



Raybow USA Brevard, NC



Early-Stage Drug Development



Up To Multi-kg cGMP Production

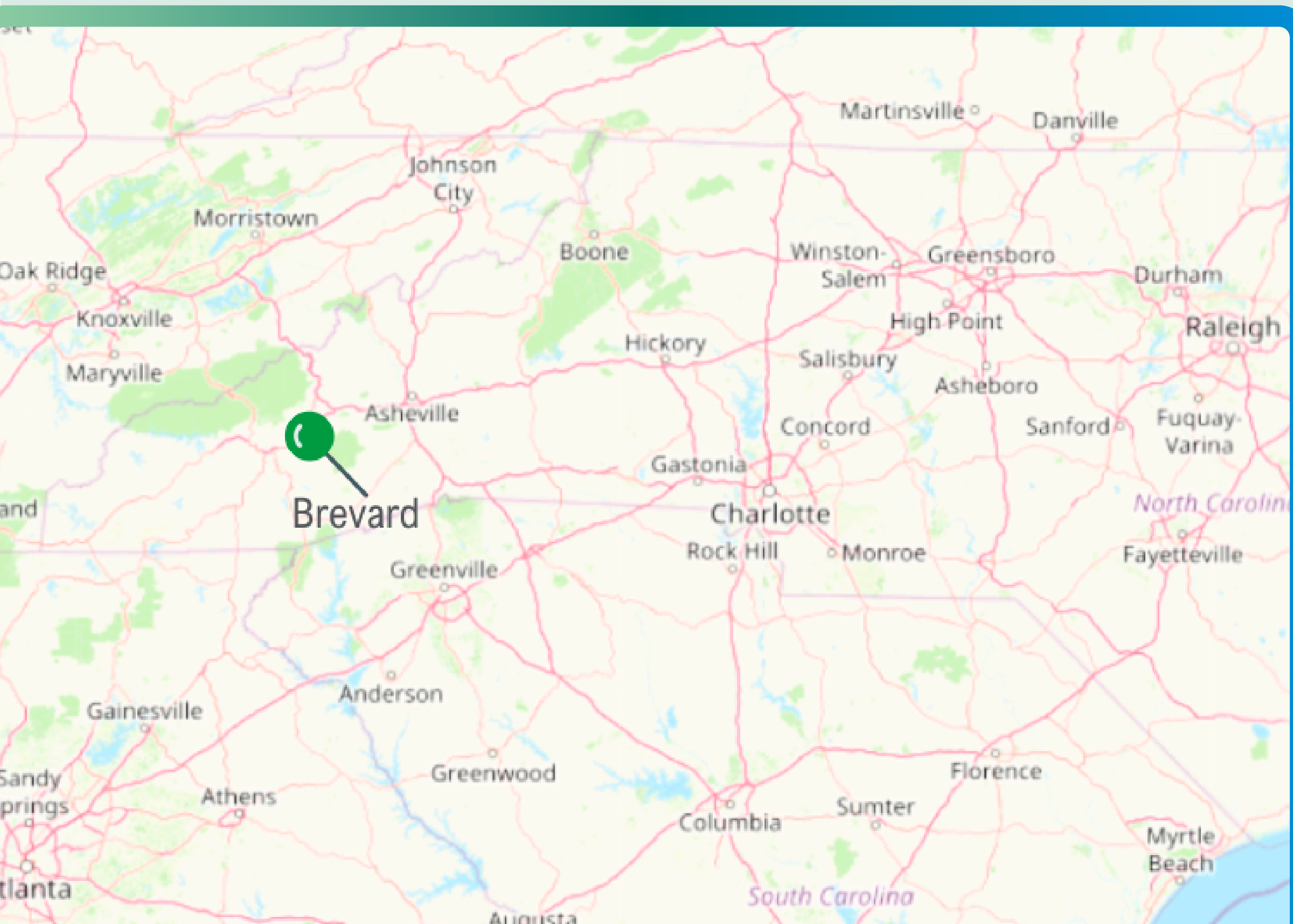


Reference Standard Qualification



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





Molecule to Market: Your Trusted Partner



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

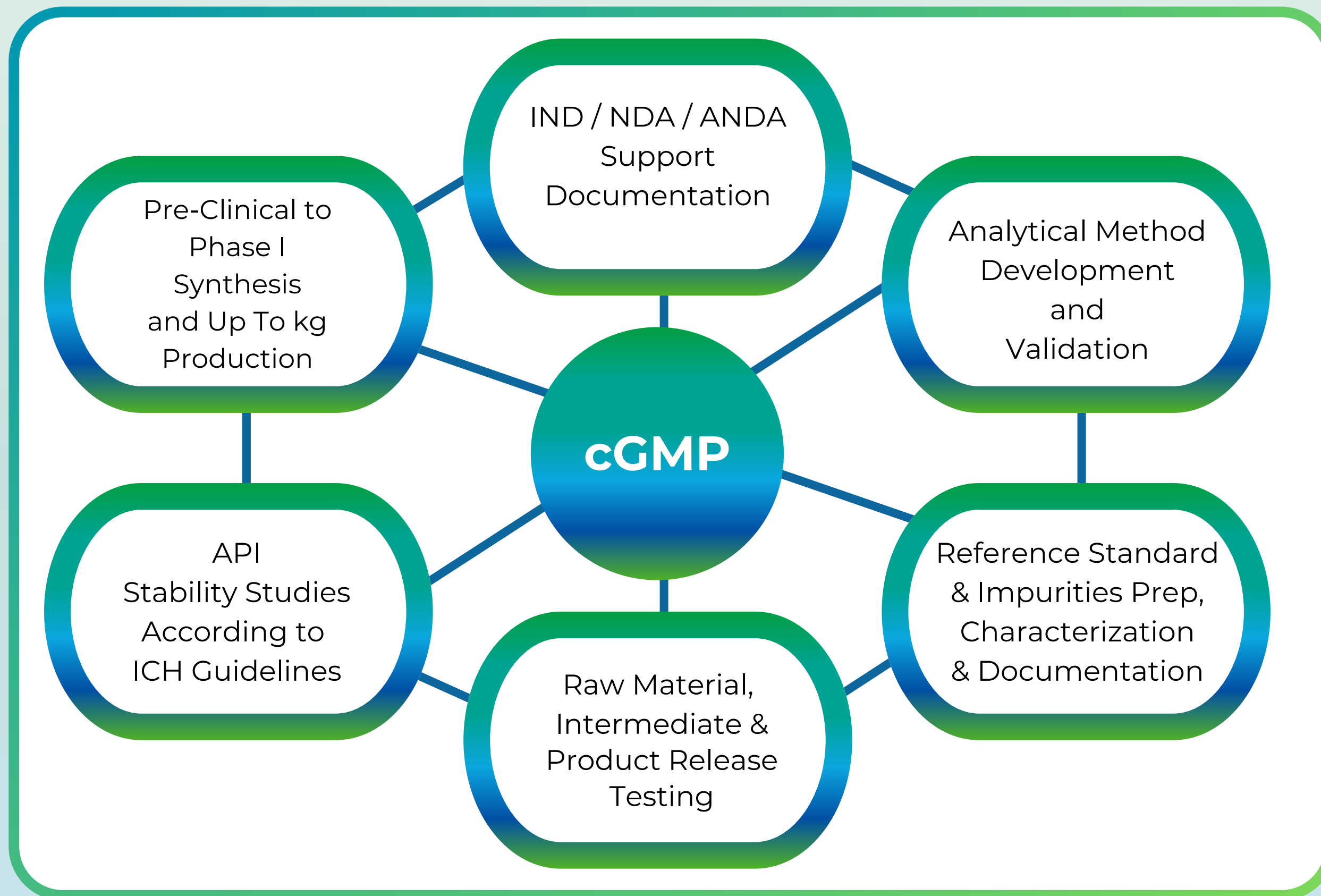
Brevard Site

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



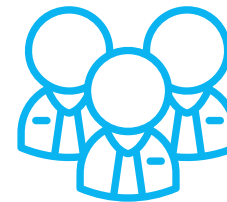
400 MHz NMR
LC/MS Triple Quad
LC/MS (APCI, ESI)
HPLC (UV, DAD, ELSD, RI, CAD)
GC/MS (EI)
GC (FID), Headspace GC
FT-IR
Cary 3500 Multicell UV-Vis Spectrophotometer
Karl-Fischer (Coulometric & Volumetric)
Particle Size Analyzer (Anton Paar PSA 990)
DSC (Waters TA 250)
XRPD (Bruker, D2 Phaser)

Raybow USA **Analytical Instrumentation**



**JiuzhouPharma
Facilities
Worldwide**

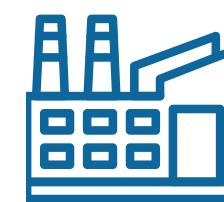
4800+
Global
Employees



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 m³
Peptide & Small Molecule
Innovative Drug Projects for
Phase III Clinical++
Pilot Plant for Process Development



Linhai I

Total capacity: 2,600 m³
13 Production Workshops
All Stages of Process
Development & Manufacturing



Linhai II

Total capacity: 4,000 m³
To be completed by 2027:
13 workshops in 191,285 m²
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



US Headquarters
for Jiuzhou Pharma
Brevard, NC USA

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

**For Additional Information
Please Contact**

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