



# Protein & Antibody Drug CDMO Service

Developing Complex Molecules Easily



## GenScript ProBio

- Global CDMO in biologics and advanced therapies
- Leader in complex molecule development
- We provide premium end-to-end service from discovery to commercialization with professional solutions and efficient processes

**90+**

protein & antibody  
CMC/CMO projects

**30+**

IND clearances

**4**

biologics or medical  
devices launched



**Pass EU QP audition**

**Biologics Manufacturing  
License**

## Developing Complex Molecules Easily

### Quality Built From the Very Beginning

- Antibody lead generation & lead optimization with strong track record
- Broad selection of In vitro / in vivo pharmacology service
- Developability assessment & optimization

### Breakthrough to Next Levels of Productivity

- Proprietary cell line platform capable to achieve 14.5g/L<sup>#</sup>
- Process optimization achieved up to 70% reduction in manufacturing cost
- Less than \$100/g\* of mAb

### Expertise in Proteins & Bispecifics

- Extensive experience in natural proteins, fusion proteins, symmetric bsAb & asymmetric bsAb
- ProBox™ platform for CQA modification and troubleshooting
- Flexible manufacturing scale from 25L to 2000L



<sup>#</sup> Data by Dec. 2023

\*DS unit price (a. Fed batch process in 2000L SUB, b. 7g/L, 70% yield, c. annual batch number ≥ 20 batches) , including FFS and material cost


## Quality Built From the Very Beginning

GenScript ProBio's cutting-edge biologics discovery platform & developability platform deliver biologics candidate of high quality




**1800+**  
antibody discovery projects





**15+**  
projects in clinical trials and above





Most advanced projects are marketed



### 3 Technical Campaigns to Get Leads with Good Qualities

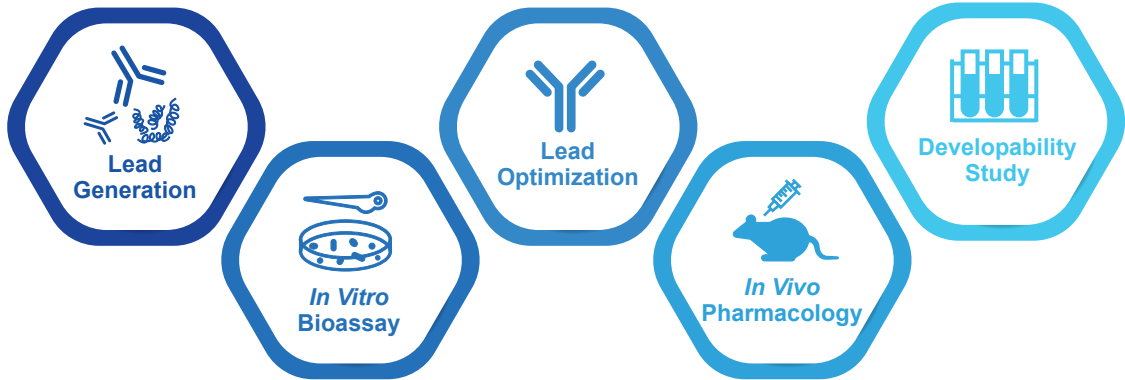
- Proprietary hybridoma platform
- ProSpeed™ single B cell screening
- Diversified library for both conventional antibody & sdAb

### Optimize Antibody from Developability and Functionality

- Ab humanization
- Ab affinity maturation
- Fc engineering
- Developability optimization

### Developability Platform to Guide CMC Strategy

- Colloidal stability study
- Molecular integrity study
- Stressed stability (high temperature, low pH, freeze and thaw)



### Comprehensive Cell-based Assays to Narrow Down Leads

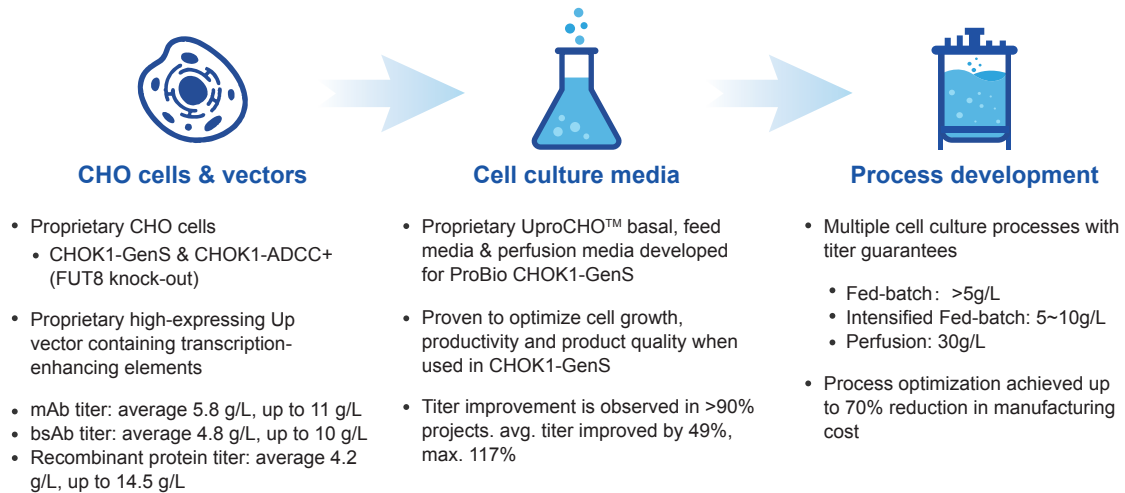
- Bioassay of mAb-Fab/Fc domain
- Bispecific Ab assay
- ADC assay
- CAR-T/NK assay, etc.

### In Vivo Pharmacology Platform to Select Final Candidate

- Pharmacodynamics
- Pharmacokinetics
- Toxicology

## Breakthrough to Next Levels of Productivity

GenScript ProBio's high-expressing, robust and well-proven cell line and process technology ecosystem enables titer as high as 14.5g/L and saves up to 70% COGS

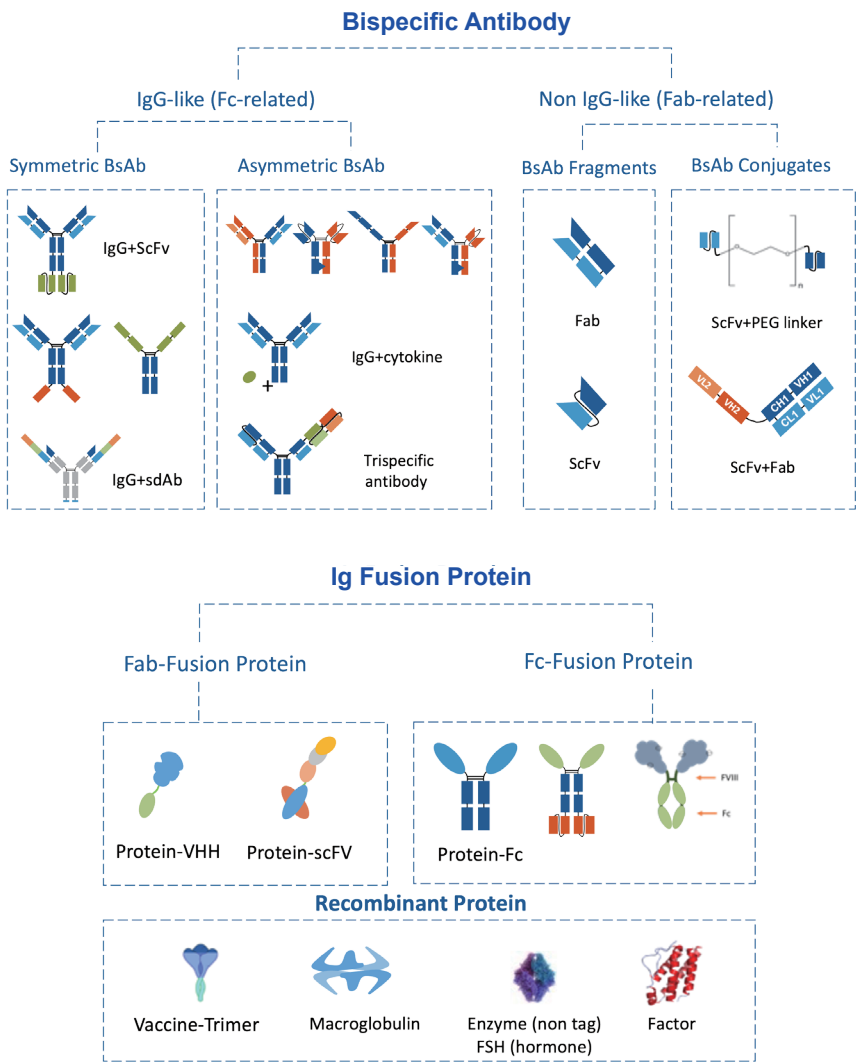


# Expertise in Proteins & Bispecifics



- ~50% projects delivered are proteins & bispecific antibodies
- Platform process for proteins & bispecifics
- Small to large scale DS GMP manufacturing capacity for proteins & bispecifics
  - 25L, 50L, 80L, 100L, 200L, 500L, 2000L
- IND clearances for multiple complex modalities: Factor VIII, cytokines, fusion proteins, antibody fragment, KIH, Duobody, scFv fused to IgG, etc.
- In-house process development intelligence database ProBox™ to empower new projects
- In-house cell line engineering team to develop assay cell line and bioassay according to MOA

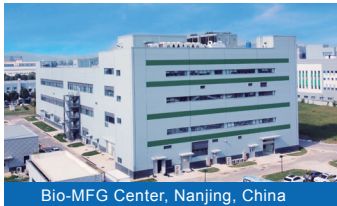
## Protein & Bispecifics Delivered by GenScript ProBio



# IND-to-BLA GMP Manufacturing Facilities of Global Quality Standard



Bio-R&D Center, Nanjing, China



Bio-MFG Center, Nanjing, China

## Nanjing GMP Manufacturing Capacity

- Drug substance manufacturing **2,800L**:  
**6×200L & 3×500L** single-use bioreactors
- Fill and finish line: vial/PFS/lyo/nasal spray
  - **0.3-20mL** high-precision filling



Commercial MFG Center, Zhenjiang, China

## Zhenjiang GMP Manufacturing Capacity

- Drug substance manufacturing **17,250L**:  
**8×2,000L** single-use bioreactors
- Fill and finish line: vial/lyo
  - Up to filling **17** million vials/year
  - **0.3-20mL** high-precision filling



Pass EU QP audit with zero observation



150+ customer audit



NMPA drug manufacturing license



PAI from BPOM (Badan Pengawas Obat dan Makanan, Indonesia FDA)

# GenScript ProBio Protein & Antibody Drug CDMO Service

### Pre-clinical/ Development



- Cell Line Development Service
- IND-enabling CMC service
  - Fed-batch
  - Perfusion

### Early Stage Clinical



- 200~500L Scale Clinical Manufacturing
- Pilot Scale Fill and Finish
  - Liquid
  - Lyophilized powder
  - PFS

### Late Stage Clinical/ Commercialization



- Process Optimization
- Process Characterization, Process Validation
- 2000L Scale Commercial Manufacturing
- Commercial Scale Fill and Finish





## Contact us

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