



## Raybow USA Brevard, NC



Early-Stage Drug Development



Up To Multi-kg cGMP Production



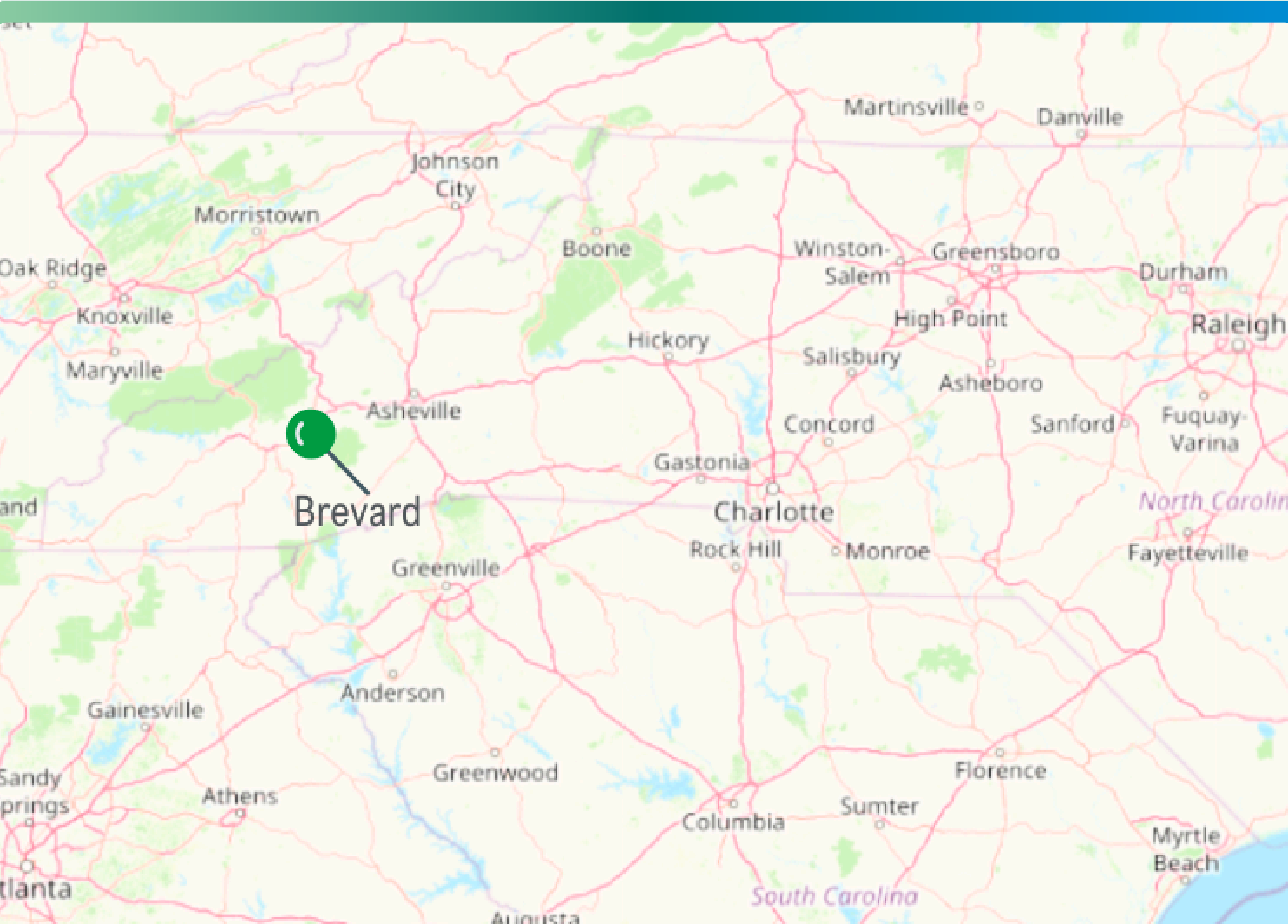
Reference Standard Qualification



On-Site Analytical Support

US Headquarters  
for Jiuzhou Pharma  
Brevard, NC USA





**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)
- 2024** Expanded & remodeled cGMP suite



## 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**

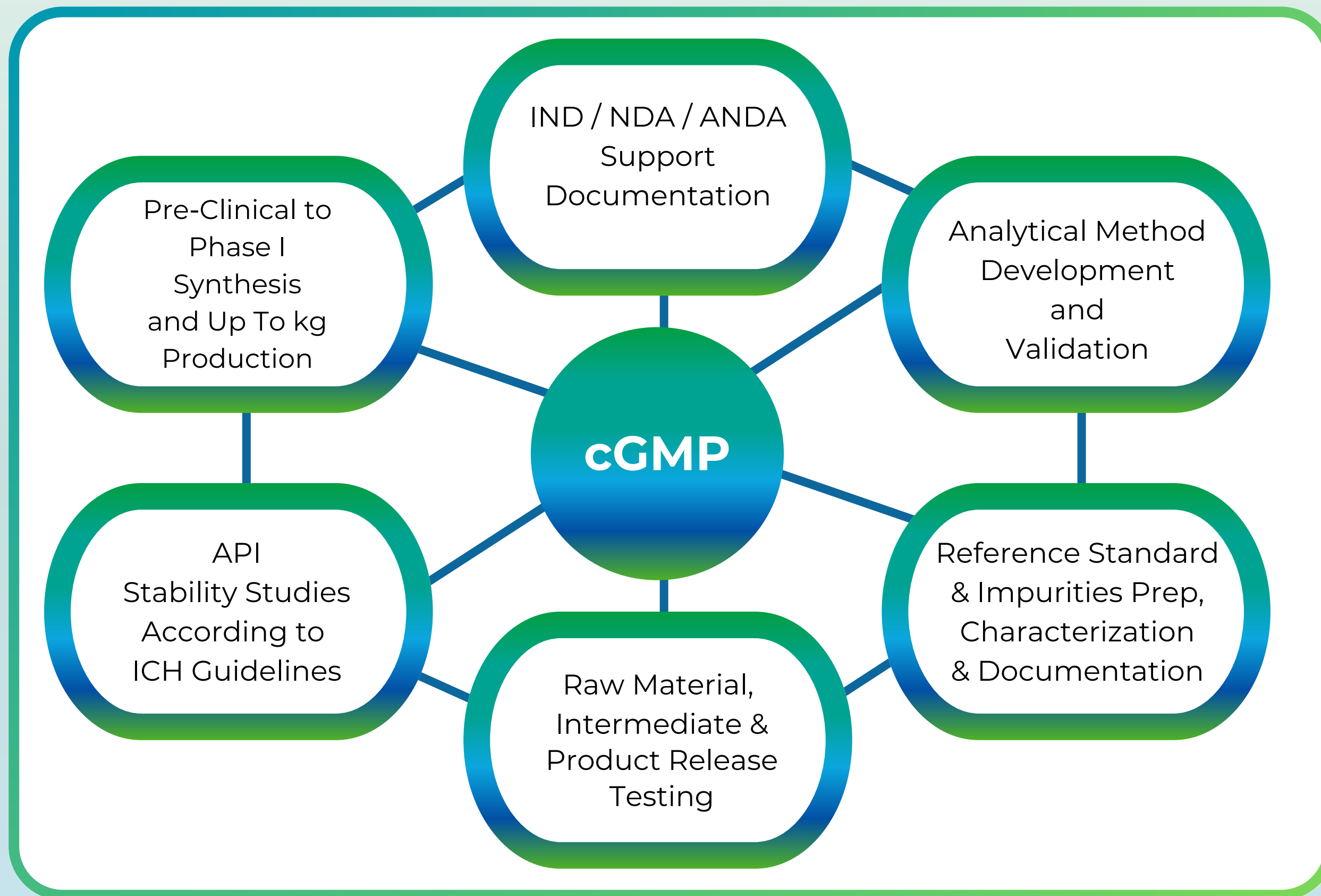
**Jiuzhou Pharma Worldwide**





## **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**



**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)

## Raybow USA Case Study: Rapid Project Completion

Raw Materials Received  
Project Kick-off  
**October 2020**

Partner Requested  
Audit  
**January 2021**

**2020 COVID-19 Vaccine Adjuvant Urgent Need: Rapid Scale-Up and Production Response**

**Mid-September 2020**  
Inquiry/NDA/TC  
Quote Issued & PO Received

**December 2020**  
Delivery of 5g  
GMP

**February 2021**  
Additional 100g  
Synthesis

**Met Client's  
Tight  
Timeline**

**Developed  
& Produced  
within 3  
months**

**Passed GMP  
Audit by  
International  
Vaccine  
Company**



## Raybow USA FDA Inspection History

Three 483 Observations  
\*Satisfactorily 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)

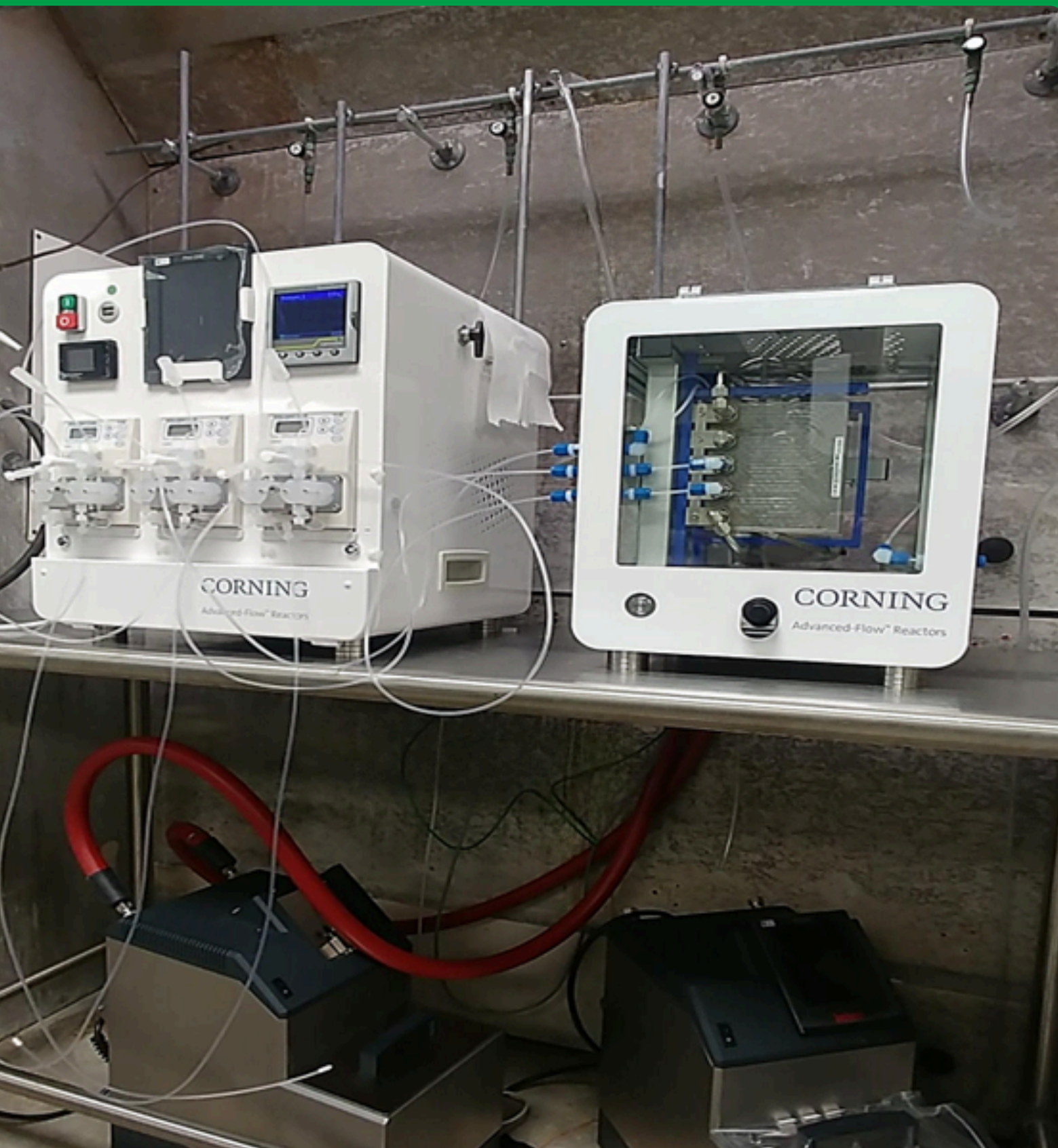
0.5 - 2.0 L Pressure Reactors

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)

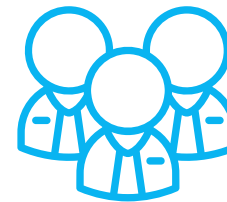
XRPD (Bruker, D2 Phaser)

## **Raybow USA** **Analytical Instrumentation**



**JiuzhouPharma  
Facilities  
Worldwide**

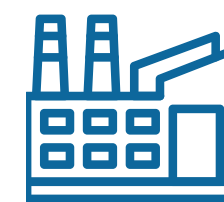
**4800+**  
Global  
Employees



**7**  
R&D  
Facilities



**10**  
Manufacturing  
Facilities



**1000+**  
New Drug  
Projects



**33+**  
Commercial  
Products





## R&D Facilities Worldwide



### Hangzhou

**160+ scientists, 15 with PhDs**  
**30+ for peptide**

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



### Linhai I

**270+ scientists**  
**4 with PhDs**

Phase I Clinical Trial to NDA  
and Full-Scale  
Commercialization



### Raybow USA Brevard

**18 scientists**  
**8 with PhDs**

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



## API Production Sites Worldwide



### Suzhou

Total capacity: 600 m<sup>3</sup>  
Peptide & Small Molecule  
Innovative Drug Projects for  
Phase III Clinical++  
Pilot Plant for Process Development



### Linhai I

Total capacity: 2,600 m<sup>3</sup>  
13 Production Workshops  
All Stages of Process  
Development & Manufacturing



### Linhai II

Total capacity: 4,000 m<sup>3</sup>  
To be completed by 2027:  
13 workshops in 191,285 m<sup>2</sup>  
facility, 1km away from Linhai I





## 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





*Molecule to Market: Your Trusted Partner*



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

**For Additional Information**

East Coast Director of Business Development:

**Tim Miley**

[tim.miley@jiuzhoupharma.com](mailto:tim.miley@jiuzhoupharma.com)

+1.919.475.5982

<https://en.jiuzhoupharma.com>

Raybow USA President & General Manager:

**Matt Lauer, PhD**

[mlauer@raybow.com](mailto:mlauer@raybow.com)

828-884-8656

158 McLean Road Brevard, NC 28712 USA

<https://raybow.com>



US Headquarters  
for Jiu Zhou Pharma  
Brevard, NC USA