

# GMP Grade Cytokines

**Strict Quality Control Standards**

**GMP Grade Quality Management System**

**Accelerating Global Regulatory Approval of Biological Products**

## GMP Grade Cytokines

Immune cell therapy, represented by CAR-T\NK cells has shown significant therapeutic effects in the treatment of various malignant tumors such as leukemia, lymphoma, and multiple myeloma. As more and more immune cell therapies enter the stage of clinical research, quality management systems have attracted more attention from the industry. During the process of immune cell therapy products, cytokines such as IL-15, IL-7, IL-21 are used as a key raw material for T\NK cell activation and amplification. FDA and Chinese Pharmacopoeia have relevant regulations about the use of these key materials. The FDA CMC recommends using FDA-approved or clinical-grade materials. For Chinese Pharmacopoeia regulations, priority should be given to the use of low-risk materials such as GMP grade materials as opposed to non-GMP grade materials. Therefore, safe, effective, and compliant cytokines are crucial for the success of R&D processes and applications of immune cell therapy drugs.

**ACROBiosystems is committed to the development of high-quality reagents that are used in the clinical stage of immune cell therapy drugs. Based on the GMP-grade quality management system platform, combined with the production specifications of cell therapy drugs, we have successfully developed a series of high-quality GMP-grade cytokines such as IL-15, IL-7, IL-21. These products are produced with strict quality management and drug-level release testing standards. Our GMP-grade cytokines\* can better assist the clinical research of immune cell therapy drugs and accelerate the global regulatory approval of biological products.**

\*ACROBiosystems GMP grade products are designed for research, manufacturing use, or ex vivo use. CAUTION: Not intended for human in vivo applications.

## ACROBiosystems GMP Quality Management System

### ■ Quality Management System

- ✓ Manufactured and QC tested under GMP compliance
- ✓ Fully batch production and control records
- ✓ Designed under ISO 9001:2015 and ISO 13485:2016
- ✓ Equipment maintenance and calibration
- ✓ Animal-Free materials
- ✓ Validation of analytical procedures
- ✓ Materials purchased from approved suppliers
- ✓ Stability studies conducted
- ✓ ISO 5 cleanrooms and automatic filling equipment
- ✓ Comprehensive regulatory support files
- ✓ Qualified and well-trained personnel
- ✓ .....

Automatic filling equipment



Sterilization equipment



■ **Strict quality standards** (Example for GMP IL-15 release standard)

- ✓ SDS-PAGE >95%
- ✓ Endotoxin level less than 10 EU/mg
- ✓ Residual Host Cell DNA content less than 0.02ng/μg
- ✓ Residual Host Cell Protein content less than 0.5ng/ug
- ✓ Biological activity >0.8 x 10<sup>7</sup> IU/mg  
(Reference the WHO Human IL-15 (NIBSC code: 90/530) as standard)
- ✓ Microbial testing
- ✓ Mycoplasma testing
- ✓ In vitro virus assay
- ✓ Comprehensive stability data support  
(accelerated, freeze-thaw, long-term, shipping stability verification)
- ✓ Batch-to-batch consistency
- ✓ .....

**Product Features**

**Strict Quality Control Standards** 🏆

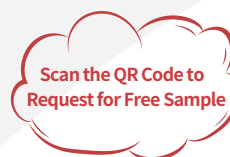
16 quality control standards  
 Excellent Safety Profile  
 (testing for sterility, mycoplasma, endotoxin, and residual impurities).  
 High stability and batch-to-batch consistency

**GMP Grade Quality Management System** 🏆

ISO 5 cleanrooms used for filling  
 Raw materials and packing materials are registered  
 Facilities are available for online and on-site audits

**Accelerating Global Regulatory Approval of Biological Products** 🏆

A comprehensive set of regulatory documents is available  
 Validation reports for analysis methods are available by request  
 FDA DMF filing in progress



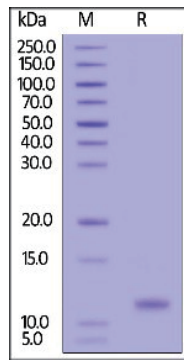
**Product list**

Molecule	Product description	Cat.No.
IL-15	GMP-L15H13	GMP Human IL-15
IL-7	GMP-L07H24	GMP Human IL-7
IL-21	GMP-L21H25	GMP Human IL-21

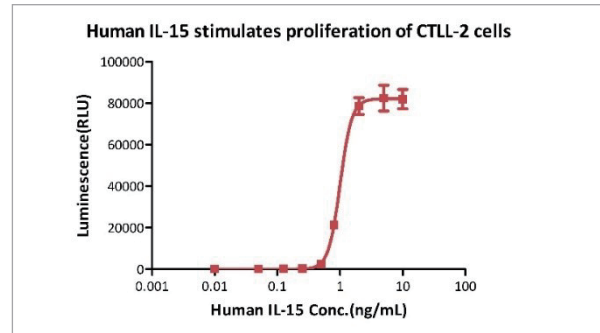
**Data**

► **High purity**

High purity than 90% of GMP Human IL-15



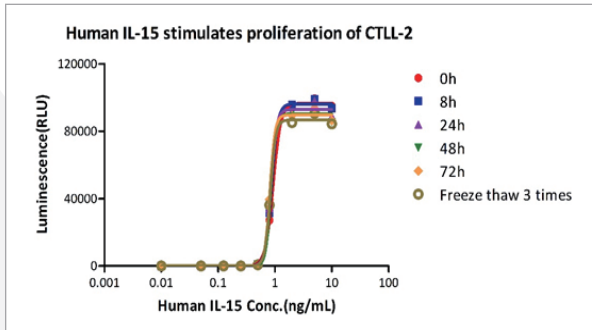
► **High bioactivity**



GMP Human IL-15 (Cat. No. **GMP-L15H13**) stimulates the proliferation of CTLL-2 cells. The EC50 for this effect is 1.004 ng/mL, corresponding to a specific activity of  $> 0.8 \times 10^7$  IU/mg, which is calibrated against human IL-15 WHO International Standard (NIBSC code: 95/554).

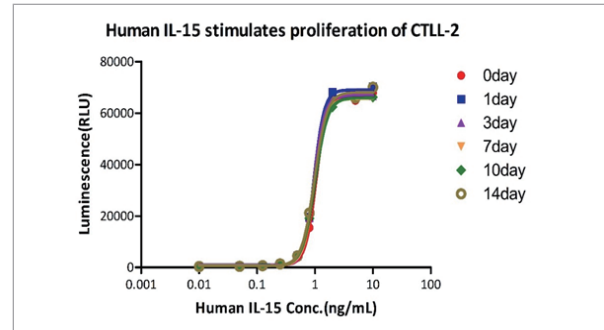
► **High stability**

Validation of Accelerate and Freeze-thaw stability



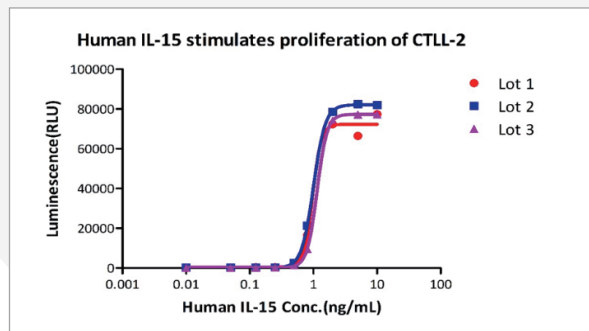
GMP Human IL-15 (**GMP-L15H13**) is stable in undiluted samples at 25°C for 72 hours and freeze-thaw 3 times without performance reduction.

Long-term stability testing (4°C)



GMP Human IL-15 (**GMP-L15H13**) is stable in undiluted samples at 4 °C for 14 days without performance reduction.

► **High batch-to-batch consistency**



Bioactivity of three different lots of GMP Human IL-15 (**GMP-L15H13**) verified by cell-based assay, and the result shows very high batch-to-batch consistency.

**Her2 BAFFR IL-7**  
**Fc Receptor Siglec-10**  
**Biotinylated Protein**  
 PD-L1 VEGF165 CD3 epsilon  
**CD20 PD-1 BCMA**  
**CD27 PVRIG**  
**CD47 PSMA**  
**CFGL1 TFPI**  
**Siglec-15 Integrin**  
**CD24 CD3E & CD3D IL-21**  
**CD19 FcRn PCSK9**  
**IL-2 R alpha**  
**CAR-T Target Protein**  
**Biotinylated Protein**  
**BCMA CD200 GITR Nectin-4**  
 VEGF165 PCSK9 IgG1 Fc CD40 **IL-15** Nectin-4 PD-L1 PSMA  
 SIRP alpha ADA Service **IL-2**  
 Nectin-4 Biotinylated Protein CD3E & CD3D Immune Checkpoint Protein  
**SPR /BLI analytical service**  
**Glypican 3 Integrin**  
**ADA Service** CD69 **MICA** **CD20**  
**LAG-3** EGF R B7-H3 BCMA CD30 **CD3E & CD3D**  
**Integrin** TIGIT TGF-beta 1 **CD20**  
**4-1BB Siglec-15**

