

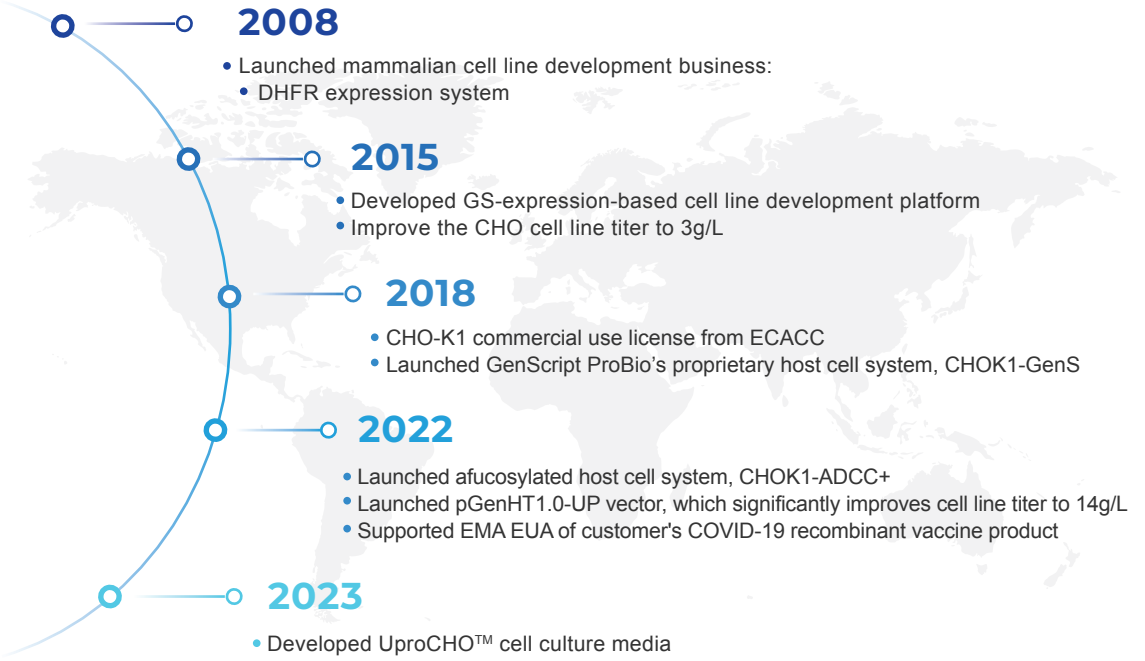


Cell Line Development Solutions for Biomanufacturing

Break through to next level of productivity

- GenScript ProBio high-expressing cell line technology ecosystem
- Stable cell line development
- ADCC-enhanced cell line development
- Service solutions and technology licenses

Introduction of GenScript ProBio Cell Line Business



GenScript ProBio has built up a high-expressing, robust and well-proven cell line technology ecosystem. It is consisted of our proprietary CHO cell lines, CHOK1-GenS & CHOK1-ADCC+, high-expression vectors, proprietary media systems and high-throughput and automated clone screening system.

To date, we have constructed more than 180 stable cell lines for IND filing using our cell line platform and process.

16+

Years of experience in CLD

180+

Cell line projects for IND filing

30+

Projects in clinical phase

3+

Projects marketed

CHO cells originated from ECACC and further developed by GenScript ProBio:
CHOK1-GenS
CHOK1-ADCC+

High-expression vectors with transcription-enhancer element:
pGenHT 1.0-UP
pGenHT 1.0-DGV

UproCHO™ proprietary media systems developed for ProBio host cell

High-throughput & automated screening platform

GenScript ProBio's cell line technology ecosystem

Statistics by Dec. 2023

ProCLD Cell Line Development



Superior Productivity

- mAb titer: average 5.8 g/L, up to 11 g/L
- bsAb titer: average 4.8 g/L, up to 10 g/L
- Recombinant protein titer: average 4.2 g/L, up to 14.5 g/L



Industry-leading Timeline

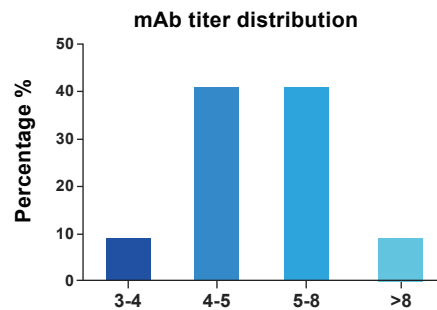
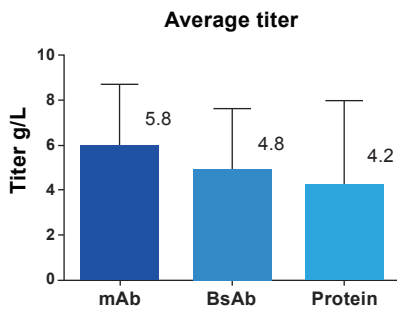
- 8 weeks from transfection to PCB
- 12 weeks from gene synthesis to PCB



Tool Boxes for Complex Molecules

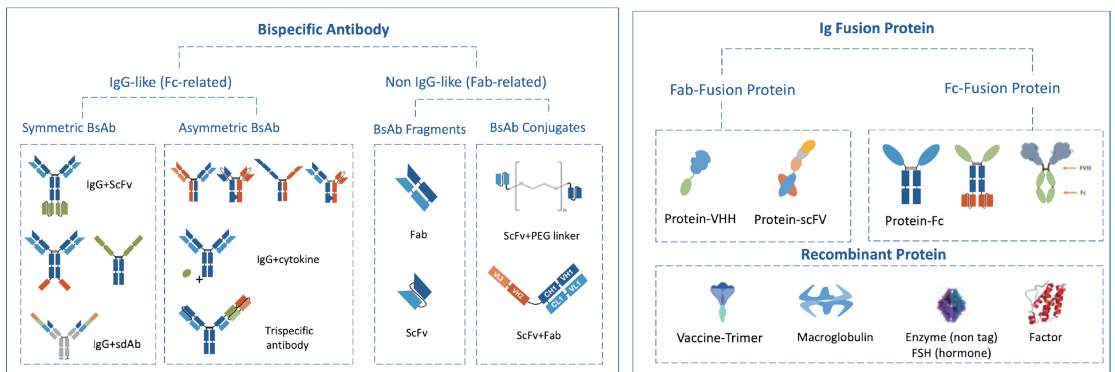
- Bispecifics: Optimize plasmids ratio / culture duration / cell culture media, to improve titer and quality, and reduce mismatches
- Proteins: Tool boxes in clone screening to adjust glycotype and PTMs

GenScript ProBio delivers cell lines with superior productivity



* The titers before process development
Statistics by Dec. 2023

GenScript ProBio has vast experiences in cell line development of complex molecules



Cell Line Development for Afucosylated Antibodies

Antibody-dependent cellular cytotoxicity (ADCC), is a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell. It is important in the efficacy of cancer antibodies, but with many approved cancer antibodies there is less ADCC than could be desired due to nonspecific IgG competing with the drugs for binding to FcγIIIa (CD16a) on natural killer cells (NK cells). Afucosylated antibodies overcome this problem through improved FcγIIIa binding.

GenScript ProBio has developed ADCC-enhanced host cell line (CHOK1-ADCC+), which can produce afucosylated antibodies with enhanced ADCC activity.



Proprietary ADCC-enhanced CHO cell line with no IP issue

- In-house developed FUT8 knockout CHO cell line
- Free to operate



Fast Sample Preparation / Cell Line Development for Different Applications

- Gene synthesis to purified afucosylated antibodies in 4 weeks
- Gene synthesis to top 6 clones in 12 weeks
- Gene synthesis to top 1 clones in 16 weeks

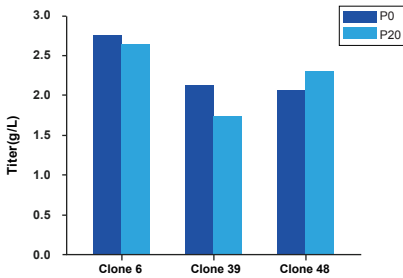


5 Analytical Methods Available for ADCC Effect Evaluation

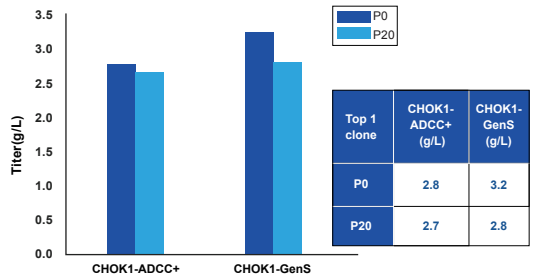
- For glycan profiling: LC-MS & HPLC
- For ADCC potency evaluation: affinity measurement to Fcγ Receptor (CD16a), reporter gene assay, PBMC-based assay

CHOK1-ADCC+ Case Study

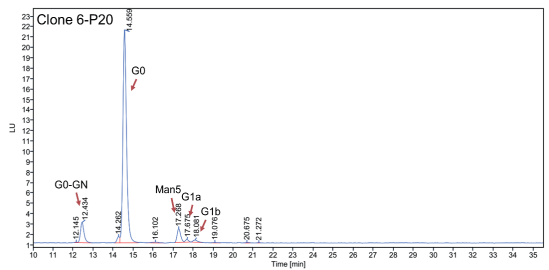
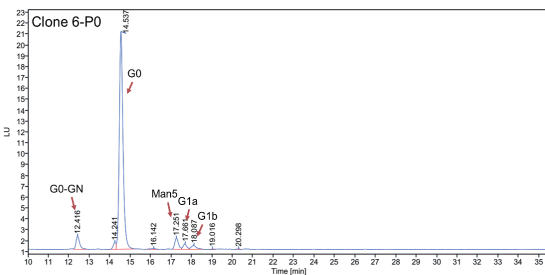
CHOK1-ADCC cell line shows great performance in stability



CHOK1-ADCC shows similar performance in productivity as compared to CHOK1-GenS (top 1 clone)



The antibody was successfully afucosylated by using CHOK1-ADCC+
No differences in glycoforms were observed between P0 and P20 samples



ProBio Cell Line Development Services

We provide 4 stable-expression-based services to meet the different needs in discovery and preclinical development stage.

	ProGram	PreCLD	ProCLD	ProCLD plus
Service content	Fast sample preparation	Cell pool development	Cell line development	Cell line development clone evaluation
Timeline	4 weeks	9 weeks	12 weeks	16 weeks
Deliverables	Target protein, ROA	4 cell pools	6 PCBs	Top 1 clone
Application scenarios	Late discovery stage	Late discovery stage	Preclinical CMC stage	Preclinical CMC stage
Applications	Determine CMC candidate Developability assessment	Determine CMC candidate Developability assessment Proceed to a stable cell line	IND	IND

ProBio Cell Line Platform License

In addition to cell line development services, we also offer the option of cell line platform license to pharma & biotech customers for regulatory filing and biomanufacturing of human and animal drugs.

The features of our cell line platform license model are summarized as below:

- Lum-sum payment
- Royalty-free
- No clinical & product launch milestone payment
- Incentives for GMP manufacturing in GenScript ProBio

Platform License Package	
Host system	CHOK1-GenS /CHOK1-ADCC+ cell line Proprietary pGenHT 1.0-DGV vector
Full Traceability Documentation	Adaptation report cGMP cell banking report cGMP cell bank testing report Vector synthesis report Vector map and key element description
Detailed Protocols and Guidance	Cell line development & cell culture protocol Clone strategy

Contact us

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