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Concept Life Sciences Opens New Pharmaceutical Manufacturing Support Services

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A new, state-of-the-art clinical and niche commercial facility to support pharmaceutical and biotechnology companies throughout the development and manufacture of active pharmaceutical ingredients (API)



Concept Life Sciences, a knowledge-based provider of integrated discovery, development and analytical services, on 18 June 2019, unveiled a new, state-of-the-art clinical and niche commercial facility to support pharmaceutical and biotechnology companies throughout the development and manufacture of active pharmaceutical ingredients (API). Located at Discovery Park in Sandwich, UK, the purpose-built facility offers a comprehensive range of services designed to allow partner organizations to take drug candidates through discovery, scale up and into current Good Manufacturing Practice (cGMP)-compliant production.

“Pharmaceutical and biotech companies of all sizes are demanding high-quality, early-stage manufacturing capabilities that can readily scale up target molecules from grams to kilograms, and then into cGMP-compliant API manufacture all while mitigating the risk typically associated with moving between different stages of the drug development process,” said Dr Paul Doyle, Chief Scientific Officer at Concept Life Sciences. “Building on our depth of scientific expertise in medicinal and discovery chemistry, the new, specialist facility strengthens our support services so we can enable our partners to boost their productivity and deliver products to market faster and more efficiently.”

With the new facility joining the company’s growing network of sites across the UK, Concept Life Sciences’ pharmaceutical manufacturing support services now comprise:

- **API process research and development, and cGMP**– both small- and larger-scale plants, including the capability to provide a demonstration, toxicology and clinical batches
- **Quality control release testing**– a unique blend of high-end characterisation techniques and standard chromatographic methods for raw material and finished product release in compliance with cGMP requirements
- **Stability studies**– in line with the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- **Out-of-specification investigations**– identification of contaminants and impurities, materials characterisation and responsiveness in emergencies to minimise production downtime

- **Extractables, leachables and sorption studies**– testing of packaging to support regulatory submissions and packaging changes
- **Cleaning verification and validation**– full cGMP-compliant capabilities to ensure optimal product protection
- **Occupational hygiene**– sensitive surrogate testing using low-hazard compounds, air quality monitoring and safe handling of biological samples, as well as development, validation and analysis of air filter and swab samples
- **Environmental monitoring**– effluent analysis, land contamination testing and emissions control