

Recipharm inaugurates state-of-the-art parenteral development and sterility laboratories

- *Expanded capabilities: new facilities strengthen Recipharm's global development and testing services.*
- *Accelerated development: support faster, seamless transition from early-stage studies to cGMP manufacturing.*
- *Enhanced client offering: provides regulatory-aligned sterility and analytical testing for clients worldwide.*

Recipharm, a leading global contract development and manufacturing organisation (CDMO), today announced the inauguration of its newly-commissioned parenteral development and sterility laboratories at its Bengaluru site in India. The purpose-built facilities significantly enhance Recipharm's capabilities in sterile pharmaceutical product development and testing, marking a strategic expansion of its analytical services function. This investment builds on Recipharm's established strengths in oral dosage and advanced therapies, further broadening its product development portfolio.

The parenteral development laboratory is designed to accelerate the development of generic and proof-of-concept injectable products. Equipped to handle formulation and feasibility studies for solutions, suspensions and lyophilised powders, the lab supports critical early-stage activities such as pre-formulation studies, prototype batch preparation using QbD (Quality by Design) principles, analytical testing, stability evaluation and compatibility studies. These capabilities create a seamless pathway for transition into cGMP-compliant and aseptic manufacturing, in particular when using Recipharm's small batch production lines for clinical supply (such as ReciDev™ PFS or ReciDev™ SFF).

The newly established sterility laboratory expands Recipharm's existing analytical and quality testing capabilities. The lab offers sterility testing through validated methods, including membrane filtration and direct inoculation, as well as bacterial endotoxin using gel clot, turbidimetric and kinetic chromogenic methods. In addition, particulate matter analysis, covering both viable and non-viable particles, ensures robust cleanroom compliance and product release support. These new capabilities are integrated into the existing analytical centre of excellence, which performs all pharmacopeia testing, stability studies, extractable & leachable and elemental impurities. Dr. Uwe Hanenberg, Head of Product Development at Recipharm, said: "The inauguration of our new parenteral and sterility laboratories in Bengaluru represents another important step in expanding our global capabilities. This investment reflects our commitment to providing end-to-end solutions for our partners, ensuring speed, compliance and scientific rigour in the development of sterile pharmaceuticals."

The sterility laboratory enhances Recipharm's ability to deliver timely, science-driven and regulatory-aligned testing services to clients worldwide. It fully complements its Cuxhaven, Germany, advanced therapy analytical services centre of excellence.

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For more information

About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) employing over 5,000 employees worldwide. Recipharm provides manufacturing services of pharmaceuticals in various dosage forms, including sterile fill & finish, oral solid dosage and biologics; clinical trial material development and manufacturing services; and pharmaceutical product development. Its Recipharm Advanced Bio segment works with customers to develop and commercialise advanced therapy medicinal products (ATMPs): pre-clinical to clinical development, commercial development and manufacture for new biological modalities, encompassing technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, nucleic acid-based mRNA and plasmid DNA production.

Recipharm manufactures several hundred different products to customers ranging from big pharma to smaller research and development companies. It operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden and the US.

For more information on Recipharm, please visit www.recipharm.com

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