

Fast CMC Service

- For mAb: 6 months from Sequence to Tox batch completion
- For bsAb: 7 months from Sequence to Tox batch completion

Up until Dec. 2023, GenScript ProBio has undertaken **>90** CMC projects and successfully helped customers obtain **33** global IND clearances. Most advanced Fast CMC project delivered has obtained IND clearances from FDA and NMPA.

33 IND

GenScript ProBio Fast CMC Service Features

Fast to Clinic

- For mAb: **6 months** from Sequence to Tox batch completion
- For bsAb: As fast as **7 months** from Sequence to Tox batch completion

ProBox™ Process Development Tool Box

- In-house cross-module database including **200+** technical challenges & solutions
- Reduce mismatches, impurities, degradation, aggregation, etc., and significantly increase expression and yield

CHO-K1 Hostcell License

- Wide type CHOK1-GenS and ADCC enhanced CHOK1-ADCC+ cell license to be chosen
- Combo license at discounted price
- Royalty free

GenScript ProBio GMP Manufacturing Capabilities



Zero-Crossover Production Lines

- Unidirectional flow design
- Physical segregation of production lines



2,800L GMP Manufacturing Capacity

- 6X200L & 3X500L bioreactors, 104 batches per year
- Fully-automatic fill and finish line (liquid, lyo, PFS, nasal spray), 110 batches per year



cGMP Quality System

- Comply with the regulations of FDA/EMA/NMPA
- Pass EU QP audit with zero observation
- A NMPA Drug Manufacturing Certificate

Current

Bio-R&D Center, Bio-MFG Center,
Nanjing, China
2, 800L GMP manufacturing capacity

2024 Q1

Commercial MFG,
Zhenjiang, China
17, 250 L GMP manufacturing capacity



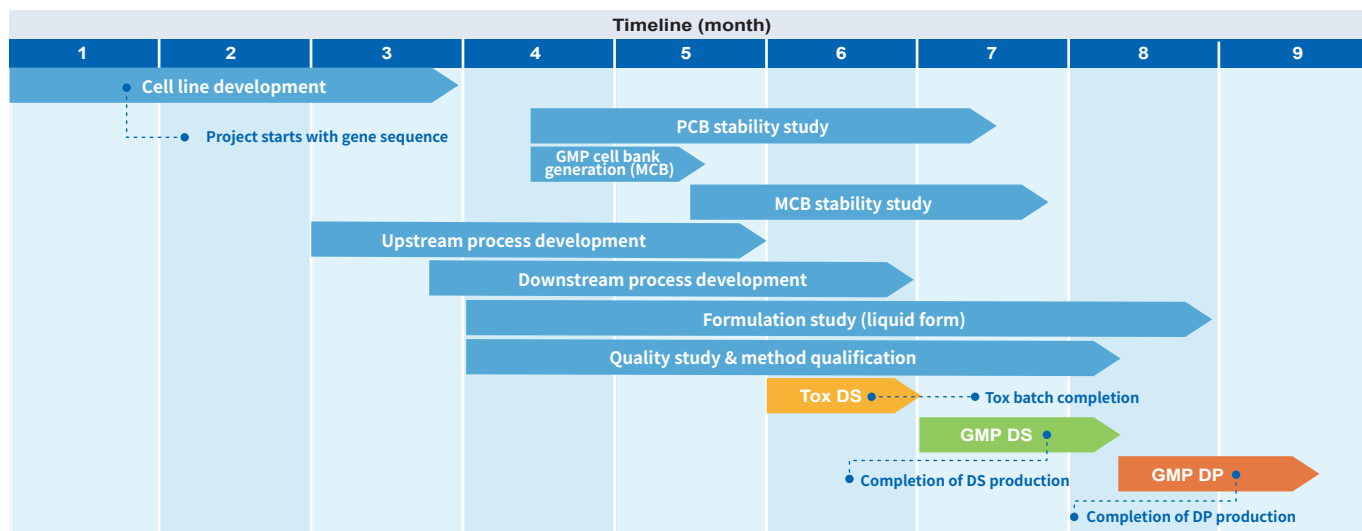
Fast CMC Workflow and Strategy

mAb Fast CMC

✓ 6 months from Sequence to Tox batch

✓ Guaranteed to deliver minimum GMP drug substance: 0.5kg/200L or 1.2kg/500L

*If the timeline is overdue or fail to reach 1.2kg/500L or 0.5kg/200L, the contract price will be discounted.

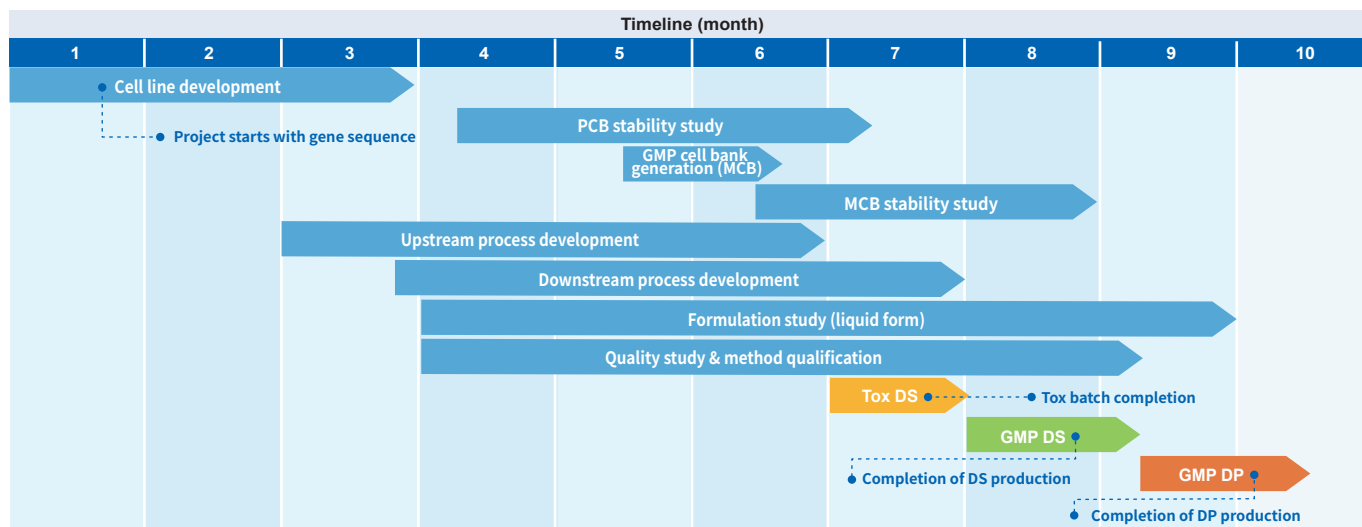


*Applicable conditions: 1.For IgG1 & IgG4 ; 2.Applicable to liquid form; 3.Available or transferrable bioassay;

bsAb Fast CMC

✓ Guaranteed 7 months from Sequence to Tox batch for symmetric bsAb

*If the timeline is overdue, the contract price will be discounted.



*Applicable conditions: *1.For IgG1 & IgG4; 2.Applicable to liquid form; 3.Final DP concentration less than 30mg/ml;

Contact us

Website:

www.genscriptprobio.com

Tel:

+1-732-885-9188 (US)

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

Address:

No.28, Yongxi Road, Jiangning Science Park, Nanjing City,
Jiangsu Province, China

Email:

USA: cdmo.us@genscriptprobio.com

China: cdmo.cn@genscriptprobio.com

APAC: cdmo.apac@genscriptprobio.com

Europe: cdmo.eu@genscriptprobio.com

Japan: cdmo.jp@genscriptprobio.com

South Korea: cdmo.kr@genscriptprobio.com