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

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 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 June 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

1900+ antibody discovery projects

15+ projects in clinical trials and above

Most advanced projects are marketed

3 Technical Campaigns to Get Leads with Good Qualities

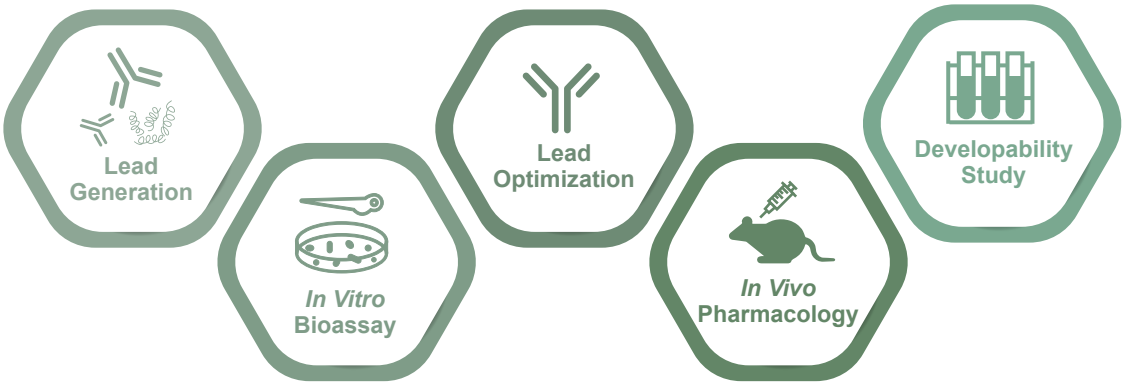
- Proprietary hybridoma platform
- ProSpeed™ single B cell screening
- Diversified library for both conventional antibody & sdAb

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

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

Data by June 2024

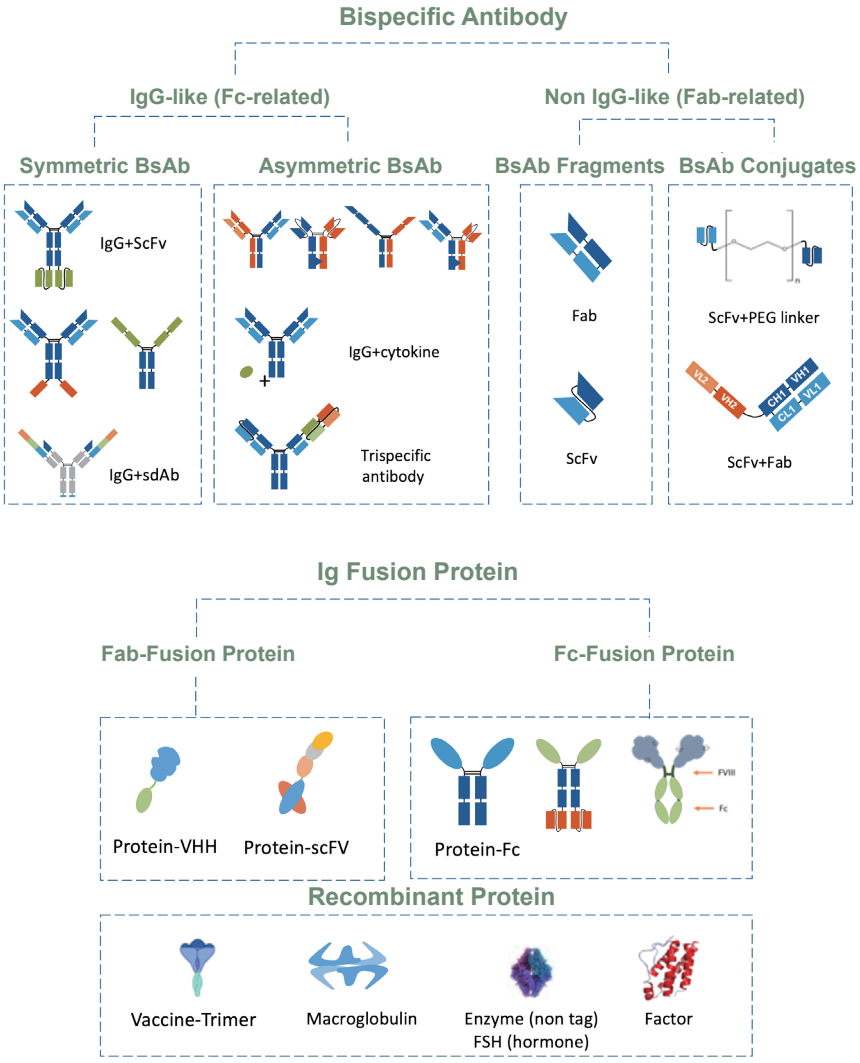
Expertise in Proteins & Bispecifics

- ***~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 **17,250L**: **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)**

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

Data by Dec. 2023

Contact us

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