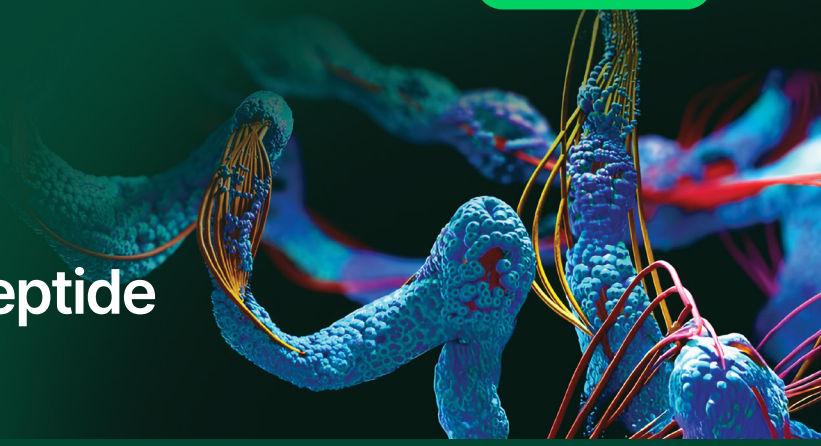
neuland

Case Study

Tackling insolubility & impurities in a 25-AA Peptide



Region: **Europe** | Molecule type: **Peptide** | Phase: **Phase II**

About the Client

A European biotech company developing an osteoporosis therapy approached Neuland with a 25-amino acid peptide sequence - but without disclosing their original synthesis route.

Challenge

The project required development of a scalable, impurity-controlled process from scratch. Key challenges included:

- Severe solubility issues during global deprotection
- Nine persistent impurities that impacted purity and stability
- No prior process knowledge or reference route
- Need for clinical-grade GMP batches with high purity and reproducibility

Neuland's Approach

Neuland's peptide team designed a robust SPPS-based synthesis and purification strategy:

- Developed a new Solid Phase Peptide Synthesis (SPPS) route
- Applied 2D orthogonal preparative HPLC for impurity isolation
- Designed purification and crystallization steps to ensure batch consistency
- Conducted stability studies under –20°C and 2–8°C conditions

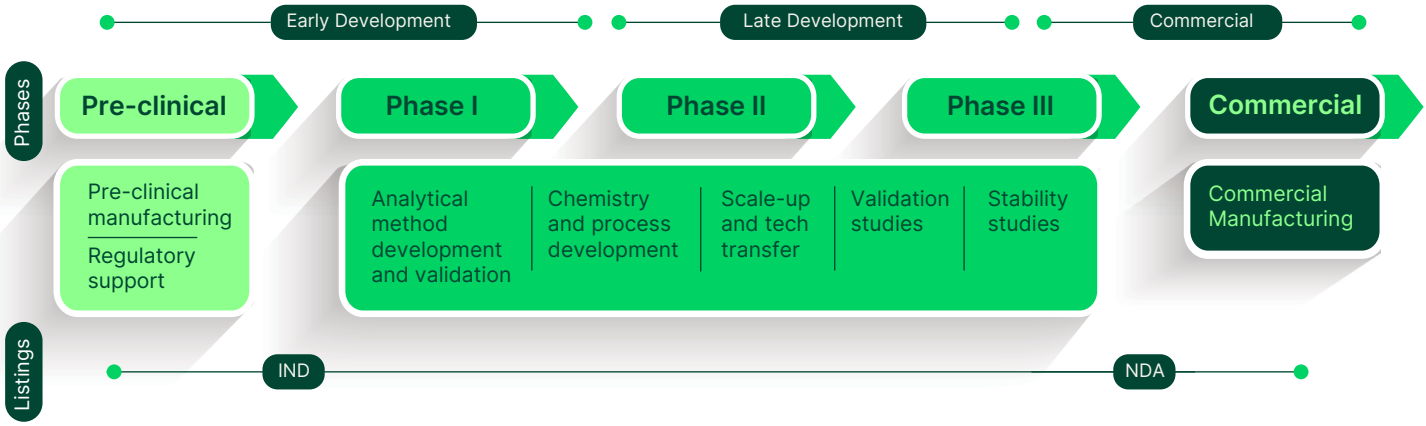
Outcome

- Achieved 30% overall yield
- Achieved >96% purity
- Produced 3 × 15 g validation batches and 3 × 40 g GMP batches

This project demonstrated Neuland's ability to innovate under uncertainty and deliver clinical-grade peptide APIs with speed and precision.

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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