

Recipharm expands manufacturing to meet demanding FDA requirements

- *Established a new, dedicated non-bacterial beta-lactam manufacturing facility in response to FDA guidance*
- *Secured a strategic partnership with an innovative biopharma company seeking rapid regulatory compliance*
- *Developed a scalable platform in Bengaluru, India, with capacity available to support future customers with similar regulatory needs.*

Recipharm, a leading global contract development and manufacturing organisation (CDMO), has developed a new, dedicated manufacturing facility to meet the latest regulatory expectations for non-bacterial beta-lactam medicines. This investment responds to regulatory guidance and to growing customer demand for compliant, dedicated manufacturing solutions.

The final draft guidance published by the US Food and Drug Administration (FDA) requires non-bacterial beta-lactam compounds to be manufactured in a manner that fully prevents cross-contamination with other pharmaceutical products. The intent of the guidance is to further enhance patient safety, as even trace exposure to these compounds can trigger allergic reactions in susceptible patients.

Listening closely to both regulators and customers, Recipharm adapted its manufacturing strategy to align with these far-reaching requirements. It has established a purpose-built, dedicated capability for non-bacterial beta-lactam tablet production, enabling customers to meet regulatory expectations quickly, while maintaining flexibility, speed and continuity of supply. The facility has been designed to comply with both US FDA and European Medicines Agency regulatory requirements.

As a direct result of this investment, Recipharm has secured a major partnership with a leading innovative biopharmaceutical company to manufacture its non-bacterial beta-lactam tablets. The client sought a solution that could rapidly meet the highly demanding FDA expectations without the need to commit significant capital, time or internal resources to building and validating a dedicated in-house facility.

Greg Behar, CEO at Recipharm said: "Regulatory change should not become a barrier to innovation or patient access. Our role as a CDMO is to adapt to our customers' need and how the market is regulated. We evolve our manufacturing capabilities so our partners can focus on what matters the most to them: researching and developing new drugs."

The partnership includes the installation of new, specialised manufacturing capabilities at Recipharm's site in Bengaluru, India. This strategic expansion not only supports the current collaboration but also establishes a strong platform with available capacity to serve additional pharmaceutical and biopharmaceutical companies with non-bacterial beta-lactam manufacturing requirements.



By responding swiftly to evolving regulatory expectations and customer requirements, Recipharm continues to demonstrate its nimble, customer-centric approach, enabling compliant, efficient and scalable manufacturing solutions.

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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 and www.recipharm-ab.com

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