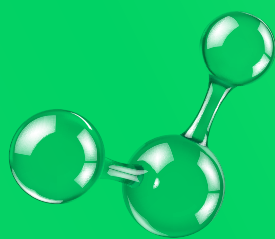




Empowering progress,
Enriching lives

Small Molecule Custom 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 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, including 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 CDMO Services

Custom Development

Process Optimization & Validation – We enhance efficiency and atom economy by analysing and redesigning processes to eliminate steps, reduce waste and increase output. Our QA and validation team ensures consistent quality from design to production.

Technology Transfer – We ensure efficient and seamless tech transfer of products, minimizing disruptions through careful planning and execution.

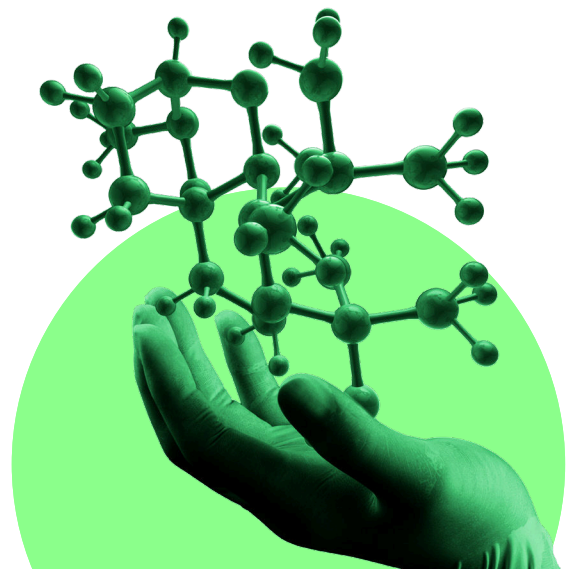
DoE & QbD Studies – Our scientific team employs rigorous tools and methodologies in R&D, including risk management and DoE software, to understand and control processes.

Process & Particle Engineering – Our process engineering team utilizes PAT tools to develop robust processes, providing customers with comprehensive data for pre-formulation.

Custom Manufacturing

Clinical Manufacturing – We have the facilities and capabilities to produce APIs for Phase I through to large Phase III clinical trials. We work closely with our customers to understand their clinical development plans and provide a bespoke clinical manufacturing solution.

Commercial Manufacturing – We have a proven track record of supplying APIs built on safe and robust processes, in regulatory compliant facilities. Our experienced and agile team works with you to overcome the challenges of commercial manufacturing.



Our Analytical Services



Method development
for complex molecules



Synthesis and
characterization of impurities



Genotoxic impurity assessment



Stability studies



Complete analytical
validation package



Reference standard
qualification



Study of solid-state
properties



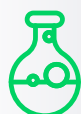
Salt screening
and optimization



Quality Control
& Assurance



Supply Chain
Management



Regulatory
CMC Services



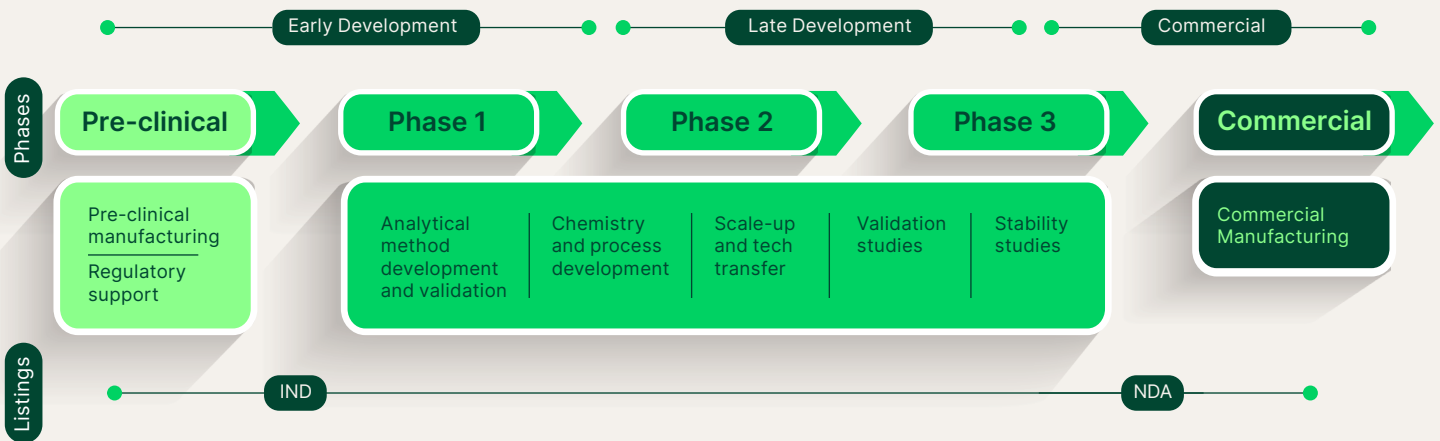
Project
Management



Intellectual
Property

Enabling Services

We provide phase-appropriate solutions across the entire drug development cycle



Business Highlights

18+ commercial APIs / Intermediates programs with global innovator companies

88 NCEs projects developed for clinical trials and commercial

5 APIs under development for NDA filing in the next 3 years

Agile tech transfer at all stages of drug lifecycle & scale-up

Three cGMP manufacturing facilities compliant with global regulatory standards such as USFDA, EMA, EDQM, PDMA, ANVISA, KFDA, TGA, etc.

State-of-the-art R&D Center - 15 Development Labs, Analytical, Kilo and Peptides

Manufacturing Facilities

	Unit I Bonthapally, Hyderabad 239 KL	Unit II Pashamylaram, Hyderabad 381 KL	Unit III Gaddapotharam, Hyderabad 321 KL
Blocks	Block - 1, 2, 3, 4, H, KL & S	Block - 1, 2, 3, FC, NMSM, Mini Plant (A&B)	Block - 1,2,4,5,7 & 8
Hydrogenation Reaction Volume	0.88 kL (250 L, 630 L) with 5 bar pressure	6 kL (5 kL, 1 kL) with 8 bar operating pressure	6 kL (5 kL, 1 kL) with 10 to 12 bar pressure
Solvent Recovery System	100 KL/D	20 KL/D	50 KL/D
Cryogenic Reaction Volume	4.7 kL (- 60 °C to - 90°C)	17 kL (- 60 °C)	16 kL (- 60 °C and - 90 °C)



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