

BIOLOGICS CMC

Scope

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

Approach

Provide high quality of product, processes, and onestop services for the life cycle of biologics.

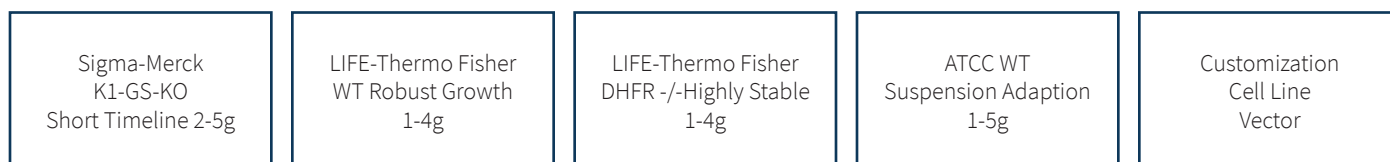
Standard

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

Integrated Biologics Development Services



Cell Line Platforms



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)
- Freeze-Drying (2.8m²) 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 filling, 2-20ml, vials, up to 1000 vials/hour and 3000 vials per batch

Integrated Biologics Development Services

Located in
Qidong, Jiangsu
Total 67,000 m²

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

DS: 8x2000L Fed batch;
3x500 L Fed batch, up
to 400KG

2-20 mL vial aseptic
DP filling line; 2x15.4m²
freeze-drying area

Protein Expression Capabilities

- Efficiency
 - From amino acid sequence to protein in as short as 5 weeks
- Multiple Choices
 - Different epitope tags
 - Various expression systems (mammalian, baculovirus, yeast, E.coli)
 - Specialized protein chromatography columns (affinity, SEC, IEX, HIC)
- Scaleup
 - Up to 300L expression cultures
 - Deliver protein in multi-gram scale
- Quality
 - Full spectrum of analytical techniques (DSF, MST, SEC, UV, MS, SEC-MALS, SDS-PAGE, CE-SDS, RPHPLC, etc.)
 - Quality support in NMR and crystal structure illustration, bioassay development/screening, compound screening, antibody screening, PD-1 Anti co-crystal structure
- Strong performance track record of success

Customized Protein Production

Statistics

	Receptors/Ligands	Cellular Signaling	Enzymes & Complexes
Number of Projects	> 200 per year	> 100	> 600
Quantity (per project)	5-100 mg	5-100 mg	5-200 mg

Example of Quality Improvement

Data Resource	Quantity	Purity	Mass Spec.	X-ray Diffraction
Client's Original Data	> 20 mg	> 99%	Double peaks (poor homogeneity)	8.0 Å
ChemPartner's Optimized Data	> 10 mg	> 99%	Single Peak (good homogeneity)	2.2 Å



Our purification protocol for the client has largely improved homogeneity and helped to obtain high-resolution crystal structure.