



Molecule to Market: Your Trusted Partner



Raybow USA Brevard, NC



Early-Stage Drug Development



Up To Multi-kg cGMP Production



Reference Standard Qualification

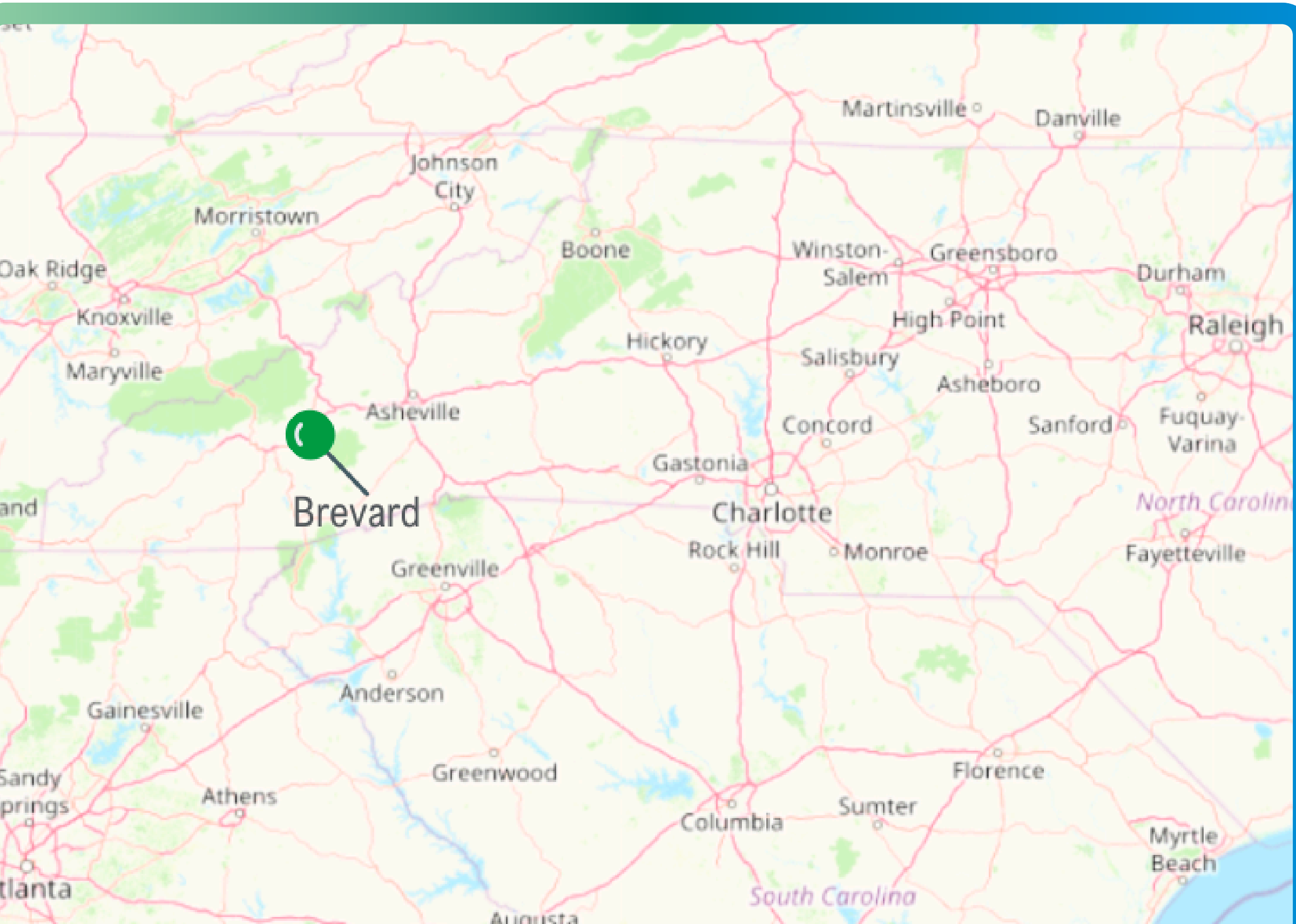


On-Site Analytical Support

US Headquarters
for Jiuzhou Pharma
Brevard, NC USA



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It's Easy to Get to Brevard

Drive Time
From AVL Airport:
30 Minutes

History of Raybow USA

- 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 2025)





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Raybow USA at a Glance

14,400
sq. ft.
Facility

60%
Ph.D.
Chemists

PR&D
cGMP
Med-Chem

Pre
Clinical

Phase
I

Phase
II

Phase
III

Registration

Commercial

Custom
Manufacturing

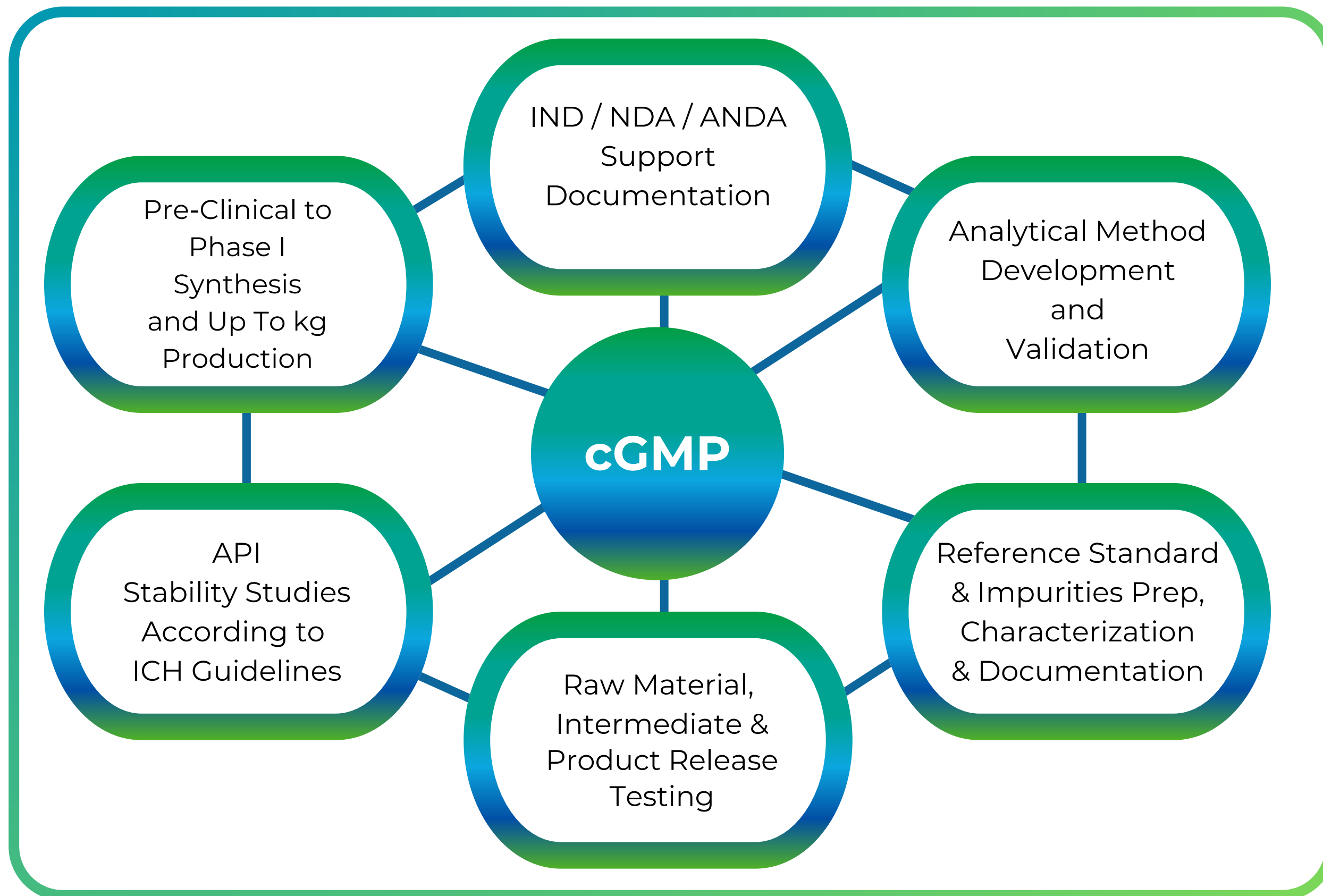
Brevard Site

Jiuzhou Pharma Worldwide



Raybow USA 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



**Raybow USA
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.

Raybow USA cGMP Production

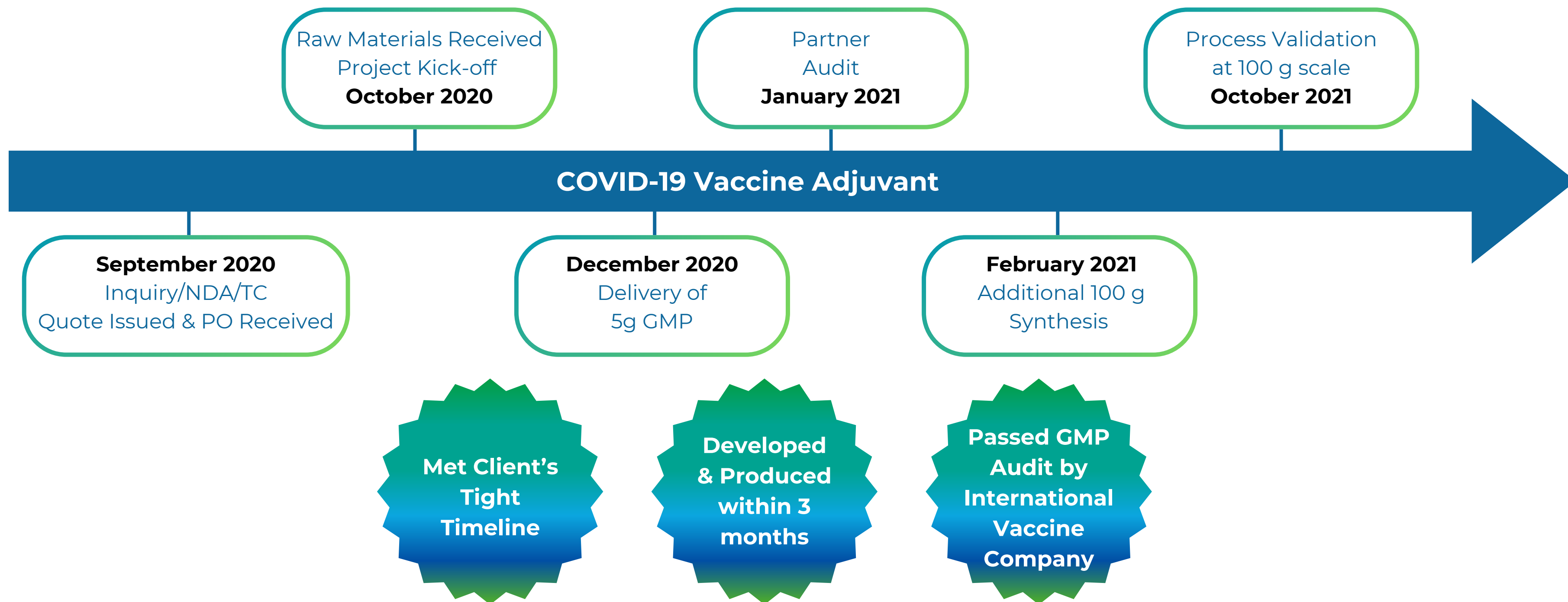
Accelerated Timelines

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

Manufacturing Expertise

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

Case Study: Rapid Development and Delivery



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

April 2026
Scheduled Delivery for
First Commercial Lot
125 kg

**Client
Communication
through
Raybow USA**

**Raybow USA
&
Jiuzhou
Synergy**

**Commercial
Manufacturing
Capability**

**NDA
Submission
Support**

Raybow USA FDA Inspection History

Three 483 Minor Observations
All Satisfactorily & Immediately Resolved
November 2011

ZERO
483 Observations
November 2021

June 2009
ZERO
483 Observations

May 2015
ZERO
483 Observations

Isolation Equipment

- Jet Mill
- Glove Box
- Lyophilizers
- 20 L Rotary Evaporators
- 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

Reactor Specs

- 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
- Corning-Bench Top Flow Reactor

Raybow USA Lab Equipment





Raybow USA 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

Raybow USA Analytical Services

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



- 400 MHz NMR
- LC/MS Triple Quad
- LC/MS (APCI, ESI)
- HPLC (UV, DAD, ELSD, RI, CAD)
- GC/MS (EI)
- 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)

Raybow USA Analytical Instrumentation





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JiuzhouPharma Facilities Worldwide

5000+
Global
Employees



9
R&D
Facilities



10
Manufacturing
Facilities



1000+
New Drug
Projects



38
Commercial
Products



R&D Centers Worldwide



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

Production Bases Worldwide

Production Bases in Taizhou



Taizhou

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

Suzhou Production Base



Suzhou

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

Hangzhou Production Base



Hangzhou

In-house API and intermediate projects

Yancheng Production Base



Yancheng

In-house API and intermediate projects

Zhongshan Production Base



Zhongshan

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



Additional Capabilities Worldwide

- 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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***Thank you for your time
and attention!***

For Additional Information:

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