



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  
Since 2024

- 42-acre site
  - 150,000 sq ft built
- Total 8kL cell culture capacity
- Phase II + for Small Molecule, ADC & Other

### Guangzhou Site

Biologics & ADC Manufacturing

Since 2019

- 39-acre site
  - 1.3 million sq ft built
- 65kL total cell culture capacity
- Liquid, Lyo, PFS capability

### Suzhou Site

Small Molecule Manufacturing

Since 2017

- 12.4-acre site
  - 460,000 sq ft built
- Total 600M Tablet/Capsule capacity

## 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, & Perfusion
- Shell for additional 4 x 2kL line (Phase II+)
- Faster expansion through modular system



Drug  
Products

### DP Production Lines

- Isolators
- Liquid vials
- Lyophilized vials
- Label & 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



## Hopewell Manufacturing Site

Princeton West Innovation Center, NJ USA

42-acre of state-of-the-art U.S. biologics manufacturing site with **\$800 million** capital investment that complement BeiGene's existing capabilities around the world

# Analytical & CMC Global 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 Programs Management

# Global Quality Systems

Growing Quality Track Records with Approved Internal & Partnered Assets and Manufacturing Authorizations



**30+** Approvals & Inspections in **5+** years  
**0** Critical Observations

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



**17** Approved Products

**30+** Clinical & Commercial Assets

**40+** Phase 3 or potentially registration enabling trials

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



BeiGene

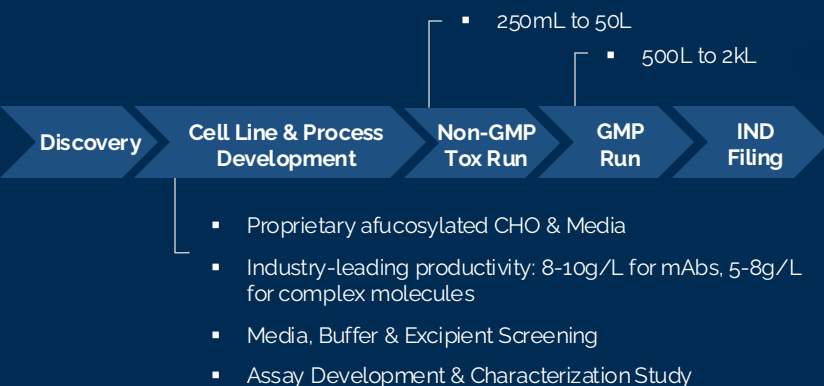


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# Molecule to IND and beyond



# Global BeiGene Network

Experienced BeiGene's global team to support collaborations



**40** offices, **10,000+** colleagues globally on **5** continents with **1,500+** Global Tech Ops Team



**~20** industry collaborations

\*Numbers as of February 2024

## Contacts

Business Development  
 BDnotices@beigene.com

**CANCER HAS NO BORDERS NEITHER DO WE**

