Navigating the Future:

Insights from Leading Indian CDMOs on the Impact of the BIOSECURE Act and the Shift from Chinese CDMOs

The pharmaceutical and biopharmaceutical sectors are undergoing transformative shifts driven by geopolitical tensions and regulatory changes. Among these changes, the BIOSECURE Act and the 2032 decoupling deadline from Chinese CDMOs stand out, prompting companies to reassess and revamp their supply chain strategies. Chloe Euripides of the International Biopharmaceutical Industry Journal recently interviewed three key representatives from leading Indian CDMOs: Alex Del Priore of Syngene International Ltd., Ramesh Subramanian of Aragen Life Sciences, and Himanshu Gadgil of Enzene Biosciences. Their responses provide a comprehensive view of how these companies are adapting to the new landscape and positioning themselves as competitive alternatives to Chinese CDMOs.

The BIOSECURE Act and Strategic Shifts

The BIOSECURE Act and the 2032 decoupling deadline are significantly shaping Enzene's strategic planning. Himanshu Gadgil, CEO, highlights that the shift has driven Western companies to explore alternatives to Chinese CDMOs, resulting in increased interest and customer visits to Enzene's facilities. To leverage these opportunities Enzene is expanding its operations, including launching a new drug discovery division and investing in innovative technologies like EnzeneX™. This expansion aims to provide end-to-end solutions and meet the evolving demands of their clients.

Ramesh Subramanian, Chief Commercial Officer, notes that the BIOSECURE Act is prompting Western pharma companies to reconsider their strategies. Aragen is preparing for these strategic shifts by investing USD 250 million to expand its R&D and manufacturing facilities in Hyderabad. This includes adding biologics manufacturing capabilities and expanding their footprint in small molecules, peptides, oligonucleotides, and ADCs. Unlike the rapid shifts during the COVID-19 pandemic, Subramanian observes a more deliberate approach as companies plan for long-term changes.

Alex Del Priore, Senior Vice President of Manufacturing Services, explains that Syngene is strategically positioned to capitalise on the supply chain shifts accelerated by the BIOSECURE Act. The company has experienced a surge in interest from biopharma companies seeking to reduce reliance on China. Syngene's strategy involves leveraging its dual growth engines – CRO services and CDMO services – while offering flexible supply chain options to cater to clients' needs for both China-based and China-independent sourcing.

Unique Strengths of Indian CDMOs

Enzene's unique strengths in the global CDMO market include their proprietary EnzeneX™ technology, which offers significantly greater productivity and cost-efficiency compared to traditional methods. With operations in India and a planned US site, Enzene focuses on innovation, quality and customer-centricity, making it an attractive alternative to Chinese CDMOs.

Aragen's strengths lie in its skilled English-speaking workforce, strong track record of quality compliance, and experience with Western regulatory guidelines. These factors, combined with rich experience in the West, position Aragen as a reliable partner for Western clients seeking high-quality CDMO services.

Syngene's integrated services from discovery to commercial scale manufacturing, coupled with their investment in next-generation technologies and a large pool of skilled scientists, make them a strong competitor in the global CDMO market. Their flexible R&D services and long-term strategic collaborations further enhance their attractiveness as an alternative to Chinese CDMOs.

Responding to Increased Interest and Demand

Enzene has seen a significant increase in site visits from big pharma, driven by geopolitical tensions and supply chain disruptions. Gadgil notes that the feedback has been overwhelmingly positive, with clients appreciating their innovative manufacturing solutions. Enzene is launching a new facility in New Jersey equipped with state-of-the-art continuous manufacturing processes to meet the high standards of their clients.

The increasing interest in Aragen's services from big pharma reflects the importance of geo-diversity in business continuity planning. Subramanian emphasises that Aragen's facilities have been audited by multiple clients and certified by major global regulatory authorities. The positive feedback from both existing and new clients highlights Aragen's focus on quality and their ability to operate as an extension of their clients' teams. To meet the growing demand, Aragen is expanding its capabilities in small molecules and biologics, with significant investments in clinical and commercial manufacturing capacities.

Syngene has also experienced heightened interest from big pharma, driven by the need to de-risk supply chains. Del Priore notes that the company's ability to deliver end-to-end solutions, its investment in cutting-edge technologies, and its robust quality assurance measures have positioned Syngene well in order to capture new opportunities. The recent acquisition of a biologics manufacturing facility and plans to expand drug substance and drug product capacities, demonstrate Syngene's commitment to scaling up operations and meeting client expectations.

Scaling Up Operations

To handle increased demand, Enzene is making strategic investments in expanding its capabilities. This includes bringing online new manufacturing lines in Hopewell, NJ, and developing

EnzeneX™ 2.0 to enhance various aspects of their processes. Additionally, Enzene is working on new cell lines designed to achieve high productivity at a lower cost, ensuring they can scale up operations effectively.

Aragen has been proactively investing in expanding its capabilities across small molecules and biologics. The company has added clinical manufacturing capacity, opened a biologics pilot plant in Bangalore, and is set to add GMP manufacturing capacities by the end of the year. With significant investments in R&D and manufacturing facilities in Hyderabad, Aragen is well-positioned to meet the surge in demand for its services.

Syngene's growth strategy focuses on scaling up and widening its operations through strategic investments. This includes expanding biomanufacturing capabilities, enhancing quality control laboratories, and integrating advanced technologies like AI and ML into their processes. Syngene's recent acquisition of additional land in Genome Valley, Hyderabad, prepares the company for future growth and expansion, ensuring they can handle the increasing demand resulting from the shift away from Chinese CDMOs.

Future Competitive Landscape for Indian CDMOs

Gadgil foresees a significant evolution in the competitive landscape for Indian CDMOs, driven by the increased focus on biologics and advanced manufacturing technologies. Enzene's pioneering use of continuous manufacturing technology, commitment to innovation, and focus on cost-effectiveness position them to lead this transformation. As industry standards evolve and regulations support continuous manufacturing, more CDMOs are likely to adopt this approach to meet regulatory and environmental demands.

Subramanian anticipates a major shift in the competitive landscape for Indian CDMOs, particularly with the growing demand for biologics and advanced manufacturing technologies. Indian CDMOs are investing in digitization and digitalisation technologies, including AI and ML tools, to enhance productivity and improve processes. Aragen's use of AI-based tools to optimise critical process parameters has already yielded significant improvements, positioning the company to lead in this evolving landscape.

Del Priore expects the competitive landscape for Indian CDMOs to evolve significantly over the next five years, driven by advancements in biologics and manufacturing technologies. Syngene's comprehensive capabilities in areas like CAR-T cells, PROTACs, mRNA, and ADCs, combined with continued government support and strategic investments, will enable the company to capture a substantial market share. Syngene's strong focus on strategic partnering, alternative supply options, and deep trust from US and European biotechs will further strengthen its position in the global market.

Conclusion

The BIOSECURE Act and the shift away from Chinese CDMOs are reshaping the global pharmaceutical and biopharmaceutical industries. Indian CDMOs like Enzene Biosciences, Aragen Life Sciences, and Syngene International Ltd. are strategically positioning themselves to capitalise on these changes. Through significant investments in innovative technologies, expanded capabilities, and a strong focus on quality and customer-centricity, these companies are emerging as competitive alternatives to Chinese CDMOs. As the industry continues to evolve, the unique strengths and strategic initiatives of these Indian CDMOs will play a crucial role in shaping the future of global drug development and manufacturing.

Alex Del Priore

Alex Del Priore has three decades of experience in developing, commercialising and life-cycle management of products in various life science industries. Holding positions in both the US and Europe, his experience includes senior roles with global P&L responsibility. As a member of the Executive Committee Alex plays a techno-commercial role, providing technical expertise to the API plant at Mangalore, while building a sustainable client base for the business in collaboration with the commercial and business development teams.

Dr. Himanshu Gadgil

Dr. Himanshu Gadgil, Chief Executive Officer at Enzene Biosciences Ltd., brings with him 24 years of experience in the pharmaceutical industry. Under his leadership, Enzene has grown from a start-up biotech to a multi-vertical, multi-site product development and manufacturing service-based biopharmaceutical company. Previously, as Sr. Vice President at Intas Pharmaceutical Ltd., he revitalised the commercial product pipeline, launching several biosimilar products globally. During his stint in the US, he led different facets of process and product development at Amgen, spearheading IND, BLA and Market authorisations of various blockbuster biotech products. At the inception of his career, he joined Waters Corporation where he pioneered development of QBD enabling multi-attribute methodologies for biopharmaceutical characterisation.

Ramesh Subramanian

Ramesh Subramanian, Chief Commercial Officer, is responsible for global business growth, leading sales, marketing, strategy and the corporate development function. With over 20 years of experience in leadership roles, Ramesh has built global businesses in Asia and Europe, raised venture capital, established transformational strategies, driven M&A, negotiated cross-border deals and managed alliances. Prior to Aragen, he served as Senior Vice President and was part of the management team at Piramal Pharma Solutions. Ramesh was previously a part of management teams at Chemizon, a firm he led from start-up to successful entry into the equity market and Jubilant Life Sciences.