CASE STUDY

US Biotech

NEULAND
WHERE OPPORTUNITY BECOMES REALITY

A US based clinical-stage Biotech company specializing in CNS treatments partnered with Neuland for the development of a NCE API. The program began when the molecule was in Phase 2 stage and eventually Neuland successfully scaled up manufacturing to meet the client's requirements for Phase 3 trials. Leveraging its decades of experience, Neuland maintained the timelines throughout the project tenure, increased the yield in all stages significantly and reduced the overall project cost by 60%. In a short span of time, Neuland became the preferred CMO for the client's development programs.

About the client:

The client is a leading US Biotech company in the CNS domain.

The Challenge:

The client was looking for a reliable partner who could support the chemical development process of a NCE API. The client's priority was to develop a timebound, safe, scalable and cost-effective process right from the lab scale to cGMP manufacturing. With its focus on Quality & Efficiency, Neuland was able to meet the client's requirements.

The compound had a low yield at each stage and also involved the usage of hazardous reagents and conditions during route development.

Project objectives and milestones:

- Develop a quick, robust, safe and scalable process to support commercial scale
- 2 X 200g lab representative sample as an outcome of lab development
- Sequential scale-up from 25kg to ~100s of Kgs output batch size
- Analytical method development and validation
- Undertake Stability studies and provide CMC documentation and regulatory filing support

Neuland's approach

An experienced group of scientists, engineers and cross functional team evaluated the process and identified the potential gaps to be focused on. Neuland established the process on commercial scale with the stage-specific achievements as listed below.

STAGE-1

Replaced hazardous Cyanating reagent with milder one

Yield improved by **52%**

STAGE-2

Reaction timeline minimized to **3hrs against 48hrs**

Replaced hazardous base with an ecofriendly base

Yield improved by **10%**

STAGE-3

Minimized work-up timelines

Avoided multiple filtrations

Yield improved by **25%**

STAGE-4

Developed a single solvent purification process to achieve a higher quality output material

Value-Adds to the Project:

Considering the growth projections in the market, Neuland also performed the following activities to add further value to the project & ensure the right outcome:

- In-house synthesis of starting material to reduce the cost, lead time and dependency
- Impurity profiling (including genotoxic impurities, absence of Nitrosamines)
- Polymorph screening & particle size distribution
- Design of Experiments (DoE), Failure Modes and Effects Analysis (FMEA)
- Analytical method development and validation
- Sequential scale-up of target API (pilot batch, scale-up batches, registration batches & validation batches)

Final Outcome:

Neuland successfully designed, developed and demonstrated the process for the target drug substance resulting in:

- Overall yield improved by 3 folds
- Project cost eventually reduced by 60%
- High conversion and yield in each stage
- Avoided hazardous reagents and reaction conditions
- Reduced the number of process in each stage through Process Optimization
- Easy isolation and crystallization methods
- Successfully upscaled the process from 25kg to 100s of Kgs output per batch

Disclaimer:

Partial details given to ensure confidentiality