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Case Study

Scaling a CNS API from Lab to Commercial

Region: **US** | Molecule type: **Small molecule** | Phase: **Phase III to Commercial**

About the Client

A leading US-based biotech company specializing in CNS therapies partnered with Neuland Labs to develop and scale a novel NCE API. The molecule was in Phase II when the collaboration began, and Neuland successfully scaled it for Phase III trials and commercial readiness.

Challenge

- Low yield at each stage of the process
- Use of hazardous reagents including cyanating agents
- Need for a safe, scalable, and cost-effective route from lab to cGMP manufacturing

Neuland's Approach

- Replaced hazardous reagents with milder, eco-friendly alternatives
- Applied Design of Experiments (DoE) and FMEA to optimize each stage
- Backward integration of RSM ensured supply security
- Conducted impurity profiling, including genotoxic and nitrosamine
- Performed polymorph screening, particle size distribution, and stability

STAGE-1

Yield improved by **52%**

Replaced hazardous Cyanating reagent with milder one

STAGE-2

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

Yield improved by **10%**

Replaced hazardous base with an ecofriendly base

STAGE-3

Minimized work-up timelines

Yield improved by **25%**

Avoided multiple filtrations

STAGE-4

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

Outcome

- Overall yield improved by 3 folds
- 60% reduction in project cost
- Seamless scale-up from 25 kg to hundreds of kg per batch
- Neuland became the preferred CMO for the client's development programs

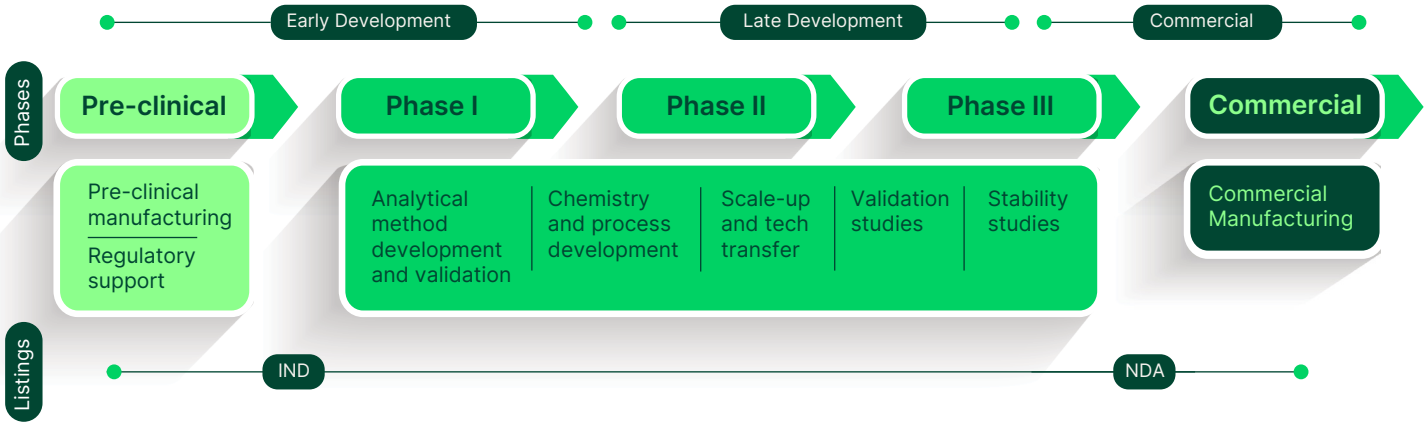
This case exemplifies Neuland's ability to deliver speed, safety, and scalability - transforming a complex CNS molecule into a commercially viable product.

Scan the QR code to access the full case study and dive into our development strategy for this project.

www.neulandlabs.com

Contact us: marketing@neulandlabs.com

Neuland's Phase-Appropriate Solutions



Experience the Neuland Difference

Proven Track Record

Over **4** decades of experience in Small molecule and Peptide API development

Clinical & Commercial Readiness

150+

NCEs projects successfully executed

Scalable Infrastructure

3 cGMP manufacturing facilities with

1174 kL

reactor volume

About Neuland

Neuland Labs is a leading global Contract Development and Manufacturing Organization (CDMO) providing an end-to-end continuum of customised chemistry services. Our services include process development, process optimization, analytical testing, and regulatory support. Right from early-stage drug development through to commercial manufacturing of complex APIs, we offer both small- scale clinical trial quantities and full commercial- scale supply with minimal tech transfer timelines. We are a project-oriented company that fosters collaborative customer relationships with a culture of agility, transparency, and quality at its core.

Make Neuland your strategic partner for improved process efficiency, quality, and ultimately, faster time-to-market for your drug product.

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