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Syngene's biologics manufacturing facility to be operational for US and European customers from mid-2024

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New facility includes 20KL of single use drug substance capacity coupled with drug product filling capacity



Bengaluru-based Syngene International, a global contract research, development and manufacturing organisation (CRDMO), will be setting the operations of its newly upgraded biologics facility, Unit 3, for clinical and commercial supply in the second half of 2024.

The facility will be available for biotech and pharma customers seeking drug substance and drug product contract manufacturing. The drug substance capacity includes two production suites with five 2KL single use bioreactors each, for a total capacity of 20KL. The facility also includes two high-speed vial filling lines capable of producing up to 1 million vials per day ranging from 1 to 100mL fill volumes. In addition to the production capacity, the site has a development suite for clinical supply of drug substance equipped with a 500L single use bioreactor.

The facility triples Syngene's bio manufacturing capacity and adds to its existing commercial manufacturing site in Bengaluru, BMP 1, which has been approved by the US FDA (with no 483 observations) and EMA, as well as a PROTAC research site in Hyderabad.

Syngene has further expansion plans for two additional vial filling isolator lines with capacity for 600 vials/minute and 100 vials/minute respectively and drug substance expansion into perfusion cell culture processing.

The $98 million manufacturing site is integrated with other biologics capabilities in the city including around 170 R&D scientists located nearby offering clients a seamless transition from discovery biology services into clinical and commercial manufacturing. The company also has a microbial cGMP facility and a mammalian cell manufacturing facility to extend end-to-end Chemistry, Manufacturing and Control (CMC) development solutions for its global clients.

In total, Unit 3 will have around 100 staff for Quality Assurance and Manufacturing, part of Syngene's 600-strong team across its biologics manufacturing services and supporting specialist functions.