



BeOne Medicines Guangzhou Manufacturing Site

Guangzhou, China Site | Biologics and ADC Campus



Guangzhou, China Site

North Campus: Clinical & Commercial Biologics production



Drug Substance

- Total 65kL Cell Culture Capacity - Single-use System (2 x 500L, 12 x 2kL), Stainless System (8 x 5kL) - Fed-batch Cell Culture And Purification
- Mammalian (Mab, BsAb/TsAb, Fabs, Fusion, Recombinant Proteins)



Drug Products

- Liquid vials (clinical & commercial)
- Lyophilized vials (clinical & commercial)
- Pre-filled Syringes (clinical & commercial)
- Label & Packaging



Lab & CMC

- QC: Analytical Method Validation & Transfer, Stability & Reference Standard Management
- PD: Cell Line & Process Development (USP to Formulation)
- MST: Tech Transfer to Continuous Process Verification



Warehouse

- ASRS (Automatic Search & Retrieval System)
- Storage Conditions: 15 - 25°C, 2 - 8°C, -20°C, -40°C, -70°C

South Campus: Clinical & Commercial ADC production

- + ADC Conjugation Room (up to 500L, SU & SS reactors)
- + ADC Purification Area Equipped with Chromatography and UF/DF Systems

- + Lyophilized Vials (ADC)
- + Labeling & Packaging (ADC)

- + PD (ADC): Conjugation & Purification Process Development, Analytical Development, Fill Finish and Lyo Process Development
- + Linker and Payload PD underway to Internalize Supply



BeOne Medicines | Global Manufacturing Capabilities Overview

Biologics Campus

Hopewell NJ US Site

42-acre site
with 400,000 sq ft built

First U.S. Biologics Manufacturing Facility



Drug Substance

- Total 8kL Cell Culture Capacity - Single-use System (4 X 2kL)
 - Batch, Fed-batch, And Perfusion
- Mammalian (Mab, Bsab/Tsab, Fabs, Fusion, Recombinant Proteins)
- **Expansion Plan:** 2nd Line Cell Culture (4x2kL), ADC Conjugation



Drug Products

- Isolators
- Liquid Vials (Clinical & Commercial)
- Lyophilized Vials (Clinical & Commercial)
- Labeling & Packaging
- **Expansion Plan:** Small Molecule & ADC

ADC Campus

Biologics Campus

Guangzhou China Site

39-acre site
with 1.3 million sq ft built

Clinical & Commercial Biologics and ADC Production



Drug Substance

- Total 65kL Cell Culture Capacity - Single-use System (2 x 500L, 12 x 2kL), Stainless System (8 x 5kL)
 - Fed-batch Cell Culture And Purification
- Mammalian (Mab, BsAb/TsAb, Fabs, Fusion, Recombinant Proteins)
- **ADC** (PD and Manufacturing)



Drug Products

- Liquid Vials (Clinical & Commercial)
- Lyophilized Vials (Clinical & Commercial)
- Pre-filled Syringes (Clinical & Commercial)
- Labeling & Packaging

Small Molecule Campus

Suzhou China Site

12.4-acre site
with 460,000 sq ft built

Clinical & Commercial Small Molecule Production



Oral Solid Dosage

- 600M Capsule & Tablet Production Capacity (Expandable To 1B)
- Primary Packaging (Bottle & Blister)
- Labeling & Packaging



Global Quality Track Record

> 30 of Approvals and Inspections in 5+ Years (US FDA, EMA, China NMPA, ANVISA, TGA, MFDS, and more)



QC & MST Lab with Global Platform

Analytical Method Validation & Transfer

Global Stability & Reference Standard Center



Global PD Lab & CMC Mgmt.

Cell Line & Process Development (incl. Formulation)

CMC & Project Management



Thanks

