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ASIA EDITION

Asia biologics manufacturers face the 'quality challenge'

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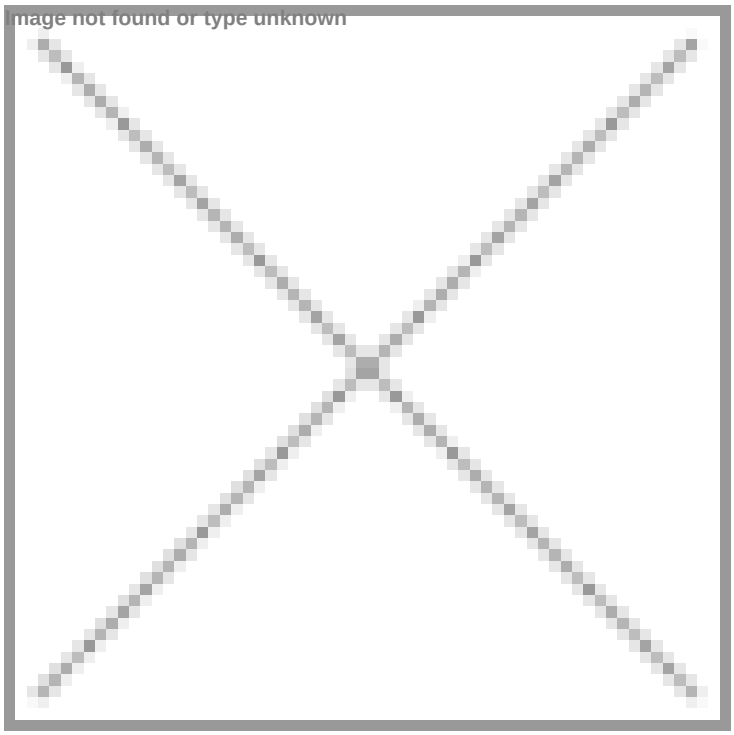

Biologics manufacturers in Asia have to be more vigilant and give higher priority to product safety and product efficacy. Even though countries like India and China can lower manufacturing cost, sponsors would pull back if there is compromise on the quality or compliance of drugs. Regulations in Asian countries need to improve in order to meet the demand of the international market. But the question is: can Asian firms live upto global regulatory standards?

Indian firms are already ramping up infrastructure to adhere to quality standards. India, has in the recent past seen companies like Shantha Biotechnics, Panacea Biotec and Bharat Biotech facing the brunt of the WHO on the vaccine front, with recall of vaccines, withdrawal of pre-qualification approvals and suspension of supplies due to non-adherence to quality standards.

Entry of multinational companies has helped Asia boost its position in biologics manufacturing Asia started attracting global biologics manufacturers in early 2000 and has since attracted companies such as Lonza (which invested over $350 million in Singapore and also in Genome Valley, India), Genentech (which developed a 1,000-liter facility in Singapore) and Boehringer Ingelheim in partnership with Kemwell (invested $51 million in a 2,500 liter cell culture GMP-compliant facility in India), among others. Novartis is constructing cell-culture production facility in Singapore, DSM Biologics is going to develop a cGMP-compliant manufacturing facility in Brisbane, Australia. Bristol-Myers Squibb (BMS) signed an agreement with Korea-based Celltrion for manufacturing biopharma products. Malaysia's InnoBiologics Biopharmaceutical is in a 10-year collaboration

agreement with Boehringer Ingelheim for biologics manufacturing since 2009.

The biologics sector in Asia has been further fueled by the increase in partnerships between various organizations. In 2011, Celltrion signed an agreement with Novacell Technology to develop biosimilars, while Dong-A Pharma signed a MoU with Pohang University for co-operation on new biotechnology-based drugs. Korea-based Samsung Biologics, in partnership with Quintiles Transnational, invested $30 million in a new venture in 2011.

Many companies in India, China and to an extent Korea have established a strong position in contract manufacturing of active pharmaceutical ingredients, however, going ahead Asia needs to build greater stength in biologics. The fact that biologics demands complex manufacturing processes with higher probability of failure has led companies in Asia to focus on cGMP and regulatory compliance as required by the US FDA. The strengthening focus of the firms on compliance has led many Asian biologics firms to win approvals. While India-based Shantha Biotechnics obtained WHO approval for its whole cell cholera vaccine Shanchol, Green Cross received WHO prequalification for its seasonal flu vaccine. With patents worth $60 billion (Rs300,000 crore) set to expire between 2012 and 2019, it is time for the Indian companies to pull up their socks to leverage the opportunity. Although regulatory challenges have been a major hurdle in India, the country has emerged as a premier manufacturing hub, and its biologics trail is blazing hot.

The proactive attitude of governments of many countries in Asia are also leading to the development of the biologics sector. In China, the government is taking significant steps. It invested $100 million in AutekBio to construct a world class R&D and manufacturing center in Beijing for international biologics developments. Genor Biomanufacturing, China, is building a cGMP facilities in Shanghai. Other companies that are planning to build biologics manufacturing facilities in China with over 10,000 litres of bioreactor capacity are Pacific MeinuoKe, Wuxi Pharma, Advanced Biologics and Kanda Biotechnology. China is making a lot of efforts to strengthen their biologics industry and this is evident in the increasing number of approvals being received by China. Furthermore, while Australia spends an estimated $62.4 million annually on payments for contract manufacturing activities, Malaysia is home to two major biologics manufacturers, InnoBio and Alpha Biologics. Singapore has invested heavily in the biologics sector, with A-Bio Pharma developing a GMP manufacturing facility that meets both the US FDA and EU EMEA GMP requirements.

The face of the pharma sector is changing substantially. While PwC says that bioengineered vaccines and biologics will account for 23 percent of the global market by 2016, BMI has projected that contract manufacturing will touch $33.7 billion by 2014. One of the reasons for this growth is the fact that although there are several disadvantages associated with biologics manufacturing, the numerous advantages clearly outwigh them. Moreover, contract and biologics manufacturing business are also offering a lot of value proposition. A recently released index by BioPlan Associates states that China has 8.5 percent, India has eight percent, and Japan and other Asian countries together have 9.2 percent of the world's biomanufacturing potential.

Many first generation biopharmaceuticals products are maturing and there will be more focus on biologics contract manufacturing. The manufacturers need to scale up capabilities, facilities, procedures and resources and most importantly, improve on regulatory compliance.

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