

### The Race for Biotech Offshoring: Will China Overcome Its Barriers?

**Background.** In the pharmaceutical industry recent trends show an increase in biotech production, and a decrease in conventional pharmaceuticals. Although biopharmaceutical manufacturing has been greatly facilitated in recent years with the development of new technologies, the difficulties of regulating biological products manufactured in different facilities has been a challenge. However, because biopharmaceuticals are very costly to develop, many Western companies are increasingly considering transferring manufacturing to developing countries that offer lower production costs.

In addition to significantly reduced production costs, China's past experience in pharmaceutical manufacturing has facilitated the country's recent growth in offshoring. Well established in generics manufacturing, China is responsible for 60% and 65% of the world's annual production of penicillin and terramycin, respectively (Xinhua News Agency Report 2004). China is one of the most prominent countries in global biopharmaceutical offshoring, and is predicted to play an even greater role in the next 10 to 15 years.

China offers several advantages in biopharmaceutical manufacturing including a highly skilled workforce and relatively well-established infrastructure and technology systems. However, many Western companies maintain that the risks do not outweigh the cost benefits. The most common concerns associated with offshoring in China include inadequate IP protection laws, regulatory issues, and language and cultural barriers.

**IP Protection Laws and Regulations.** After China's entry into the World Trade Organization in 2001, IP protection laws and regulatory environments greatly improved. Although the legislation for biotech product patents in China is relatively recent, 1993, there has been significant government support of China's biotech sector over the last 10 years that has led to tremendous growth (Jacoby 2006). As a result, many foreign biopharmaceutical companies with independent patents are increasingly considering offshoring in this newly emerging Chinese market.

China's past reputation for producing counterfeit generics has negatively influenced Western companies that are considering offshoring in the country. However, the Chinese government's recent efforts to control negative production have been relatively successful. The increase in quality products manufactured in China can be primarily attributed to stricter government monitoring and regulations.

**Chinese Biotech.** Unlike other countries in Asia, such as Malaysia and Singapore, China has a history of scientific research. Deng Xiaoping's reform policies in the late 1970s and early 1980s restored China's science and technology sectors. Between 1997 and 2002, the number of biotech companies increased exponentially fueled by China's participation in the Human Genome Project, China's sequencing of the rice genome, and an influx of returning immigrants with biotech experience.

Between 2001 and 2005, substantial government investments in the Chinese biotech industry further facilitated growth. The development and production of the new cholera vaccine tablet, one of the world's first gene therapy products, reflects China's emerging role in the biotech industry (Collins 2008). Currently, China produces 8 of the world's top 10 genetically engineered therapeutics and vaccines (Langer 2007). Among the

most commonly manufactured Chinese biopharmaceuticals are protein therapeutics, gene therapy products, vaccines, antibodies, blood products, and diagnostic agents.

Recently, with increasing worldwide demand to produce more affordable prescription medications, China's biogenerics sector has shown great potential for growth. Biogenerics in China currently account for 95% of biologics manufacturing and include products such as the interferon series, erythropoietin, colony-stimulating factor series, tumor necrosis factor, insulin, growth hormone, and interleukin-2 (Chervenak 2008). Although most biogenerics have been developed in Western countries such as the United States, this is gradually changing as China increases its R&D capabilities.

In addition, many multinational biotech companies have started to work with Chinese biological-service providers because of their lower labor costs and expertise. The most commonly outsourced molecular biology services are nucleotide sequencing and synthesis, protein expression, and library construction. This expertise in molecular biology greatly facilitates China's biologics development and manufacturing capabilities.

**Companies Favor Shanghai and Beijing.** China's biotech infrastructure is still evolving, and although many cities offer biotech facilities, the intellectual workforce and most reliable services are concentrated in Beijing and Shanghai (Allen 2008). Large biotech centers, such as Zhangjiang Hi-Tech Park in Shanghai, are increasingly common offshoring locations for Western biotech companies. In addition to government incentives and significantly reduced manufacturing costs, they offer modern laboratory facilities, highly skilled personnel, and a growing R&D sector.

However, because of the unique challenges involved in the manufacturing of biologics, companies are still concerned about transferring biotech manufacturing to China. Biologics manufacturing is an already complicated process, and additional variables such as geographic distance, linguistic challenges, and cultural differences create further barriers. Many companies think that close interaction between scientists and plant workers, primarily during scaling-up, limits some of the potential risks involved in biologics production. As a result, many biotech companies prefer to keep facilities nearby.

Despite their reservations, however, companies are finding it difficult to manage product development costs and are considering offshoring to China, if not already doing so. For companies based in the San Francisco Bay Area of California, offshoring is an especially attractive alternative to the extremely high costs associated with establishing local facilities. Matthew M. Gardner, President and CEO of BayBio, Northern California's Life Science Association, explains "I don't view this as companies leaving the Bay Area- I view it as the arrival of biotech maturity. Our companies are stronger by relying on specialists, wherever they may be, for components of their business" (Tansey 2004).

Although multinational pharmaceutical companies have been offshoring to China for many years, several recently added R&D facilities. In addition, several have expanded their manufacturing capabilities. Many major biopharmaceutical companies, not exclusively from the Bay Area, have transferred a portion of their biotech to Chinese facilities. Roche, Novartis, AstraZeneca, Wyeth, Eli Lilly & Co., Pfizer, Johnson & Johnson, Novo Nordisk, Amgen, Biogen Idec and Genzyme have all expanded their presence in China (Wong 2008). AstraZeneca is reportedly opening a new "Innovation Center" in Shanghai in 2008 (Allen 2008).

Bridge Pharmaceutical Inc., a U.S. company that contracts research in China for biotech companies, opened a research center in Beijing last year. The company's experience in China explains this trend. According to Bridge, Chinese companies currently operate in accordance with U.S. regulatory guidelines, and their development costs are about 80% lower than in the United States. This is largely because salaries of research scientists in China are estimated to be one-fifth to one-tenth those in North America (Allen 2008).

**India vs. China** India is China's largest competitor in global offshoring. Currently, China ranks second after India according to the Economist Intelligence Unit ranking (McKenna 2005). India's current lead in biogenerics manufacturing can be attributed to high English proficiency among recent Indian graduates entering the field. In addition to India's language advantage, quality control standards and regulatory legislation are stronger than in China. As regulatory issues in China evolve, and because Chinese employee wages are reportedly less than those for equally qualified Indian employees, Western biotech companies are expected to increase offshoring in China. China is expected to overtake India position as leader in biopharmaceutical offshoring by 2015 (Minevich & Rickter 2005).

**Language Issues** As noted by one expert in offshoring, Lionel Carrasco managing director and global VP of Strategic Solutions & Alliances, NEORIS, "The challenge for China's growth will be business domain expertise and huge language and cultural barriers. India has the British heritage and China has the Great Wall of China that remains conceptually" (Minevich & Rickter 2005).

Mandarin Chinese, the official language of mainland China, is the primary language of communication and the written language for official documents. In addition to Mandarin, several other languages are spoken in China such as Cantonese. The most common foreign languages are Taiwanese, Japanese, and Korean. Many Chinese companies employ English teachers to help employees improve their skills, and government funding of English language university programs has been significant (Allen 2008).

Despite these efforts, much of the population does not speak English as a second language. Specifically, many manufacturing plant employees are not fluent in English, so manufacturing Standard Operating Procedures (SOPs) are translated into Mandarin Chinese. According to Dr. Hua Zheng, director of global regulatory affairs at Tibotec, offshoring to China requires that all documentation be translated into Mandarin Chinese, as do clinical trial applications (Glaser 2007). In addition, regulatory documents, Good Manufacturing Practices (GMPs), are translated into English or other languages. Lastly, to ensure that any concerns of local employees are appropriately addressed, managers' site visits are normally conducted in the presence of a local interpreter. Interpreters must have a background in biotech manufacturing in order to effectively address problems encountered by local employees.

**Cultural Differences** In addition to language barriers, there are many differences in acceptable cultural standards. For example, Chinese cultural attitudes may prevent employees from discussing problems with their Western managers, making it difficult to resolve issues. After recent Chinese government programs, better understanding is evolving (Allen 2008). If Western companies want to create effective offshoring bonds, they must share equal responsibility in overcoming cultural barriers. Thus, the importance of implementing translation and localization expertise must not be overlooked.

At a recent Linus Pauling Biotech Symposium entitled "Cultural Barriers to the Development of Biotechnology in China," Mao Mao, a scientist at Merck & Co., explained the Chinese mentality about business, "To be a scholar is to be at the top of the society; businessmen are always treated as the second class in China. At the central government level, the national biotechnology program is led by academics. The advisory board of the biotechnology development agency consists of Nobel laureates and professors" (Wong 2008). In the past few years, Chinese attitudes about business have changed, and scientists with business positions are better accepted.

**Hai Gui "Returning Sea Turtles"** In a study conducted by the Public Policy Institute of California, 43% of Chinese-born scientists interviewed in San Francisco said that they would consider returning to live in China (Stipp 2002). Many scientists who left China in the 1970s acquired graduate degrees in the Western educational system and work experience in biotech companies or academic institutions. During the past few years, primarily because of greater work opportunities in China, there has been a reverse brain drain from the West back to

China. An increasing number of highly educated, Western-trained Chinese scientists referred to as “sea turtles” are returning to work in China. Ge Li, chairman and CEO of WuXi PharmaTech in Shanghai, is one of many examples of returnees from the West. Ge Li spent 12 years in the United States earning a doctorate in organic chemistry at Columbia University and then cofounding a New Jersey pharmaceutical company, Pharmacopeia. In 2001, Dr. Li moved to Shanghai and founded WuXi PharmaTech, a contracting chemistry company that deals mainly with U.S. and European companies (Pollack 2005).

Returning scientists will definitely play an important role in bridging the gap between China and the West. Transnational partnerships between companies are becoming increasingly common. The advantages of partnering with Chinese scientists who are well accustomed to speaking in English and working in the West are further incentive for companies considering China. Many of these expatriates have completed their graduate and post-doctoral education in the West and have experience conducting research in Western biotech companies. Therefore, they are well equipped to deal with the challenges of bringing Eastern and Western industries together. Jonathan C.K. Knowles, head of global research for Roche explained Roche’s comfort with transferring facilities to China, “U.S. academia had been run by Chinese post-docs for the last 10 years, if not 15” (Pollack 2005). In addition to its existing manufacturing facilities, Roche has recently opened a research center in Shanghai.

The growing presence of returning scientists in the industry, however, does not eliminate the need for translation and localization experts. Despite the abilities of expatriates to communicate well in both Mandarin Chinese and English, many Chinese employees are not adequately proficient in English. Thus, language remains an issue. In order to maintain standards and ensure quality biopharmaceuticals, manufacturing SOPs must be translated into Mandarin Chinese. Although the growing number of expatriates in biotech management positions will be an added advantage in overcoming cultural barriers, language and cultural factors must still be considered.

**Conclusion** Government funding, cost benefits, improved regulatory legislation, and the influx of Western-trained scientists have all greatly facilitated growth of the Chinese biotech industry. Tom Bliss, director of licensing at Amgen observed, “Although China's current life sciences capacity is really very small, its potential is enormous” (Wong 2008). Thus, as past barriers are overcome, the future of biotech in China looks very promising.

China is expected to become a world leader in biopharmaceutical manufacturing. Its biogenerics sector is one of the most dominant in the world. A greater number of foreign biopharmaceutical companies will invest a portion of their biotech capabilities in the country, including R&D and manufacturing facilities. Especially as future offshoring trends continue toward greater multinational access of resources and expertise, China will further its ties with the West. However, overcoming language and cultural barriers, in particular, will play a major role.

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