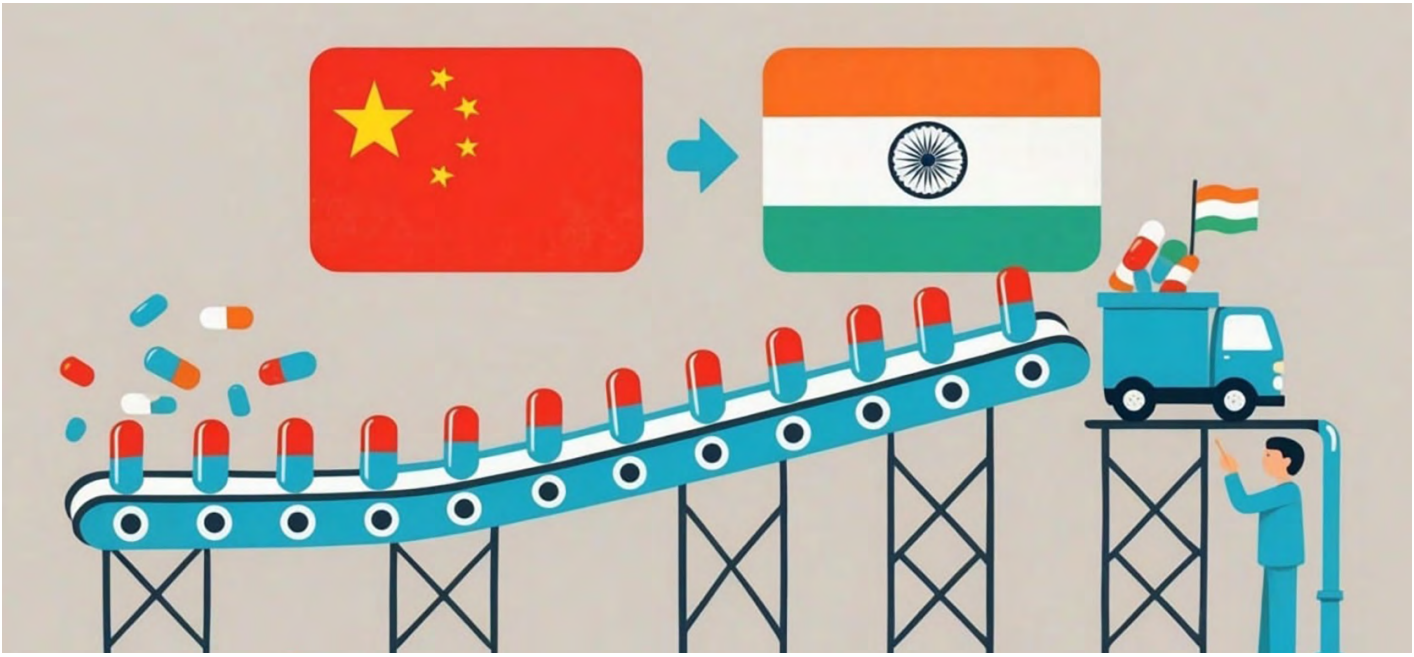
CDMO trends post-Wuxi's exit from the US: who will take its place?

By **Jules Adam** | July 11, 2024



A few months ago, we discussed the WuXi Apptec controversy and the consequences of the BIOSECURE Act on the global biotech industry. For context, the Chinese company WuXi Apptec is a leading contract development and manufacturing organization (CDMO) involved in one-fourth of the drugs commercialized in the U.S., and their contracts in the U.S. accounted for 65% of their reported revenue in 2023 with over $5 billion (36.6 billion Chinese Yuan). However, its activities with the U.S. seem to be coming to an end.

Early in 2024, U.S. intelligence reported allegations that the CDMO had transferred information about its American clients to the Chinese government without authorization. The controversy triggered a fast legal response from the U.S. to protect its companies' information from Chinese CDMOs, the BIOSECURE Act. In a few words, this bill aims to prevent U.S. biopharma companies from contracting with companies from sensitive countries like China.

While the bill has not become law yet, it is progressing through the legislative process and WuXi Apptec, and other "biotechnology companies of concern" are going to leave a gap in the CDMO space. Who is going to fill it?

Indian CDMOs to the rescue of the biopharma industry

Since the WuXi controversy, several CMDOs located in India have observed the number of site visits from foreign biopharma increase and the general interest in their solutions intensify. Alex Del Priore, senior vice president and manufacturing at Syngene International, a CDMO headquartered in India, is witnessing this industry trend: "In the recent past, we are seeing a step up in the interest levels from pharma and biotech, certainly getting more visitors coming to our campus, that's leading to more exploratory discussions."

And this is not an isolated case. Enzene, another Indian CDMO, is also attracting important biotech and pharma companies. "We are observing a significant increase in interest and site visits from big pharma and biotech companies. Many are looking to diversify their supply chains and reduce dependency on China while also establishing secondary suppliers if U.S.-China tensions worsen. So far this year, we have witnessed a substantial uptick in customer visits, indicating a strong demand for our manufacturing solutions especially for complex biologics," confirmed Himanshu Gadgil, chief executive officer (CEO) of Enzene.

> **"The BIOSECURE Act and wider potential capacity issues are prompting several Western pharma biotech and life sciences companies to explore alternative CDMO options. In particular, Indian CDMOs appear to be the biggest immediate beneficiaries."**
>
> Himanshu Gadgil, chief executive officer of Enzene

Indeed, Indian CDMOs that have demonstrated success in commercial manufacturing for Western markets are particularly well-positioned to capitalize on this industry trend, especially as they often can couple this with lower costs. Gadgil claims the EnzeneX bioprocessing technology can deliver up to ten times higher productivity and decrease the operational footprint by 70% compared to traditional fed-batch methods.

Manni Kantipudi, CEO of Aragen Life Sciences, yet another CDMO experiencing an increase in site visits since the BIOSECURE Act development, takes this as an opportunity for his company and his Indian competitors too. "I think the competitive landscape for the Indian CDMO sector is poised for significant evolution over the next five years, particularly due to the increasing focus on biologics and advanced manufacturing technologies."

Why India could be a potential replacement for Chinese CDMOs in the industry

When it comes to CDMO services, India didn't wait for the BIOSECURE Act and is already very well established in the biotech industry. "India has already set a reputation for small molecule manufacturing and has a large number of U.S. FDA-approved (Food and Drug Administration) facilities. Indian CDMOs are now increasingly investing in setting up biologics manufacturing capacities to replicate this success in the large molecule space. With the evolving technology landscape, there is an increasing focus on using the latest in digitization and digitalization technology including artificial intelligence (AI) and modern language (ML) tools," said Kantipudi.

It has also been part of Indian CDMO's strategy to remain independent from Chinese suppliers. "One significant area that we have explored for our clients is the resiliency of their entire manufacturing supply chains. We have led the industry in introducing a China-independent supply chain, whereby the entire manufacturing of a potential drug is done without resources from China-based suppliers. This approach helps mitigate risks associated with overreliance on China. More generally, we focus on evaluating all supply partners to ensure lower risks and greater resiliency," explained Del Priore.

Del Priore also thinks the reality of the situation is different than what we perceive in all the fuss about the BIOSECURE Act. "While the perception may be that clients are coming to India as a strategic hedge, the reality is that they are driven by the technical problem-solving capabilities we offer. This trend is expected to be a long-term strategic shift across global drug development."

When we asked the three Indian CDMOs if this controversy and the developments around the BIOSECURE Act had had an impact on their strategy or triggered any particular strategic move, all agreed their strategy remained unchanged.

"Our strategy remains intact. From a purely Syngene's perspective our growth is built on our reputation for high-quality standards and the depth of our capabilities to drive scientific innovation from discovery right through to commercial supply," claimed Del Priore.

But that doesn't mean things aren't moving. For instance, Kantipudi said Aragen was making strategic investments in expanding capabilities across its small molecule and biologics businesses by adding clinical manufacturing capacity. On Enzene's side, the company announced at the BIO convention the launch of a drug discovery division and is also launching a new 54,000-square-foot facility in Hopewell, New Jersey in Q3 2024.

Del Priore maintained that Syngene was focused on investing in strategic areas of the industry. "We continue to invest in novel modalities such as PROTACs (proteolysis targeting chimeras) and antibody-drug conjugates (ADC) as well as stepped up our investments in artificial intelligence, automation, and digitization, which we think will be key to increased efficiency, high quality, and faster delivery times for customers."

It would seem that the WuXi controversy only accelerated and set in stone a trend that was already developing. "We have been observing a steady change since the pandemic, global pharma companies increasingly started looking to India and Southeast Asia as alternative supply chain destinations. Undoubtedly, the recent news in the U.S. has accelerated this trend coming out of the backend of the pandemic," noted Del Priore.

Three years ago, long before the BIOSECURE Act, Mantell Associates was already predicting that India was going to witness the biggest growth in the CMDO space. According to Mantell Associates, this growth is due to a combination of factors, lower cost R&D, and state-of-the-art facilities, so with WuXi heading towards the exit in the U.S., it is not a surprise to see Indian CDMOs swoop in.

Indeed, according to Kantipudi, the times are different and the trend is more durable than the COVID pandemic shift. "The COVID-19 pandemic established that outsourcing is no longer a 'good-to-have' but a 'must-have' strategy for the global life sciences industry. The Act and the controversy are prompting several Western pharma, biotech, and other life sciences players to revisit their strategy. This careful planning and a shift in approach is expected to be a longer-term trend, unlike during Covid times when customers were moving rapidly, in panic mode."

What does the future hold for biopharma CDMOs?

While the revised version of the BIOSECURE Act gives more flexibility to biopharma companies currently contracting with Chinese CDMOs, there is only a little doubt that the ultimate result will be the migration away from the organizations designated in the bill. In the evolving landscape, suddenly disrupted by the WuXi controversy, the Indian CDMOs seem to be very well-positioned to gain the most shares in the market.

But Gadgil thinks it is also the global demand for CDMO services that is on the rise. "The demand for CDMO services is gearing up for significant growth in the next few years. Biologics outsourcing, in particular, has surged thanks to increasing trust and maturation in the sector. Coupled with biotech funding returning, and the fact that biotechs are now more likely to advance targets further into development while pharma is advancing more targets than before, it's easy to forecast a robust medium-term outlook for the sector."

WuXi controversy and BIOSECURE Act aside, Del Priore identified another trend in the CDMO industry. "Both big pharma and biotech want to work with fewer but more capable CDMOs so that they can simultaneously advance more targets at the same time," he said. "The other notable trend is the CDMOs will need to invest for the drugs of tomorrow ahead of demand, which is why we continue to look at areas like titer improvement technologies – notably perfusion – but also the role AI can play in discovery and optimizing processes."

The BIOSECURE Act has reshuffled the deck, and there is a significant opportunity for CDMOs to replace WuXi Apptec.

https://www.labiotech.eu/more-news/cdmo-industry-trends-biosecure-act/