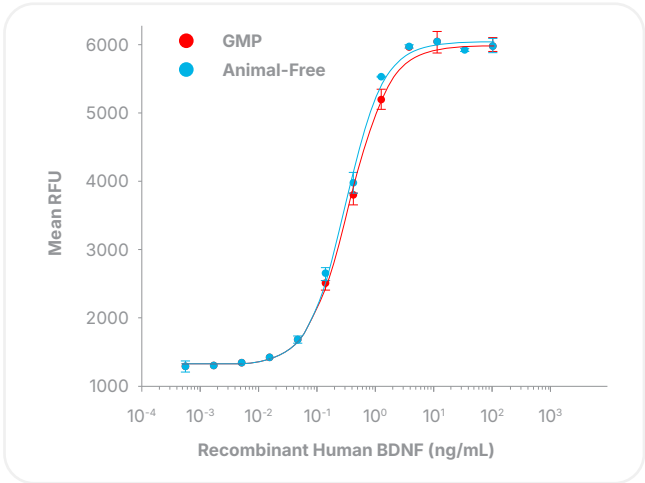


	DEVELOPMENT	PRECLINICAL	MANUFACTURING
	RUO Proteins →	Animal-Free Proteins →	GMP Proteins
Lot-to-lot consistency	●	●	●
Scalability	●	●	●
Reliable bioactivity	●	●	●
Bioburden testing to USP <61>	●	●	
Produced in the same animal-free facility		●	●
Activity reported in ED <sub>50</sub> and units		●	●
Quality assurance oversight on all batch records			●
Sterility testing to USP <71>			●
Host cell protein and host cell DNA testing			●
Drug Master Files			●



# Equivalent Bioactivity Across Animal-Free RUO and GMP-Grade Proteins

Manufacturing animal-free RUO and GMP-grade proteins using identical processes ensures both grades offer equivalent bioactivity and consistent performance.



**Simplify the Transition**  
Scan the QR Code or Visit:  
[bio-techne.com/ruo-to-gmp](https://bio-techne.com/ruo-to-gmp)

# Innovations to Simplify Your Cell Therapy Processes

We are committed to streamlining cell therapy manufacturing through ongoing innovation in products and solutions to reduce variability and embrace process scalability.

## Eliminate Reconstitution Errors with Liquid Cytokines

Enhance your cell culture efficiency with our liquid frozen formulations of animal-free RUO and GMP IL-2, IL-7, and IL-15. These ready-to-use cytokines eliminate reconstitution errors while maintaining potency and consistency comparable to lyophilized proteins. Simply thaw and add to your culture.

## Reduce Aliquoting Variability with Single-Use Process-Sized Vials

Optimize your immune cell therapy workflow with cytokines delivered in single-use, process-sized vials. Available for IL-7 and IL-15, these 10 µg vials eliminate manual touchpoints and aliquoting, reducing the risk of errors.



**Learn More**  
Scan the QR Code or Visit:  
[bio-techne.com/ready-to-use-cytokines](https://bio-techne.com/ready-to-use-cytokines)

## Custom Services

When our standard offerings don't quite fit, our custom team steps into craft solutions that meet your exact needs. Our dedicated teams, including project managers, regulatory experts, and protein scientists, ensure that the final materials meet your exact specifications, facilitating the transition from pre-clinical to clinical applications.

Our services include:

- Custom pack sizes in liquid or lyophilized forms
- Custom GMP lot manufacturing
- GMP protein conversion from Bio-Techne catalog or using your own sequence/plasmid
- Accelerated and real-time stability studies
- Drug Master File (DMF) support



**Get Started**  
Scan the QR Code or Visit:  
[bio-techne.com/services/custom-protein-services](https://bio-techne.com/services/custom-protein-services)



**01**  
Understand Your Goals



**02**  
Consult With Our Experts



**03**  
Document Milestones



**04**  
Initiate & Communicate



**05**  
Deliver Your Product or Service

# GMP Cytokines for *Immune Cell Therapy*

Protein	Animal-Free RUO	GMP	Special Formats	GMP Source
IFN-gamma	AFL285	285-GMP (DMF on file)		E.coli
IL-1 beta	AFL201	201-GMP		E.coli
IL-2*	BT-002-AFL	BT-002-GMP	Liquid ProPak Closed System	E.coli
IL-3	AFL203	203-GMP		E.coli
IL-4	BT-004-AFL	BT-004-GMP (DMF on file)		E.coli
IL-6	AFL206	206-GMP (DMF on file)		E.coli
IL-7*	BT-007-AFL	BT-007-GMP (DMF on file)	Liquid Process-Sized ProPak Closed System	E.coli
IL-10	AFL1064	1064-GMP (DMF on file)		E.coli
IL-15*	BT-015-AFL	BT-015-GMP (DMF on file)	Liquid Process-Sized ProPak Closed System	E.coli
IL-18		Coming Soon		E.coli
IL-21	BT-021-AFL	BT-021-GMP	Liquid	E.coli
TNF-alpha	AFL210	210-GMP		E.coli

\*Our IL-2, IL-7, and IL-15 cytokines are offered through our ScaleReady™ partnership for immune cell therapy manufacturing.

ScaleReady brings together the complementary strengths of Bio-Techne reagents and Wilson Wolf bioreactors to deliver rapid, cost-effective production of T cells and NK cells at scale.



**Discover ScaleReady**  
Scan the QR Code or Visit:  
[bio-techne.com/scaleready](https://bio-techne.com/scaleready)

# GMP Cytokines and Growth Factors for *Stem Cells/ Regenerative Medicine*

Protein	Animal-Free RUO	GMP	GMP Source
Activin A		338-GMP (DMF on file)	CHO
Betacellulin	BT-BTC-AFL	BT-BTC-GMP (DMF on file)	E.coli
BDNF	BT-BDNF-AFL	BT-BDNF-GMP	E.coli
BMP-2		355-GMP	CHO
BMP-4	AFL314E	314E-GMP	E.coli
EGF	AFL236	236-GMP (DMF on file)	E.coli
FGF basic/FGF2	BT-FGFB-AFL	BT-FGFB-GMP (DMF on file)	E.coli
FGF basic/FGF2 Heat Stable	BT-FGFBHS-AFL	BT-FGFBHS-GMP	E.coli
Flt-3 Ligand/FLT3L	BT-FT3L-AFL	BT-FT3L-GMP (DMF on file)	E.coli
GDF-8/Myostatin		788-GMP	NSO
GDNF		212-GMP	NSO
GM-CSF	AFL215	215-GMP	E.coli
HGF		294-GMP	NSO
IGF-I	AFL291	291-GMP (DMF on file)	E.coli
KGF/FGF-7	BT-KGF-AFL	BT-KGF-GMP	E.coli
LR3 IGF-I		8335D-GMP	E.coli
M-CSF	AFL216	216-GMP	E.coli
Noggin Fc tag		3344-GMP	NSO
PDGF-AA	AFL221	221-GMP	E.coli
PDGF-BB	AFL220	220-GMP	E.coli
SCF/c-kit Ligand	BT-SCF-AFL	BT-SCF-GMP (DMF on file)	E.coli
Sonic Hedgehog (C24II) N-Terminus	AFL1845	1845-GMP	E.coli
Sonic Hedgehog N-Terminus		1314-GMP	E.coli
TGF-beta 1		240-GMP (DMF on file)	CHO
Thrombopoietin	BT-TPO-AFL	BT-TPO-GMP	E.coli
VEGF	BT-VEGF-AFL	BT-VEGF-GMP (DMF on file)	E.coli
Wnt-3a		5036-GMP	CHO

### Successfully Scale Toward Commercialization

In addition to GMP proteins, we offer a comprehensive range of solutions for cell and gene therapy development and manufacturing, including GMP small molecules and GMP cell culture media.



**Explore Solutions**  
Scan the QR Code or Visit:  
[bio-techne.com/cgt](https://bio-techne.com/cgt)



**Find Out More & Request a Sample**  
Scan the QR Code or View:  
[bio-techne.com/gmp-proteins](https://bio-techne.com/gmp-proteins)

## Contact Us

**Global** [info@bio-techne.com](mailto:info@bio-techne.com), [bio-techne.com/find-us/distributors](https://bio-techne.com/find-us/distributors)

**North America** TEL 800 343 7475

**Europe // Middle East // Africa** TEL +44 (0)1235 529449

**China** [info.cn@bio-techne.com](mailto:info.cn@bio-techne.com), TEL 400.821.3475

For research use or manufacturing purposes only. Trademarks and registered trademarks are the property of their respective owners.  
6458962046\_032725



Global Developer, Manufacturer, and Supplier of High-Quality Reagents,  
Analytical Instruments, and Precision Diagnostics.

**INCLUDES** R&D Systems™ Novus Biologicals™ Tocris Bioscience™ ProteinSimple™ ACD™ ExosomeDx™ Asuragen™ Lunaphore™