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Recipharm announces Centre of Excellence for Advanced Biologics Analytical Services

- *Lab staffed with expert biochemists and biologists*
- *Centre of Excellence provides customers with faster, more cost-effective access to the highest quality analytical testing*
- *Lab is a critical asset for advanced therapy medicinal products (ATMPs) and biologics, complementing Recipharm's existing analytical services capabilities.*

Recipharm, a leading global contract development and manufacturing organisation (CDMO), announces the designation of its Cuxhaven facility as the Centre of Excellence for Analytical Services tailored to advanced modalities.

The Cuxhaven site has evolved into a strategic hub supporting customers' analytical needs across both the US and EU. With newly renovated, state-of-the-art 500 m² CGMP analytical laboratories and scalable capacity, the site is equipped to support projects from early development through commercial manufacturing.

Designed to support customers' innovations

With over 15 years of experience in analytical method development and qualification, the Cuxhaven team specialises in both compendial and non-standard assays. The team's comprehensive capabilities span drug substance and drug product QC testing, including microbiological and viral assay validation, nucleic acid quantification, and complex techniques such as ddPCR, qPCR, and Western blot, making the site a critical asset for advanced therapy medicinal products (ATMPs) and biologics.

Operational agility and expanded capacity

Purpose-built for flexibility and speed, the Cuxhaven lab streamlines analytical workflows by concentrating test samples in a single location. This minimises reliance on third-party services, accelerates timelines, and ensures seamless method onboarding by a team of highly-trained biochemists and biologists.

Vikas Gupta, President of Recipharm Advanced Bio segment, said: "By adding key analytical services in Cuxhaven, we are reducing our reliance on external third-party labs, and providing our customers with faster, more cost-effective access to the highest quality analytical testing. Our expanded capabilities position us to better support the growing demands of advanced modality development and manufacturing."

Key features of the Cuxhaven analytical services hub include:

- Newly expanded GMP lab with increased capacity
- In-house QC and stability chambers for all ICH conditions
- In-house sterility testing
- Expert implementation of new and custom analytical methods
- Standard and customisable assays across multiple modalities
- Substantial cost savings compared to traditional CROs.

This strategic move reinforces Recipharm's commitment to innovation and operational excellence across the full product lifecycle, from information transfer and analytical development to GMP release and stability testing, in the dynamic advanced biologics market.

Recipharm Advanced Bio brings deep expertise and a proven track record across advanced therapies, including plasmid DNA, xRNA, lipid nanoparticles, microbiome, viral vectors and sterile fill and finish. With end-to-end capabilities from process development through clinical and commercial manufacturing, Recipharm offers a "bench to clinic" pathway within a single CDMO network.

The Cuxhaven site is a 9,300m^2, BSL-2, multi-product facility providing end-to-end support from preclinical through commercial readiness. Capabilities span viral and bacterial cell banks; viral-based therapies including AAV, lentivirus, and oncolytic viruses; sterile fill and finish; analytical services; and recombinant proteins/monoclonal antibodies. As a multi-service, flexible site and centre of excellence for oncolytic and viral vector programmes, Cuxhaven's expansive in-house QC capabilities accelerate production and limit reliance on third-party services, ensuring robust pathways to commercial readiness.

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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 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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