

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

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.

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**
- **Trusted Shipping**
- **Secure Electronic Document Sharing**



7-Step Process Timeline

- **September 2021** - Client presented Tech Package and Requests 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.
- **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.
- **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.

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.

Start the conversation about your project today.



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