

BIOLOGICS

CMC

SCOPE

Focus on biologics CMC development and production for IND, clinical trials, and commercial launch

APPROACH

Provide high quality of product, process, and one-stop services for the life cycle of biologics

STANDARD

Comply with ICH guidelines and the highest standards of SDA, FDA and EMA

INTEGRATED BIOLOGICS DEVELOPMENT SERVICES

CELL LINE
DEVELOPMENT &
BANKING

CELL CULTURE
DEVELOPMENT

PURIFICATION
DEVELOPMENT

FORMULATION,
ASEPTIC FILLING
& FINISH

ANALYTICAL &
QUALITY CONTROL

CELL LINE PLATFORMS

Sigma-Merck
K1-GS-KO
2-5 g
Short Timeline

CHOZN

LIFE-Thermo Fisher
WT
1-4 g
Robust Growth

CHO-S

LIFE-Thermo Fisher
DHFR -/-
1-4 g
Highly Stable

CHO-DG44

ATCC
WT
1-5 g
Suspension
Adaption

CHO-K1

Human Cell Line
Transient
Transfection
Stable Pool

CUSTOMIZATION

PILOT SCALE GMP CAPACITY

PRODUCTION FUNCTIONS (800 m² clean room)

Upstream Manufacturing

- Cell banking (class A/C)
- Media prep (class D)
- Cell culture area (class D)



Downstream Manufacturing

- Buffer prep (class D)
- Initial Purification (class C)
- Final purification (class C)



Fill and Finish Manufacturing

- Component prep (class C)
- Aseptic Filling (class A/B)
- Lyophilization and Capping (class A/B)



Capable of generating 500-1000g of DS per batch to meet pre-IND and phase I & II clinical demand

Aseptic fill 2- 20 ml vials, up to 900-1800 vial/hr and 5000 vials per batch; 1.4m² freeze-drying shelf area

BIOLOGICS GMP MANUFACTURING

Located in Qidong,
Jiangsu
total 67,000 m²

Phase I mAb production
plant (13,000 m²) under
construction

DS: 2x2000L Fed batch;
1x500 L Fed batch, up to
200KG

DP: 10000 bottle/batch
aspect filling line for
vials and PFS; 25 m²
freeze-drying line