GenScript PROBIO

www.genscriptprobio.com

ProIND Fast CMC Service for mAb

- **6 months from DNA to Tox batch delivery**
- **Guaranteed to deliver minimum GMP drug substance: 0.5kg/200L or 1.2kg/500L**

Up until Mar. 2022, GenScript ProBio has undertaken >50 CMC projects and successfully helped customers obtain 15 global IND clearances.

15 IND

GenScript ProBio service features

Fast to Clinic

- ***6*** months from DNA to Tox batch delivery
- ***8*** months to GMP batch ready
- ***12*** months from DNA to IND

High quality delivery

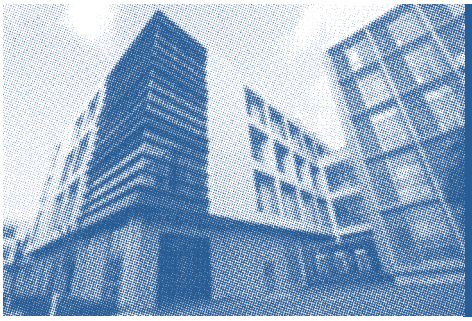
- Guaranteed to deliver minimum GMP drug substance: ***0.5kg/200L or 1.2kg/500L***

CHO-K1 host cell license

2 cell lines:
- wild-type CHO-K1
- ADCC-enhanced CHO-K1

Accessible commercial license
- Royalty-free
- Direct sublicense from ProBio

Proprietary pGenHT 1.0-DGV expression vector



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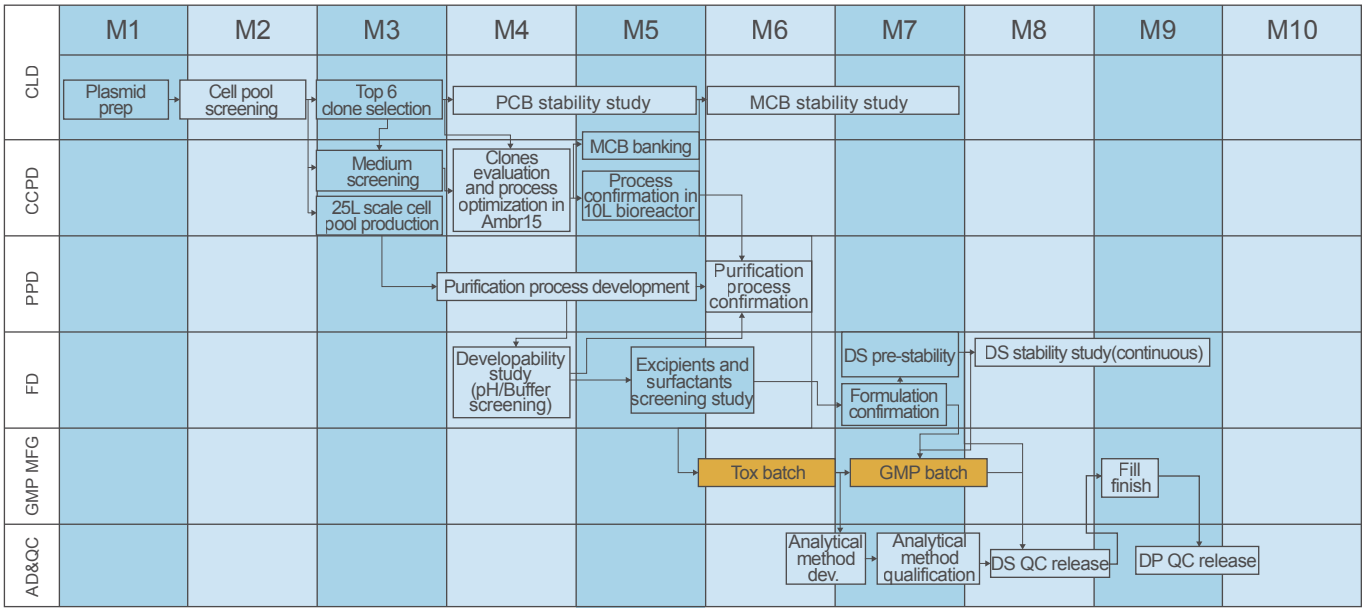
Fast CMC workflow and strategy



Terms and conditions of Fast CMC:

If **the titer in the cell pool stage does not reach 2g/L,** the Client has the right to terminate the Work Order. If terminated at this decision gate, the amount paid by Client under the Work Order will be fully refunded. Or the Client choose to continue the project.

If the **timeline* from gene synthesis to Tox* batch delivery is more than 6 months.** Or in the case of excluding the samples used for viral clearance validation and other reserved samples, **drug substance dose not reach 0.5kg each 200L GMP production (drug substance dose not reach 1.2kg each 500L GMP production),** which is applicable or are both applicable, the customer will have discounts.

GenScript ProBio GMP manufacturing site

2,600L GMP Manufacturing Capacity

- 8X200L & 2X500L Bioreactors, 104 batches per year
- Fully automatic fill and finish line (liquid, lyo, PFS), 110 batches per year

Zero-Crossover Production Lines

- Unidirectional flow design
- Physical segregation of production lines

cGMP Quality System

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

Current
Bio-MFG Center, Nanjing, China
2,600L GMP manufacturing capacity

Nov. 2022
Bio-MFG Center, Nanjing, China
Launch fill and finish line

2023 Q4
Commercial MFG, Zhenjiang, China
16,000L GMP manufacturing capacity

PROIND FAST CMC SERVICE FOR MAB