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Asia leverages on the biologics opportunity

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Asia leverages on the biologics manufacturing opportunity



Many companies in India, China and to an extent Korea have established a strong position in contract manufacturing of active pharmaceutical ingredients, but they still need to build their strength in biologics manufacturing. Besides, it is unlikely that the path of success in biologics manufacturing will be as smooth and defined as that in chemical drugs, given that it demands complex manufacturing processes with higher probability of failure.

"There are significant opportunities for biologics manufacturing in Asia, a promising market with relatively low costs that is attracting significant interest from major biopharma companies. Key biomedical hubs are under development in countries such as China, India and Singapore," says Mr Christian Gabel, vice president, Quintiles.

Today, Singapore's A-Bio, China's AutekBiom, India's Biocon, Kemwell, Reliance Life Science and Dr Reddy's Labs, Korea's Samsung and Celltrion, and Malaysia's Alpha Biologics and InnoBio are some of the leading biologics manufacturers of the region.

Companies in Asia have adopted several strategies to enter into and strengthen their biologics manufacturing. Some of them have set up their own manufacturing facilities, while others have joined hands with multinational companies to achieve higher growth.

This has attracted global investment and facilities in the region are coming up with current good manufacturing practices (cGMP) compliance. In terms of regulatory compliance, Indian companies have been ahead of the Chinese companies in meeting standards of cGMP required by the US Food and Drug Administration (FDA).

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India-based Kemwell has shown eagerness in biologics manufacturing and joined hands with Boehringer Ingelheim to construct a biopharmaceutical production facility that will feature a 2,500 liter vessel for cell culture. With an investment of $51 million, the GMP compliant facility is scheduled to be completed in 2012. The new Kemwell Biopharma facility of 15,000 sq m will be designed for process development, production, purification and formulation of biologics for early-phase preclinical and clinical studies. It will also consist of a cGMP drug substance manufacturing facility.

Mr Sanjay Lodha, senior director, operations, Kemwell, says India's rising prominence in the field of biologics, specifically in biosimilars, is evident from the fact that the highest number of biosimilar products from India have received marketing approval. In terms of volume, India is the world's second largest supplier of childhood vaccines and fourth largest supplier of pharmaceuticals.

Another leading company from India, Shantha Biotechnics, is into manufacturing of vaccines and biotherapeutics, both as bulk and finished products to be sold in the market. Shantha's facilities qualify the standards set by Indian regulators and the World Health Organization, enabling it to export products to several countries. Very recently, the company also obtained WHO approval to manufacture and commercialize its whole cell cholera vaccine Shanchol.

Dr Harish Iyer, CEO, Shantha Biotechnics, India, says the biotech industry in India is still in its nascent stage, but growth has been rapid. "Shantha is one of the top companies that are involved in biologics manufacturing in India. Overall and across companies, the level of investment in manufacturing has been significant. There have been several new products in the biotech sector, both in the vaccine space and the biopharma space. The availability of vaccines made by biologics manufacturers, such as the hepatitis B vaccine, has made them more affordable for people. Additionally, the availability of biopharmaceuticals, such as interferon, erythropoietin and insulin, has also increased significantly due to stress biopharmaceutical manufacturing," he says.

Over the last couple of years, biologics sector in Korea too has witnessed rapid growth. In 2011, Celltrion signed an agreement with Novacell Technology to develop biosimilars, while Dong-A Pharma signed a memorandum of understanding with Pohang University of Science and Technology for co-operation on new biotechnology-based drugs. The same year, a seasonal flu vaccine by Green Cross also received WHO prequalification.

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Jumping on the bandwagon, Korea-based Samsung Biologics, in partnership with Quintiles Transnational, invested $30 million in a new venture in 2011. The facility is slated for completion in 2012 with operations scheduled to begin by early 2013. The facilities will be certified by the US FDA and designed to comply with the cGMP standards.

China's capacity in biologics manufacturing is still at an early stage but the government is taking significant steps towards becoming a successful destination for biologics manufacturing. Giving a boost to its biologics manufacturing capacity, China has invested $100 million in AutekBio to construct a world class R&D and manufacturing center in Beijing for international biologics developments. The facility will have combined volumes of bioreactors of up to 20,000 litres in multiple production lines.

Genor Biomanufacturing, one of the leading contract biomanufacturing companies of China, is building a cGMP clinical-scale facility and cGMP commercial facility with international quality system and global manufacturing network in Shanghai. Other companies that are planning to build biologics manufacturing facilities in China with 10,000+litres of bioreactor capacity are Pacific MeinuoKe, Wuxi Pharma, Advanced Biologics and Kanda Biotechnology.

Sharing his thoughts on China's position as biologics manufacturing hub, Dr Wu Ke, founder and president of Shanghai BravoBio, says, "Although China has become the fourth biggest player in pharma manufacturing in the world, its biologics manufacturing, especially manufacturing of genetically-engineered therapeutic proteins, is still at an early stage. However, several conditions, including strong support from government and a large talent pool, ensure a brilliant prospect for China biopharma manufacturing."

Australia currently lacks contract manufacturing activities, but it is estimated that the country spends $62.4 million annually on payments for contract manufacturing activities. Malaysia too is supporting biopharmaceutical industry and is home to two biologics manufacturers, InnoBio and Alpha Biologics.

Singapore too has invested heavily in the biologics sector through subsidiaries of its Economic Development Board over the past decade. Singapore-based A-Bio Pharma is one of Asia's pioneering contract manufacturers for mammalian cell-derived biologics, offering a full range of manufacturing services from process development to GMP production. The GMP manufacturing facility of A-Bio meets both the US FDA and EU EMEA GMP requirements.