CMS

Custom
Manufacturing
Solutions

NEULAND
WHERE OPPORTUNITY BECOMES REALITY

40 years in small molecule API Development and Manufacturing

Neuland Labs is a leading global Contract Development and Manufacturing Organization (CDMO) and has been supporting innovator Pharma and Biotech companies in custom small molecule API development and manufacturing for over four decades. Three USFDA and cGMP compliant manufacturing facilities, state-of-the-art R&D center, experience in complex chemical processes help handle a range of chemistry services from pre-IND through commercial manufacturing. We offer both small-scale clinical trial quantities and full commercial-scale supply with minimal tech transfer timelines.

Our services

- Designing & Developing manufacturing processes
- Process optimisation for competitiveness
- cGMP manufacturing of APIs & Intermediates
- Filing of CMC/DMF for the API
- Solid state & pre-formulation technologies

Project Management

Reliability, transparency and flexibility are tightly integrated into Neuland's manufacturing operations. Our project management system uses real-time updates to not only give clients a true pulse of the project but also to encourage the completion of tasks to meet the overall project timelines.

Why Neuland?

- 88 novel APIs developed for clinical trials and commercial
- 18+ commercial APIs / Intermediates programs with global innovator companies
- 5 APIs under development for NDA filing in the next 3 years
- Manufactured Novel decapeptide (35 kg) and the program is in phase 3 clinical trials
- 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
- Agile tech transfer at all stages of drug lifecycle or for scale up
- CMC Documentation
- USFDA pre-approval inspections (PAIs) in manufacturing facilities
- Filed CMC variation to NDA, MAA and Japan NDAs as an alternate API supplier

For more information please visit www.neulandlabs.com

Custom Manufacturing Solutions

Infrastructure and Manufacturing Capabilities

Process R&D Center
More than 356 scientists with separate departments for Process engineering, Development QA, and Analytical.
11 laboratories, each equipped with 5–6 fume hoods.
Dedicated lab for high-pressure reactions.
Lab-scale micronization.
1 x 0.75 L, 2 x 1 L, 2 x 2 L and 1 x 5 L autoclaves (Hydrogenation).
Kilo lab with all glass SS and Hastelloy equipment with cryo facility equipment (20 L to 100 L).

Analytical R&D Labs
Neuland has demonstrated expertise in process validation of API for NDA filings, including support for the management of potential genotoxic impurities (investigation and control) and solid-state studies using modern equipment like NMR, LCMS, ICPMS, Ion Chromatography, PSD, DSC, TGA and XRPD.
37 Analytical HPLCs, 10 UPLCs with detectors like CAD, RI, ELSD, PDA, UV.
Advanced equipment like LC-MS/MS, GC-MS/MS, ICP-MS, GC-HS.
Chromatography Data System like Empower and Lab Solutions.
Stability chambers with conditions as per ICH Q1.

Peptide R&D Labs
2 laboratories with 12 fume hoods.
2 preparative HPLCs with 150 mm and 50 mm DAC columns, 7 analytical HPLCs, 3 UPLCs,
20 L & 9 L lyophilizers.
600MHz NMR LC-MS/MS for peptide characterization.

cGMP Kilo Lab (U.S. FDA pre-approval inspection for an NCE API)
All glass vessels ranging from 50 L to 250 L.

cGMP Pilot Plant
2 production areas with 2 class-100,000 clean rooms. SS reactors from 250 L to 1600 L.
Glass lined reactors from 100 L to 1000 L. Micronizer (90% <3 microns).

cGMP Peptide Manufacturing Plant
1 x 100 L glass SPPS synthesizer and 2 x 250 L glass lined reactors with isolators to handle OEB 4 molecules, 2 lyophilizers, 2 preparative HPLC systems, dedicated QC area, class 100,000 clean room.
Ability to produce 10–100 kg of peptide APIs, and high-value complex building blocks.

cGMP Peptide Suite
Class 100,000 pharma area. Rotary Evaporators: 1 x 20 L, 1 preparative HPLC, 2 DAC columns, 2 lyophilizers, 1 VTD (12 trays), 2 x 250 L glass lined reactors & 1 x 100 L glass synthesizer.
API precursors (intermediate stages) are being manufactured in other production blocks.
Ability to produce 100 g–1 kg of peptide APIs, and high-value complex building blocks.

cGMP Vitamin D2, D3 Suite (High-Potency Containment)
Class 100,000 clean area. Analytical lab attached to facility. 5 x 10 L 4 neck round bottom flasks.
1 x 5 L reactors. 1 x 2 L reactors, Rotary Evaporators: 1 x 20 L.

Hydrogenation Capabilities
250, 1000, 1600, 2500, 3000, 5000 L SS autoclaves, designed pressure: 10 kg/cm^2.

Micronization
Small-scale to plant-scale micronization capabilities. Currently micronizing APIs for COPD, Ophthalmic, and Injectables. Achieved PSD of D90, 200 microns to less than 3 microns.

Regulatory Support
CMC documentation review and preparation for the APIs intended for IMPD, IND, NDA, and ANDA registrations, response to the deficiencies, preparation of comprehensive risk assessment reports, tracking regulatory developments and ensuring regulatory compliance.

Manufacturing Facilities

Unit 1: U.S. FDA inspected 7 times. All other major regulatory bodies inspected. 7 Production units. 9 class 100,000 clean rooms. Total reactor volume of 239 KL. Reactor sizes ranging 5 L to 6300 L (SS, GLRs & all glass reactors).

Unit 2: U.S. FDA inspected 7 times. All other major regulatory bodies inspected. 6 Production units. 5 class 100,000 clean rooms. Total reactor volume of 382 KL. Reactor sizes ranging from 100 L to 8000 L (both SS and GLRs).

Unit 3: Inspected by USFDA as an Advanced Intermediates site in 2015. Inspected by USFDA in May 2023. 6 Production units. 3 Class 100,000 clean rooms. Total reactor volume of 320 KL. Reactor sizes ranging from 100 L to 10000 L (both SS and GLRs) and 5 KL Hydrogenator facility.

Neuland Highlights

- Awarded with 'Silver Sustainability Rating' by Ecovadis in 2023
- Awarded an ESG score of 64 out of 100 by S&P Global in 2023
- Awarded the prestigious IP Excellence Award 2024 for "Best Patent Portfolio, Large Enterprises (Life Science)"
- State-of-the-art manufacturing facilities (USFDA, EDQM and PDMA approved) and R&D facility

Capabilities

- Synthesis of Complex Molecules
- Deuterated molecules
- Peptides in solid phase, solution phase and hybrid technology
- Peptide Building Blocks (RSMs)
- Steroidal Bile Acids and Vitamin D derivatives
- Carbohydrate chemistry
- Macrolides/Ketolides
- Heterocyclic compounds
- Chiral compounds manufacturing
- Organometallic Carbon-carbon bond formation
- Cyanation & Bromination
- Birch reduction
- Asymmetric hydrogenation

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www.neulandlabs.com

The Dedicated 100% API Provider

GDS — Generic Drug Substances
CMS — Custom Manufacturing Solutions
Peptides — Peptides