



BeOne Medicines U.S. Biologics Manufacturing and Clinical R&D Facility

Princeton West Innovation Campus,
Hopewell, New Jersey, USA

State-of-the-art, clinical and commercial-stage biologics manufacturing facility and clinical R&D center spans 42 acres, represents an \$800 million capital investment, and complements BeOne's existing capabilities around the world.

Diversified Modalities

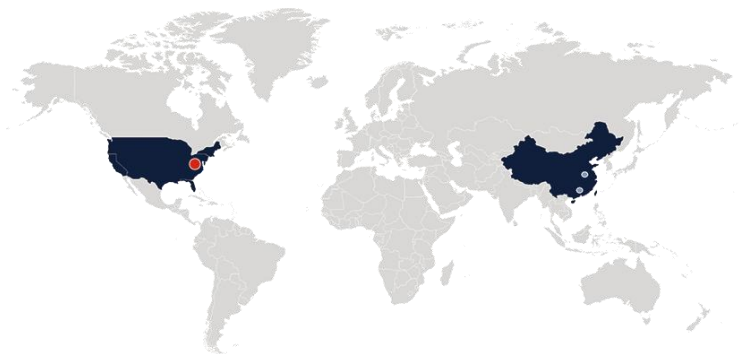


Biologics | Mammalian (mAb, BsAb/TsAb),
ADC & Fabs, Fusion, Recombinant
Proteins



Small Molecule | OSD Tablets & Capsules

Global Manufacturing Footprint



Hopewell Site

Flagship U.S. Biologics Manufacturing Center

- 42-acre site, 400,000 sq ft built
- Total 8kL cell culture capacity
- Phase II + for small molecule, ADC & other

Since 2024

Guangzhou Site

Biologics & ADC Manufacturing

- 39-acre site, 1.3 million sq ft built
- Total 65kL cell culture capacity
- Liquid, lyo, PFS capability
- ADC conjugation up to 500L

Since 2019

Suzhou Site

Small Molecule Manufacturing

- 12.4-acre site, 460,000 sq ft built
- Total 600M tablet/capsule capacity

Since 2017

Hopewell Manufacturing Site

Expansion of State-of-the Art Manufacturing Facility



Drug Substance

Manufacturing Capabilities

- Total 8kL cell culture capacity
 - Single-use system (4 x 2kL)
 - Batch, fed-batch, and perfusion
- Faster expansion through modular system
- Room reserved for additional 4 x 2kL



Drug Products

DP Production Lines

- Isolators
- Liquid vials (clinical & commercial)
- Lyophilized vials (clinical & commercial)
- Labeling & packaging



QC & MST Labs

Lab Capabilities

- Analytical method development, validation, and transfer
- QC testing (release, IPC, stability and more)
- Tech transfer, process validation, MFG tech support



Warehouse

Equipped with Latest Technology

- ASRS (automatic search & retrieval system)
- Storage conditions: 2 – 8°C, -20°C, -70°C

Partnering with BeOne

State-of-the-Art Facilities, Biologics Expertise, Global Scale

- **Accelerate market entry** with high quality and cost efficiency
 - 200 scientists and engineers in process development and CMC
 - End-to-end CMC solutions with proprietary cell line and media
 - mAb, BsAb, TsAb, and ADC
 - Global scalable network that mitigates supply chain & geopolitical risks
 - Track record of scaling up 30+ clinical and commercial assets, 50L tox to 5,000L commercial
- **Strategic partner** with deep experience in developing, producing, distributing globally
- **Flexibility in partnering model** to create win-win outcomes

Contact Us

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Analytical & CMC Capabilities



QC Lab

Global Testing Platform

- Analytical method validation & transfer
- Global stability center & reference standard management center



PD Lab

Large Molecule Development Platform

- Cell line & process development
- Media development, proprietary media
- Formulation development



CMC

End-to-End CMC Strategies & Management

- Fast to IND, BLA strategies
- Internal & external program management

Molecule to IND and Beyond



- 250mL to 50L
- 500L to 2kL
- Proprietary afucosylated CHO & Media
- Industry-leading productivity: 8-10g/L for mAbs, 5-8g/L for complex molecules
- Media, buffer & excipient screening
- Assay development & characterization study

Global Quality Systems



30+ Approvals & inspections in **5+** years
0 critical observations

(US FDA, EMA, China NMPA, ANVISA, TGA, MFDS +)



16 Approved products
40+ clinical & commercial assets
45+ phase 3 or potentially registration enabling trials

- **Globalized Quality System** enables the quick and efficient biologics CMC development
- **Phase-Appropriate Strategy** meets international GMP regulatory requirements

Global Network



40 offices, **~12,000** colleagues across **6** continents **1,600** + global technical operations team



~20 industry collaborations

*Numbers as of November 2025