Raybow Pharmaceutical

Molecule to Market: Your Trusted Partner



US Headquarters
for Jiuzhou Pharma
Brevard, NC USA

Raybow USA

- Early-Stage Drug Development
- Up To Multi-kg cGMP Production
- Reference Standard Qualification
- On-Site Analytical Support

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Custom Solutions

- Synthesis Design
- Process Development & Optimization
- cGMP Production up to kilo Scale
- Full Service Analytical Lab
- Analytical Method Development & Validation
- Containment to OEB 3

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At a Glance

14,400 sq. ft. Facility	60% Ph.D. Chemists	PR&D cGMP Med-Chem

Brevard Site

Pre Clinical → Phase I → Phase II → Phase III → Registration → Commercialization → Custom Manufacturing

Jiuzhou Pharmaceutical's Worldwide Network of Sites

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Synthesis Equipment



- Jet Mill
  - Glove Box
  - Lyophilizers
- Balances and Scales
- Rotary Evaporators at 5 L & 20 L
- Vacuum Tray Dryers at 0.5L to 20 L
- 1-5 kg C22 Hastelloy Filter Dryer
  - Basket Centrifuge (316 stainless, 14”)
  - Prep MPLC Systems to 12 kg silica
  - Prep HPLC up to multigram scale
  - Reactors
    - Reactors & Work-Up Stations (glass) to 72 L
    - 50 L Glass Jacketed Reactors
    - 19 L Pressure Reactor (316 stainless)
    - 0.5 - 2.0 L Pressure Reactors

All items ready for R&D

Items qualified for GMP

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Flow Chemistry

Development & Small Scale

Corning Lab-Scale Reactor Allows for Development and Scale-Up to Multi-kg Production Levels

Scale-Up

Scale-Up to Multi-Ton Reactions with Jiuzhou Pharma’s Corning G1 and G4 units

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Analytical Services

- Methods Development & Validation
- CoA Review and Approval
- Reference Materials Qualification
- Impurities Identification & Characterization
- ICH Stability Studies
- Forced Degradation Studies
- Residual Solvents Testing

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Analytical Instrumentation

- 400 MHz NMR
- LC/MS Triple Quad
- LC/MS (ESI)
- HPLC (UV, DAD, RI, CAD)
- GC (FID), Headspace GC
- FT-IR
- Cary 3500 Multicell UV-Vis Spectrophotometer
- Karl-Fischer (Coulometric & Volumetric)
- Particle Size Analyzer (Anton Paar PSA 990)
- DSC (Waters TA 250)
- XRPD (Bruker, D2 Phaser)

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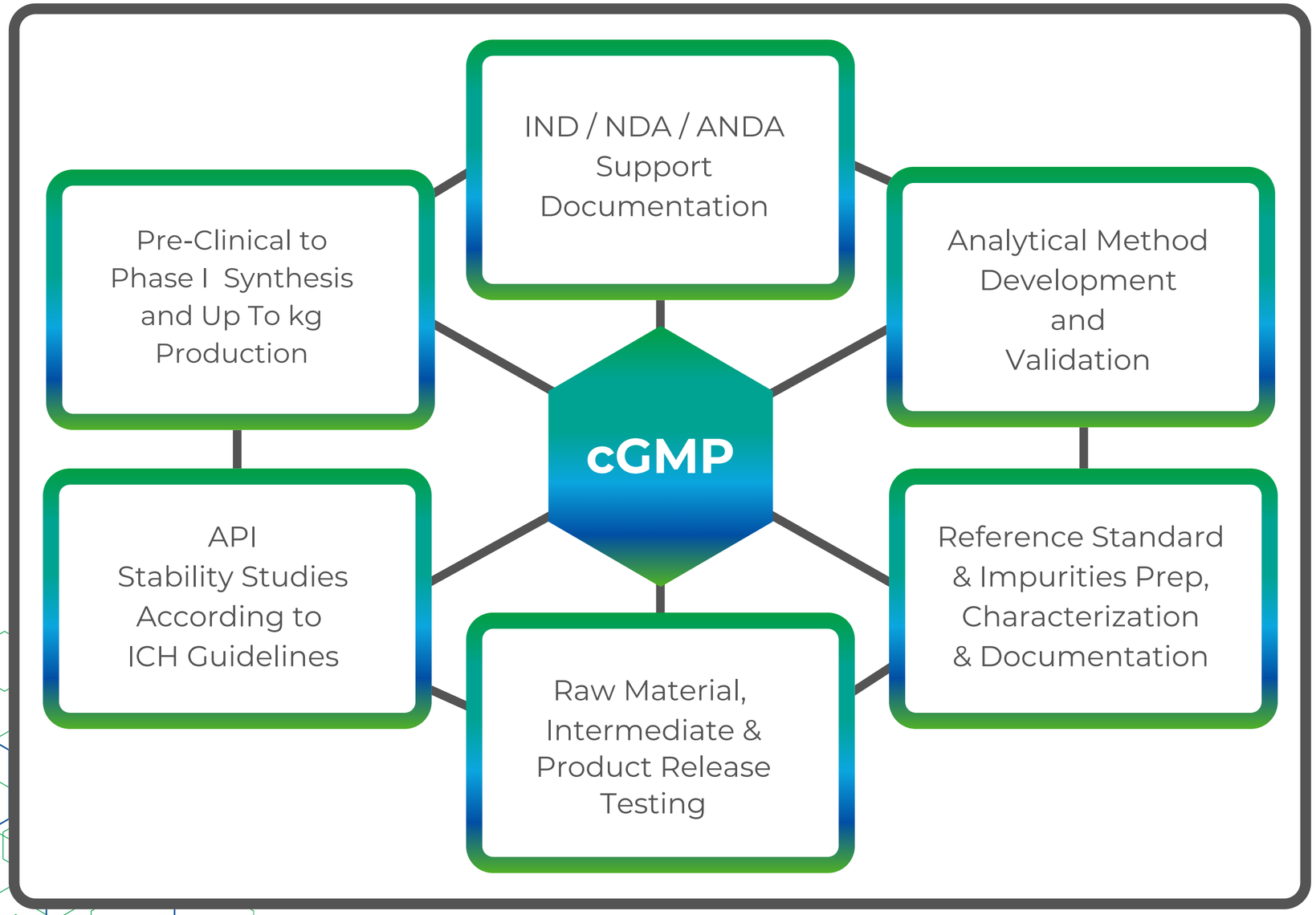

cGMP Services

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Quality Assured Documentation

- Batch Records
- Specifications
- Test Methods

Expert-Led Projects

Chemists with in-depth project knowledge oversee the chemistry from start to finish.

Accelerated Timelines

R&D process chemists directly execute cGMP synthesis for faster project turnaround

cGMP Production

Manufacturing Expertise

All chemists are extensively trained in current Good Manufacturing Practices (cGMP)

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Case Study: Rapid Development and Delivery

COVID-19 Vaccine Adjuvant

September 2020
Inquiry/NDA/TC
Quote Issued & PO Received

December 2020
Delivery of
5g GMP

February 2021
Additional 100 g
Synthesis

Raw Materials Received
Project Kick-off
October 2020

Partner
Audit
January 2021

Process Validation
at 100 g scale
October 2021

Met Client's Tight Timeline

Developed & Produced Within 3 Months

Passed GMP Audit by International Vaccine Company

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Case Study: Clinical Trial Support & Tech Transfer for Commercial Production

Familiarization & Stepwise Scale-Up to 1 kg delivered
April 2022

Raybow USA transfers Tech Package to Jiuzhou Pharma to manufacture 3 x 10 kg Registration Lots
July 2023

NDA Submission
December 2025

Injectable Drug for Cancer Treatment

September 2021
Raybow USA Receives Tech Package, Requests for Process Development, Method Validation, & GMP production

October 2022
Raybow USA Delivers 2 kg to Support Phase III Clinical Trial

May 2025
Process Optimization & 3 Process Validation Lots completed at 25 kg scale to support NDA

March 2026
Delivery for First Commercial Lot 125 kg

- **Client Communication through Raybow USA**
- **Raybow USA & Jiuzhou Synergy**
- **Commercial Manufacturing Capability**
- **NDA Submission Support**

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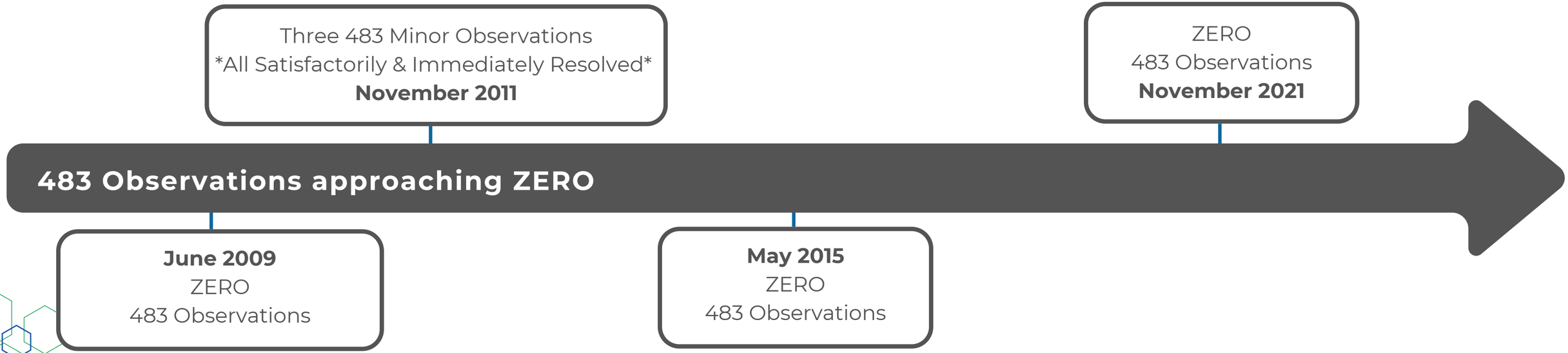
FDA Inspection History



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History of the Brevard Site

1998 Founded by (the late) Roger Frisbee (L) and Pete Newsome (R) as PharmAgra Labs in Arden, North Carolina

2003 Purchased and up-fitted Brevard facility (11,400 sq. ft.)

2007 Installed cGMP Lab & FDA registered as API Manufacturer

2011 Registered with DEA (currently Schedule 1-5 R&D/Analytical)

2019 Acquired by Raybow Pharmaceutical unit of Jiuzhou Pharma (Shanghai Stock Exchange: 603456.SH)

2025 Expanded & remodeled cGMP suite (to be completed Q4 2026)

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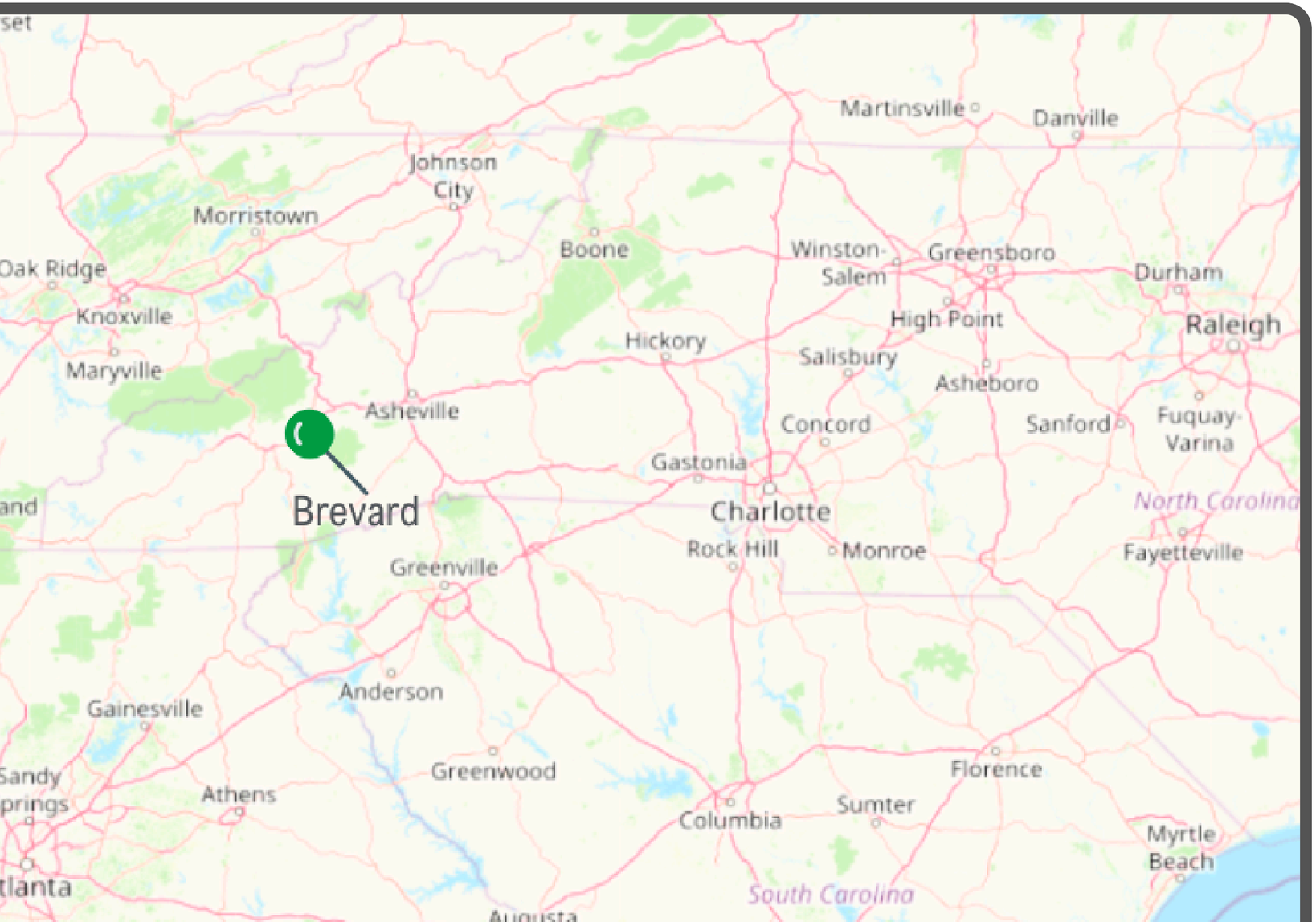

It's Easy to Get to Brevard

30 Minute Drive Time From the Asheville Airport (AVL)

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Client Data Protocols

- All client data resides exclusively in the US
- Data servers are on-site in North Carolina
- Exchange Online mailboxes, SharePoint, and OneDrive data/files reside in US (NAM) data centers
- Raybow USA data is isolated from Jiuzhou Pharma systems
- Data sharing with Jiuzhou Pharma only occurs with express consent from the client

Client-First Security

US Controlled

China Isolated

Jiuzhou Pharma Worldwide Facilities

5000+	9	10	1000+	38
Global Employees	R&D Facilities	Manufacturing Facilities	New Drug Projects	Commercial Products



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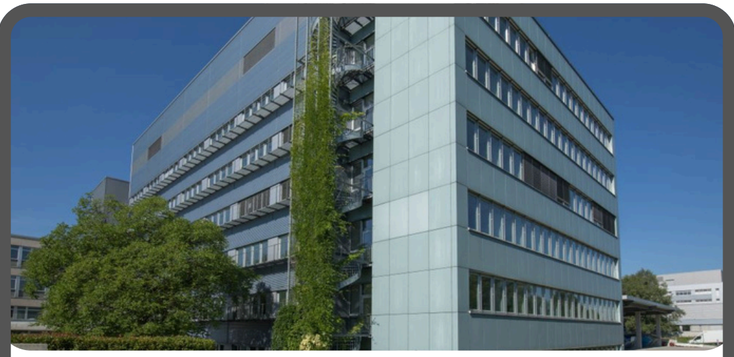
6 Global R&D Centers



Raybow USA Brevard
R&D for API Projects
from Pre-Clinical
up to Phase II



Germany
R&D focusing on
innovative synthetic chemistry
CRO services.



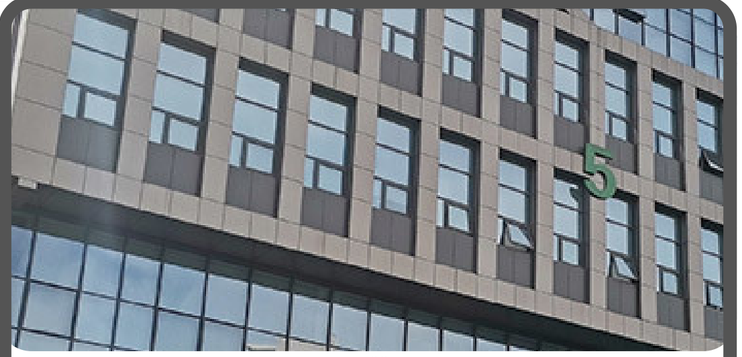
Japan
R&D mainly engaged
in innovative drug
CRO services



Taizhou
R&D for Small Molecule APIs from
preclinical development to NDA &
Commercialization



Hangzhou
R&D for Small Molecule APIs, Peptide &
Drug Conjugates, from Pre-Clinical to NDA
& Commercialization



Nanjing
Small Molecule and Peptide Innovative
Drugs from Pre-Clinical to NDA
Development

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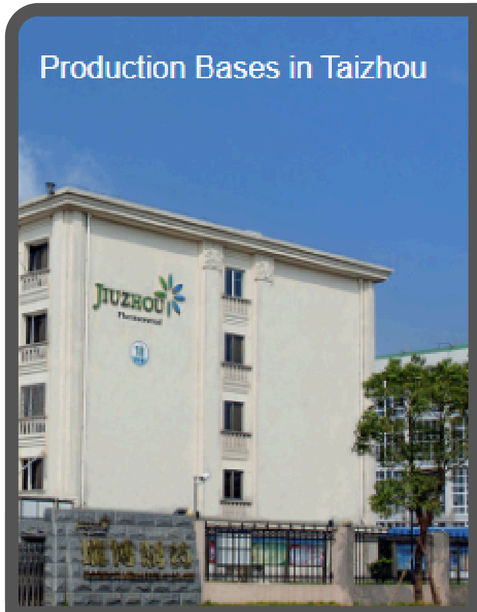
5 Production Bases Worldwide



Taizhou
Linhai and Jiaojiang production bases serve global customers for integrated API and DP projects



Suzhou
Innovative Small Molecule drugs and Peptides from phase I clinical trials through commercialization



Hangzhou
In-house API and intermediate projects



Yancheng
In-house API and intermediate projects



Zhongshan
End-to-end services for drug products from preclinical research to commercial manufacturing

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Worldwide Capabilities

- Large Scale API Manufacturing
  (up to 10,000 L Reactor)
- Flow Chemistry
  (up to 100 ton/year)
- High Pressure Reactions
- High Temperature Reactions
  (up to 350 °C)
- Cryogenic Reactions
- Enzymatic Reactions
- Chiral Separations
- High Potency Workshops
- Peptide & Conjugate Drug Development
- Formulation, R&D, and Production

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