neuland

Peptide Development and Manufacturing

Established in 1984, Neuland Labs is a leading global Contract Development and Manufacturing Organization (CDMO) providing an end-to-end continuum of customised NCE and peptide development services. We have a team of experienced and dedicated scientists, engineers, and technicians who leverage their expertise and the latest technologies to meet the evolving needs of our customers.

We work with pharma and biotech organisations to advance and support their chemistry requirements from early stage through to commercial manufacturing. Our services include process development, process optimization, analytical testing, and regulatory support.

Whether you need a single step or a complete synthesis, we have the capabilities and the flexibility to handle your projects from start to finish. We offer both small-scale clinical trial quantities and full commercial-scale supply for new chemical entities (NCEs), key starting materials (KSMs), active pharmaceutical ingredients (APIs) and their intermediates with minimal tech transfer timelines.

Our Peptide API & NCE Services

Synthetic peptides are being increasingly used as therapeutics, diagnostics, for antibody production, and as tools for understanding biological processes.

Neuland's custom peptide synthesis services include production of peptides from milligrams to multi-kilogram scale by standard sequential chemical peptide synthesis and segment condensation strategies. We enable synthesis of linear as well as cyclic peptides with dedicated state-of-the-art for custom peptide synthesis while adhering to green chemistry principles.

Our core expertise

- Solid phase peptide synthesis
- Solution phase synthesis
- Hybrid technology for complex peptides

We have experience in enhancing the purity of peptides via salt formation, azido-peptides for click chemistry, cyclic (peptides with multiple disulfide bonds, cyclic amides) and PEGylated peptides.

Neuland has delivered 35 kg of a Decapeptide NCE (cGMP) produced by solution phase synthesis to a US company

Several peptides and peptide intermediates (3AA to 40AA) under development on 100s of gram scale to 15 kg scale for clinical trials and commercial supply

Our Capabilities

Custom peptide synthesis

from simple peptides to complex peptides

Analytical R&D

- Analytical method development and validation
- Impurity profiling and validation
- Stability studies
- Supply of analytical reference standards

Process development

- Route scouting
- Optimization & validation
- Impurity profiling
- Characterization and Qualification

Large scale cGMP manufacturing

of complex amino acids and FMOC-building blocks

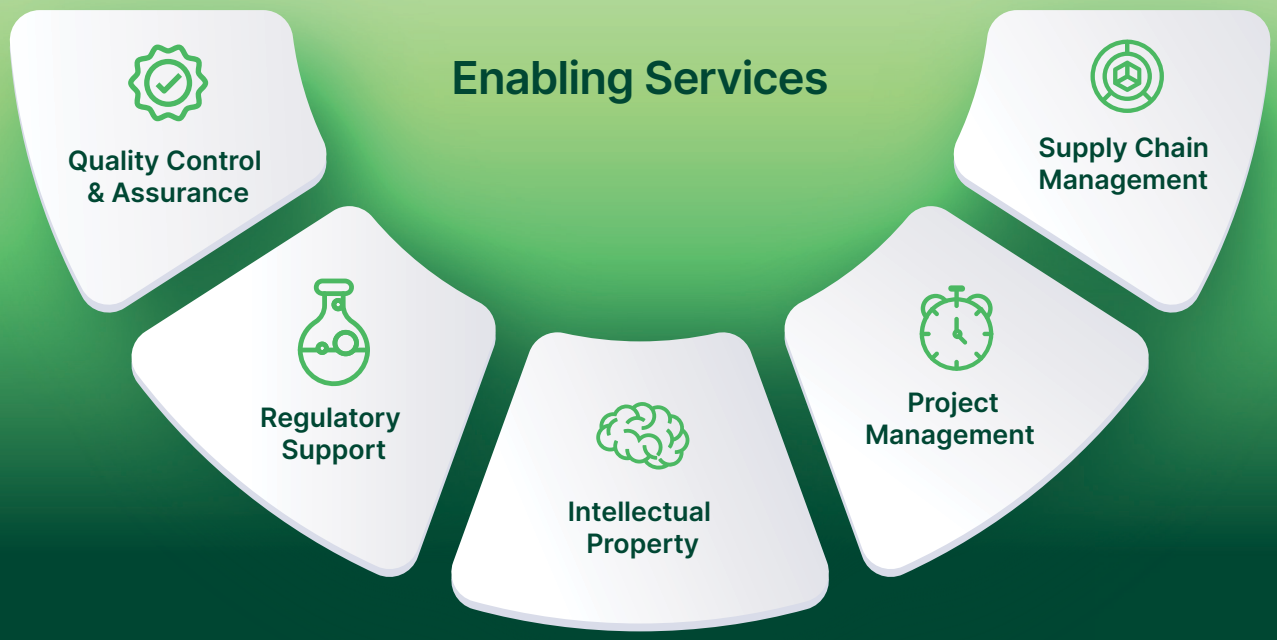
Drug development support

- Supply of material for clinical trials
- Scale up from lab to pilot to commercialization

Regulatory support

- For IND, NDA and other filings

Enabling Services



List of Building Blocks

- Pseudoproline Dipeptides
- Dmb Derivatives
- Hmb Derivatives
- N-Methyl Amino Acids
- Lysine Derivatives

Our cGMP peptide plant is equipped with

SPPS reactors – **100 L**	Glass lined and SS reactors – **3kL**	Nutsche filter SS316 – **50 L**
Vacuum Tray Drier SS316 – **12 Trays**	Tray Lyophilizer (Vertis G35EL5) with OEB 4 and OEB 5 handling capabilities and isolator arrangements – **2 * 35 L**	**3** fume hoods
Preparatory HPLCs -2 (can be increased based on purification work) - (DAC column)	Class **100,000** clean room area	Rotovaps - **20 L**

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