

ProIND Fast CMC Service for mAb

6 months from DNA to Tox batch delivery
12 months from DNA to IND

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

- **4-8g/L** titer in upstream process development
- **70%** average recovery rate in downstream process development

CHO-K1 host cell license

2 cell lines:

- wild-type CHO-K1
- ADCC-enhanced CHO-K1 (coming soon)

Accessible commercial license

- Royalty-free
- Direct sublicense from ProBio

Proprietary pGenHT 1.0-DGV expression vector

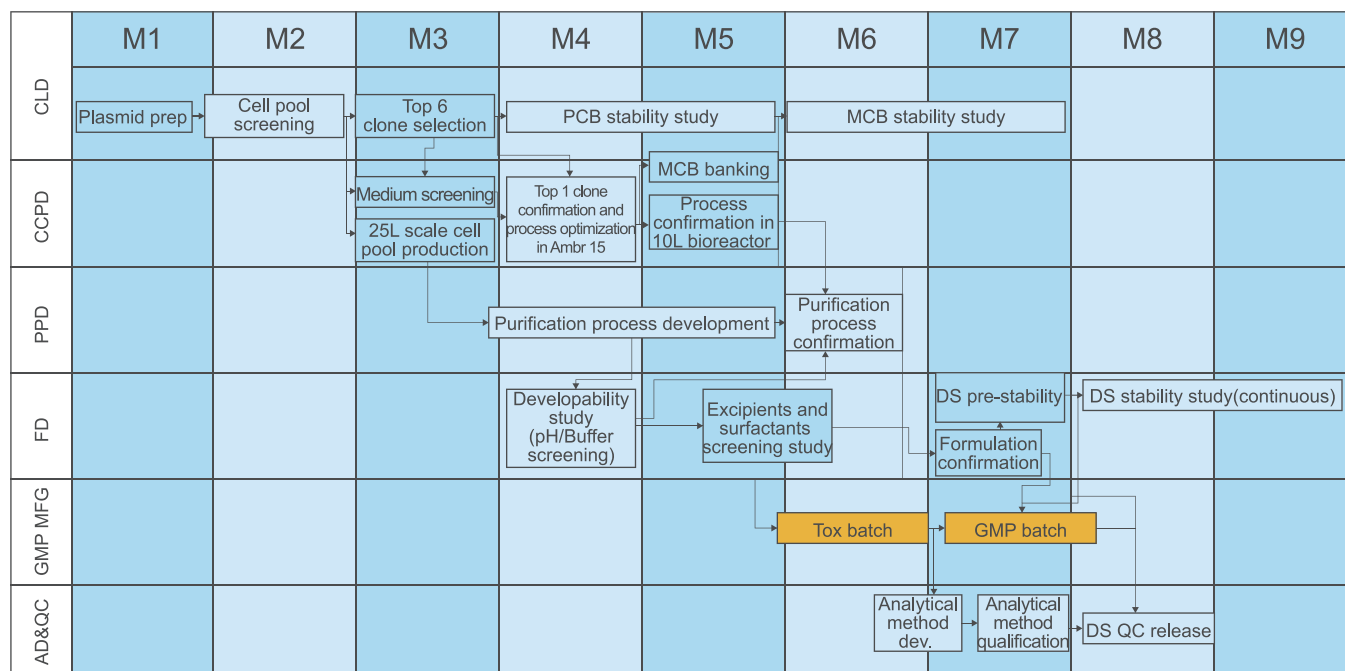


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Fast CMC workflow and Strategy



 **Cell Pool Samples**
 **CCPD/PPD/FD in parallel**
 **Platform Approach**

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