Home and US CAPEX places India on brink of bioCDMO breakthrough

Indian CDMOs are becoming a major force in the biologics space. Ahead of BIO, we spoke with Aragen, Syngene, and Enzene to discuss responding industry's needs in light of the BIOSECURE Act.

Dan Stanton, Managing editor | June 3, 2024

As our recent ebook discussed, India – historically the 'pharmacy to the world' due to its heritage in small molecule production and supply – is finally making strides on the large molecule front. The country has seen a host of investment in third party biologics capacity and is likely to be propelled further as a growing hub of bioproduction if the BIOSECURE ACT passes, effectively stopping US biotech from working with Chinese firms.

Ahead of trade body BIO's annual conference, which takes place this week in San Diego, California, we spoke to Indian contract development and manufacturing organizations (CDMOs), Aragen BioScience, Syngene, and Enzene, about the proposed Act and their individual expansions in India and beyond.

Enzene has operations in India and a planned US site opening later this year. "The increased customer visits at our facilities this year reflect a shift driven by geopolitical tensions and supply chain disruptions, and we're aligning our capabilities and technology accordingly," the company told BioProcess Insider.

Similarly, Aragen CEO Subodh Deshmukh told us his firm is seeing an increase in inquiries from both large pharma and biotechs that are looking to leverage its capacity and capabilities. "In view of geo-political developments such as the BIOSECURE Act, there is significant interest from US-based companies who are reviewing their supply chains."

Aragen recently opened a pilot site in Bangalore, which is already being used for non-GMP production for batches up to 50 liters, we were told. The plant will be augmented with a GMP manufacturing suite, coming on stream by the end of the year, equipped with multiple single-use bioreactors at a 2,000 L scale.

Syngene too is prime to benefit from BIOSECURE. "It's a big story in the press clearly, but our role is a little different – yes are perceived as being 'winners' from this shift. But "The reason we are potentially going to do very well in the next few years is much more nuanced and capability based," Alex Del Priore, senior vice president of manufacturing services at Syngene, told us. "We offer large R&D teams and combine this with readily available capacity. It means we are one a very select few providers that can take a project, or even an entire drug discovery program from a major pharma, and advance that with dedicated teams."

Syngene paid INR 702 Crores ($86 million) last year to acquire what once was a dedicated plant for the production of Russia's Covid vaccine Sputnik Light from Stelis Biopharma.

"The Bangalore site will be available for biotech and pharma customers seeking drug substance and drug product contract manufacturing," said Del Priore.

"The drug substance capacity includes two production suites with five 2KL single use bioreactors each, for a total capacity of 20KL as well as a development suite for clinical supply of drug substance equipped with a 3 x 200L single use bioreactor and drug substance expansion into perfusion cell culture processing. 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."

Coming to America

Unrelated to BIOSECURE, both Aragen and Enzene have also invested in capabilities outside their native country, specifically in the US.

Enzene's 54,000 square-foot New Jersey facility is set to begin its first phase of operations in Q3 2024, equipped with 500 L and 2,000 L bioreactors. "This commercial-scale GMP facility aims to support clinical and commercial manufacturing, with continuous manufacturing processes," the company told us.

"With our US site, our intention is to create access equity for biological assets whether human or animal and in any phase of development, by providing cost-effective local manufacturing. The US has the maximum number of novel molecules, especially in small start-up companies. These promising lifesaving molecules often struggle to find local manufacturing partners, which can significantly hinder their path to launch. Our first step in the US aims to create access equity by providing state-of-the-art, cost-effective continuous manufacturing to small and mid-size companies."

For Aragen, its Morgan Hill, California site is already handling non-GMP manufacturing for batches from 1 L to 250 L.

"The US site is a fully self-sufficient R&D entity with experienced staff offering expertise at all stages from discovery to development.," Deshmukh said. "When fully operational at the end of this year, staff on the new Indian site will offer integrated development and manufacture backed by extensive QA and QC facilities."

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