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Shilpa Biologicals unveils new gene to GMP manufacturing platform SB HiMax for biotechs

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Designed to expedite gene to GMP manufacturing for biotechs in as little as 9 months



Shilpa Biologicals, a subsidiary of Shilpa Medicare, has launched its new gene to GMP manufacturing platform, SB HiMax which will empower biotechs to take suitable monoclonal-antibody programmes from gene to GMP clinical supply in as little as nine months, and complex bispecific and trispecific antibodies in approximately 11 months.

The new service – being launched at CPHI Milan, 6–8 October 2026 – has been specifically created for biotechs seeking accelerated development timelines but struggling to find partners able to offer the necessary speed and flexibility.

Unlike conventional cell-line development platforms, SB HiMax provides an integrated pathway from clone development and cell-bank creation through upstream and downstream process development, analytical-method development, GMP drug-substance manufacturing and drug-product filling.

CMC development and regulatory support are embedded throughout, enabling customers to progress towards clinical studies without repeatedly transferring their programme between different providers.

Significantly, SB HiMax, not only helps clients improve timelines but also improves yield, with the platform typically achieving >5 g/L, which is significantly above the industry average for 1–3 g/L for CHO fed-batch processes. The service is available not just across monoclonal targets but is available to customers with ADCs, bioconjugates, microbial-expressed products and recombinant proteins.

SB HiMax accelerates development by running clone screening, process development and key CMC activities in parallel, supported by established platform processes and single-use GMP manufacturing. The platform scales to 2,000 L while maintaining critical quality attributes and less than 10% titre variation, helping customers establish a commercially viable process from the outset.