

BIOLOGICS CDMO

We are ChemPartner, a life science CRO/CDMO and experts in innovative pharmaceutical research, providing services for pre-clinical R&D, biologics CMC, and biologics commercial manufacturing. We transition your projects seamlessly from discovery to biologics CMC development and cGMP manufacturing in support of overall IND and NDA application and beyond.

Our one-stop service covers stable cell line development, process development and GMP production from cell culture, purification, and aseptic filling and lyophilization at pilot-scale. We fulfill biologics production demands for our global clients during Clinical Phase III and Commercial Launch and act as the positive role for the Marketing Authorization Holder (MAH).

CMC DEVELOPMENT

- Developability
- Cell line development, banking, and stability
- Cell culture process
 development
- Purification process development
- Formulation development
- Freeze -drying process
 development
- Analytical development and qualification

PILOT-SCALE MANUFACTURING

- 200L, 250L, 500L DS GMP manufacturing
- DP GMP manufacuring (Liquid/ Lyo)
- Release testing of DS and DP
- Protein characterization
- Comparability study
- Stability study
- IND dossier authorship

TECH TRANSFER AND SCALE-UP

- Process transfer
- Analytical transfer
- Process optimization scale-up
- 500L, 2000L GMP manufacturing
- Process/product comparability
- Post IND amendment
- authorship
- Regulatory services

LATE-STAGE CMC AND COMMERCIAL MANUFACTURING

- Process characterization
- Process validation
- PPQ manufacturing
- BLA dossier authorship
- 500L, 2000L GMP manufacturing
- Continuous process
 improvement
- Post BLA amendment
 authorship

FACILITIES

ChemPartner has two state-of-the-art manufacturing facilities in China. The pilot-scale GMP manufacturing facility is in Shanghai and the commercial GMP manufacturing facility is located in nearby Qidong.

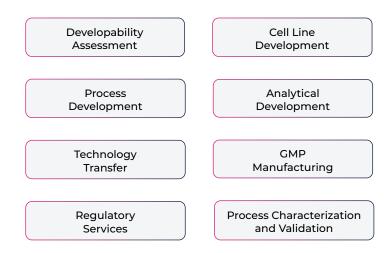
PILOT-SCALE MANUFACTURING FACILITY

- 3 upstream production lines:
 - 200L (Cytiva)
 - 250L (Thermo)
 - 500L (Thermo)
- 2 downstream production lines (Pall/Millipore):
 - AKTA ready/process
 - Automatic UF/DF system
- Bosch liquid filling line, 2R 20R format
- Liquid filling max batch size: ~2800 4000 vials (depends on format)
- IMA lyophilizer freeze-drying line
 - Lyophilization max batch Size: ~2800 4000 vials (depends on format)

COMMERCIAL GMP MANUFACTURING FACILITY

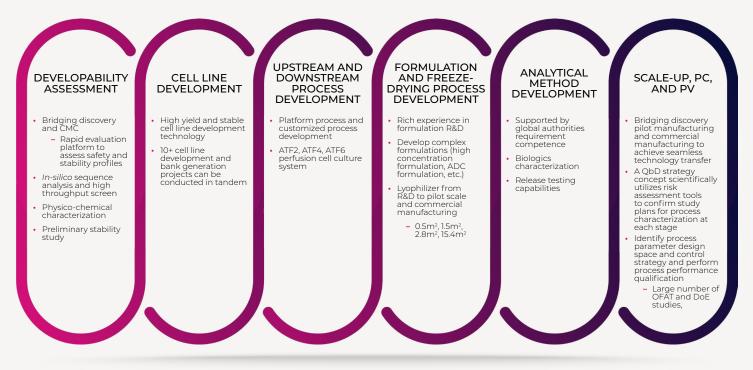
- 2 upstream production lines
 - Suite A: maximum design capacity of 6x2000L
 - Suite B: maximum design capacity of 3x2000L
- 2 downstream production lines:
 - AKTA, Millipore pre- and post-viral segregation rooms
- IMA liquid filling line, 2R 20R format
 - Liquid: 200 vials per minute, 100,000 vials per batch, 10 million vials per year
- IMA (2x15.4 sqm) lyophilizer freeze-drying line
 - Lyo(20R): 38,000 vials per batch, 2 million vials per year
 - Lyo(2R): 130,000 vails per batch, 6.5 million vials per year

ONE STOP CDMO SERVICES





TECHNOLOGY PLATFORMS



LEARN MORE AT CHEMPARTNER.COM/SERVICES/BIOLOGICS-CMC/