neuland

Case Study

Phase-appropriate scale-up and optimization of a low-yield NSAID API process

Region: **Europe** | Molecule type: **Small molecule** | Phase: **Pre-clinical**

About the Client

A European biotech firm needed to scale a 5-gram medicinal chemistry process to 500 grams for pre-clinical trials of a novel NSAID. The original process suffered from low yields, hazardous solvents (DMF, dioxane), and inefficient purification steps.

Challenge

The existing route presented multiple scale-up barriers:

- Low yield across key stages
- Use of Class 2 solvents (DMF, dioxane)
- High catalyst loading and raw material consumption
- Column chromatography unsuitable for scale
- Impurity levels exceeding acceptable thresholds for preclinical use

Neuland's Phase-Appropriate Approach

Neuland applied a phase-appropriate strategy to redesign the process for safety, scalability, and cost-efficiency:

- Replaced hazardous solvents with safer alternatives
- Reduced catalyst and raw material usage
- Eliminated column chromatography in favor of anti-solvent crystallization
- Optimized hydrogenation to suppress impurity formation

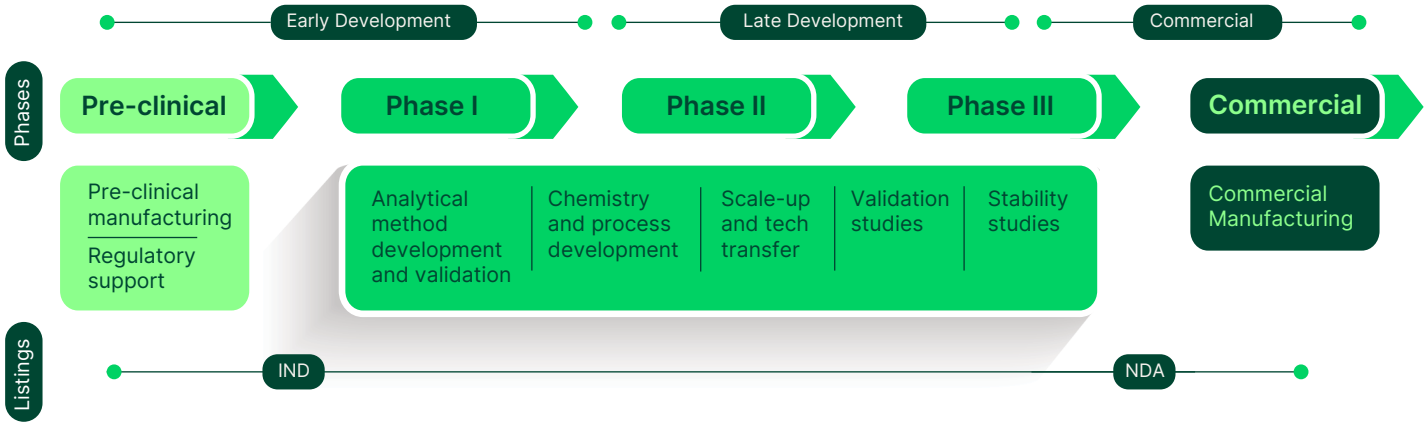
Outcome

- Overall yield increased by 80%
- Raw material costs reduced by 50%
- 500 g delivered two weeks ahead of schedule
- Impurities reduced to <0.35%, suitable for preclinical use

Neuland successfully delivered 500 g of high-purity API, laying the foundation for future GMP production and tech transfer.

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

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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