

ProBio

Protein & Antibody Drug CDMO Service

Developing Complex Molecules Easily



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

100+

protein & antibody
CMC/CMO projects

50+

IND clearances

4

biologics or medical
devices launched

6

ProBio supports partners
in the license-out projects
(including 2 projects
with buyers from MNCs)



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 15g/L#
- 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



Data by Dec. 2024

*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

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

2000+
antibody discovery projects

17+
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

ProBio's high-expressing, robust and well-proven cell line and process technology ecosystem enables titer as high as 15g/L and saves up to 70% COGS



CHO cells & vectors

- Proprietary CHO cells
 - CHOK1-GenS & CHOK1-ADCC+ (FUT8 knock-out)
- Proprietary high-expressing Up vector containing transcription-enhancing elements
- mAb titer: average 5.7 g/L, up to 15 g/L
- bsAb titer: average 6.7 g/L, up to 10 g/L
- Recombinant protein titer: average 4.6 g/L, up to 14.5 g/L



Cell culture media

- Proprietary UproCHO™ basal, feed media & perfusion media developed for ProBio CHOK1-GenS
- Proven to optimize cell growth, productivity and product quality when used in CHOK1-GenS
- Titer improvement is observed in >90% projects. avg. titer improved by 49%, max. 117%



Process development

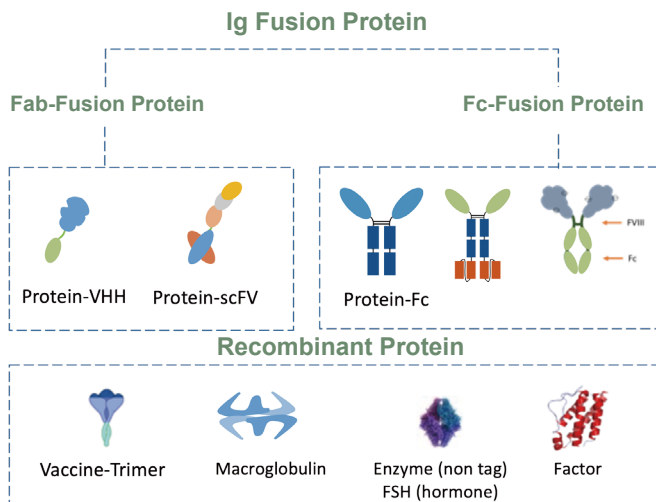
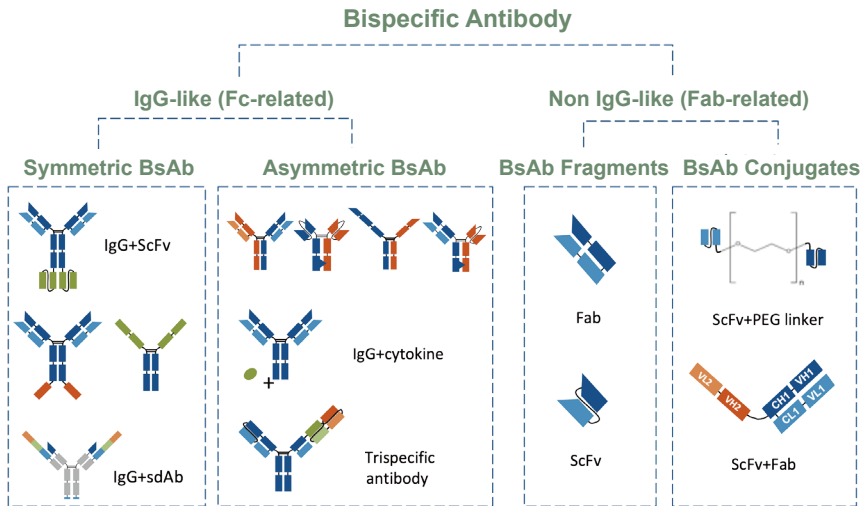
- Multiple cell culture processes with titer guarantees
 - Fed-batch: >5g/L
 - Intensified Fed-batch: 5~10g/L
 - Perfusion: 30g/L
- Process optimization achieved up to 70% reduction in manufacturing cost

Expertise in Proteins & Bispecifics



- ~50% projects delivered are proteins & bispecific antibodies
- IND clearances for multiple complex modalities: Factor VIII, cytokines, fusion proteins, antibody fragment, KIH, Duobody, scFv fused to IgG, etc.
- Platform process for proteins & bispecifics
- 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
- Small to large scale DS GMP manufacturing capacity for proteins & bispecifics
 - 25L, 50L, 80L, 100L, 200L, 500L, 2000L

Protein & Bispecifics Delivered by 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 **17,200L**:
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 4 times

- 170+ customer audit

- NMPA drug manufacturing license

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

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

Website :

www.probiocdmo.com

Tel:

+1-732-885-9188 (US)

+86-400-025-8686-3172 (CN)

Address :

ProBio Inc. Building 9, 311 Pennington Rocky Hill Rd,
Pennington, NJ 08534