

Novel Route Design and Process Development

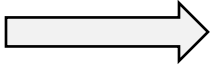
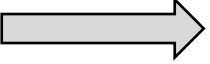
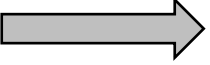
Statement of Need

The client needed novel API for initial testing and IND-enabling studies, within their financial budget and time constraints.

Raybow USA Responses

- Reproduced client's 3-step process.
- Produced initial batch on gram scale.
- Designed novel 4-step route to save client time & money.
- Developed 4-step route into a robust and scalable process.
- Delivered High-Q material ahead of time & under budget.
- Supported client into IND submission stage.
- Continued communication and support to the client.

Process Development Outcomes

Original 3-step Process		Novel 4-step Process
Expensive Starting Material with lead time of 2+months		Starting Material readily available at >90% reduction in cost
Two column purifications Not suitable for scale-up		High Q material with no column chromatography
Low overall yield of 30%		Improved overall yield at 53%

Scope of Work

- Process development
- Process optimization
- Production
- Analysis
- Quality

Outcome Summary

- ✓ **Rapid Product Delivery**
We rapidly delivered small batches of API for IND-enabling studies.
- ✓ **Novel Route Development**
We discovered a faster, robust, scalable route for the customer's process.
- ✓ **Saved Time and Money**
We delivered cost-savings through continued process improvement.
- ✓ **Timely Product Submission**
We assisted the client with meeting their IND submission timeline.

Ownership

All IP belongs to the client. Including refinements.



Effective Interactions

Interactions are key to project success. We employed multiple methods to receive direction from the client, keep the client informed of progress and results, deliver product batches, and achieve the client's project goals.

- **Virtual Meetings**
- **Phone Calls**
- **Emails**
- **Reliable Shipping with Tracking**
- **Secure Electronic Document Sharing**

Process Timeline

- **September 2022** - Raybow and client agree on scope of work and client issues PO.
- **November 2022** - Raybow demonstrates route feasibility and produces initial batch on gram scale.
- **April 2025** - Raybow produces second batch on multi-gram scale. Raybow identifies an alternative route.
- **August-December 2025** - Working closely with the client, Raybow develops the new process and delivers 500 g+ of high-quality API.
- **2026** - Kilo-scale GMP production is scheduled to start Q3 2026.

Guiding Professional Concepts

- ✓ **Dedication:** We allocated the time, equipment and staff necessary to ensure efficiently meet the client's needs.
- ✓ **Knowledge:** We drew upon our team's expertise and experiences to fine-tune protocols and deliver cost-saving results.
- ✓ **Responsiveness:** We listened to the client's needs and formed an action plan, exceeding their goals and deadlines.
- ✓ **Quality:** We applied established Quality-by-Design practices to ensure accuracy throughout the project.

Start the conversation about your project today.



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