CHEMPARTNER
BIOLOGICS

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

- Developability Assessment
- Cell Line Development
- Process Development
- Analytical Development
- Technology Transfer
- GMP Manufacturing
- Regulatory Services
- Process Characterization and Validation

TECHNOLOGY PLATFORMS

DEVELOPABILITY ASSESSMENT

- Bridging discovery and CMC
  - Rapid evaluation platform to assess safety and stability profiles
- *In-silico* sequence analysis and high throughput screen
- Physico-chemical characterization
- Preliminary stability study

CELL LINE DEVELOPMENT

- High yield and stable cell line development technology
- 10+ cell line development and bank generation projects can be conducted in tandem

UPSTREAM AND DOWNSTREAM PROCESS DEVELOPMENT

- Platform process and customized process development
- ATF2, ATF4, ATF6 perfusion cell culture system

FORMULATION AND FREEZE-DRYING PROCESS DEVELOPMENT

- Rich experience in formulation R&D
- Develop complex formulations (high concentration formulation, ADC formulation, etc.)
- Lyophilizer from R&D to pilot scale and commercial manufacturing
  - 0.5m^2, 1.5m^2, 2.8m^2, 15.4m^2

ANALYTICAL METHOD DEVELOPMENT

- Supported by global authorities requirement competence
- Biologics characterization
- Release testing capabilities

SCALE-UP, PC, AND PV

- Bridging discovery pilot manufacturing and commercial manufacturing to achieve seamless technology transfer
- A QbD strategy concept scientifically utilizes risk assessment tools to confirm study plans for process characterization at each stage
- Identify process parameter design space and control strategy and perform process performance qualification
  - Large number of OFAT and DoE studies,

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