Raybow Pharmaceutical

Molecule to Market: Your Trusted Partner

A professional services summary

Clinical Trial to Commercialization with Tech Transfer

Statement of Need

The client needed to supply their API to their formulator on a tight timeline, to support their clinical trials and move to NDA submission.

Raybow USA Responses

- reproduced the established procedures
- developed procedural refinements
- produced 2 kilograms of GMP materials for clinical trials
- initiated tech transfer to parent company Jiuzhou Pharma
- manufactured 3 x 10 kilograms registration lots
- completed process optimization
- prepared 3 process validation lots at 25 kg scale
- supported NDA Submission
- scheduled delivery for first commercial lot at 125 kg

7-Step Process Timeline

September 2021
Client presented Tech Package andRequests for Process Development, Method Validation, and GMP production.

April 2022
Completed Familiarization & Stepwise Scale-Up. Delivered 1 kg.

October 2022
Delivered 2 kg to Support Phase III Clinical Trial.

February 2023
Coordinated seamless Tech Transfer [process familiarization & analytical method transfer] from Raybow USA to parent company, Jiuzhou Pharma. Scaled to 1 kg in R&D prior to Registration Lots.

September 2023
Completed all 3 Registration Lots on 10 kg scale.

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7-Step Process Timeline

November 2023

Salt screened 60 salt–solvent combinations, with XRPD, TGA, and DSC characterization, identifying at least 15 distinct polymorphs.

December 2023

Initiated impurity strategy, including spike-and-purge studies, synthesis of impurity standards, and integration into Quality Risk Assessment (QRA), utilizing nitrosamine and genotoxicity assessments.

April 2024

Identified variable quantification of impurity in API assay. Developed, validated and implemented a new analytical method on tight timeline, enabling production release and stability studies.

November 2024 - April 2025

Specifications set and test method validated for all intermediates and raw materials.

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7-Step Process Timeline

May 2025
Pre-validation and 3x validation lots completed at 25 kg scale to support NDA.

March-June 2025
Executed batch records and production reports completed for each step in English and Chinese.

December 2025
NDA submission.

November 2025 - Ongoing
Support for European submission.

March 2026
Completion of first commercial production at 125 kg.

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Scope of Work

process development

process optimization

synthesis

analysis

formulation

production

Outcome Summary

Developed Process and Analytics

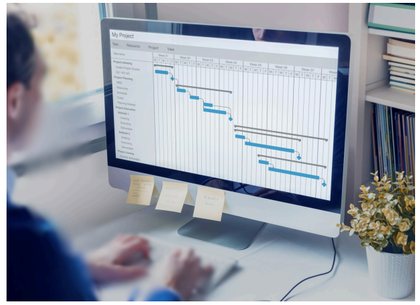
★★★★★

Our R&D, QA, & QC ensured reliable product and methods for manufacturing.

Executed Tech Transfer

★★★★★

We provided efficient tech transfer to our parent company, Jiuzhou Pharma.



Met Client's Timeline Needs

★★★★★

We supported the client's on-schedule submission to the FDA .

Prepared Product for Commercialization

★★★★★

We supported the initial US commercial launch and expansion into other markets.

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Fluid Interactions

Interactions with clients are key to project success. Raybow employed multiple tools for receiving direction and feedback, and for delivering progress reports and results. Raybow's seamless project management provided continuity straight through tech transfer, Jiuzhou Pharma manufacturing phases, and beyond.

- **Virtual Meetings**
- **In Person Meetings**
- **Phone Calls**
- **Emails**
- **Shipping**
- **Secure Electronic Document Sharing**

Ownership

All IP belongs to the client.
Including refinements.

Guiding Professional Concepts

Dedication

We allocated time, equipment and human resources to ensure all client needs could be met in a timely fashion.

Knowledge

We drew upon our team's education and experiences to fine-tune protocols to deliver the highest quality data.

Responsiveness

We listened to the client's needs and determined an action plan to meet their goals and deadline.

Attention

We applied best established practices to ensure quality and accuracy throughout the project.

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Start the conversation about your project.

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