Shilpa Launches 'hybrid CDMO' at DCAT

Integrated CDMO has capabilities spanning small and large molecules as well as peptides with 'off-the-shelf' commercially ready formulations for license

10/03/25, India: Shilpa Medicare launches its new full service 'hybrid' CDMO at DCAT 2025. The newly formed CDMO will see Shilpa serve both small and large molecules customers as well as peptides – with oncology a particular therapeutic specialism.

In addition to offering comprehensive discovery, clinical, and commercial outsourcing services, Shilpa's 'hybrid CDMO model' also includes commercially ready 'off-the-shelf' novel formulations for exclusive b2b licensing. This dual approach enables pharmaceutical companies to leverage Shilpa's extensive expertise in oncology without the direct risks and lengthy timelines associated with development.

The CDMO currently has multiple assets in its pipeline and three late-stage products available for licencing at DCAT. Through this model, pharma companies can expedite their market entry by licensing fully developed products while still benefiting from Shilpa's robust development and manufacturing capabilities.

Commenting on the business realignment and hybrid model, Vishnukant C. Bhutada, Managing Director of Shilpa Medicare, commented: "Our goal is to offer pharmaceutical and biotech customers multiple flexible pathways to bring commercial products to market. On the one hand, they can leverage our development teams, cutting-edge technologies, and world-class facilities in a traditional CDMO partnership – with both our GLP-1 and biologics services in high demand at DCAT. On the other, we have a pipeline of fully developed products that are available for exclusive licensing, eliminating development risks for our partners. However, we remain strictly a b2b-only company, ensuring we never compete with our clients."

Shilpa Medicare has seen rapid growth in recent years, achieving a turnover of over \$150 Million. The company is well-positioned to capitalize on the increasing trend of pharmaceutical outsourcing to India, offering an extensive infrastructure with five state-of-the-art R&D centers and six manufacturing facilities. These include two dedicated drug substance plants, three drug product plants, and advanced platform technologies for high-potency compounds (OEB 5), ADCs, peptides, and polymers. The total API reactor volume exceeds **800 KL**, with two separate commercial drug product lines featuring advanced formulation technologies such as liquid-lyophilization, nano liposomes, and microfluidization.

Its peptide capabilities span both solid and solution phase peptide synthesis or a combination of both. The integrated facilities – including inhouse regulatory and IP teams – provide fill/finish services for both cartridges & devices, with an annual capacity of 20 million units, and peptide drug substance production capacity of 40kg API/year.

For <u>biologics customers</u>, Shilpa operates a dedicated facility covering drug substance, product, and packaging. In response to increasing global demand, the company has 8KL capacity for monoclonal antibodies (mAb) that can increase **16KL**, with a further large **200KL** microbial fermentation facility set to be operational later this year.

The CDMO is supported by a diverse talent pool of over 3000 professionals, including more than 350 scientists and 1000 manufacturing specialists.

Keshav Bhutada, Director at Shilpa Medicare Group added, "We are building an integrated platform company and we have a very clear expansion vision to sell global partners. So, we expect to sign a number of prominent deals at DCAT. There is a real shortage globally of full-service partners with our breadth of capabilities from discovery to commercial supply and across multiple modalities whether small molecule, biological, peptide and even GLP-1. Consequently, demand is growing incredibly quickly as those with large DS and DP capabilities are able to advance projects more quickly for partners."

Shilpa's CDMO formulation services span oral solids, topicals, injectables, transdermal patches, ophthalmic delivery and oral thin films. While its manufacturing sites have approvals from global regulators including the FDA, EMA, PMDA, TGA and MHRA.

-ENDS-

Notes to editors

About Shilpa Medicare

Shilpa Medicare is a leading global pharmaceutical company specializing in contract development and manufacturing services for small and large molecules. With a strong emphasis on oncology and a growing presence in biologics, the company offers comprehensive solutions from discovery to commercial supply. Shilpa Medicare operates world-class R&D and manufacturing facilities, serving partners across North America, Europe, and Asia.