



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

