

## China Pharma CRO: The Silk Road Frontier

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2007 marked the coming of age of the Chinese pharmaceutical industry as demonstrated by the tales of two companies: WuXi Pharmatech's spectacular IPO on the New York Stock Exchange in September and the landmark research and development (R&D) collaboration deal between Hutchinson Medipharma in Shanghai and Eli Lilly, focusing on novel compounds in oncology and inflammation.

Although these successes are significant, companies are finding that with biotech venture capitalists becoming more risk-averse, an enormous financing gap exists for both small start-ups and more established yet equally cash-squeezed biotech entities. Both may look east for a new model of partnering and financing to not only survive but thrive in this changing world. It is worth noting that both WuXi and Hutchinson are either founded by and/or their management teams are heavily staffed with overseas Chinese returnees, or "sea turtles," who are leading the rapidly changing nascent life sciences industry in China.

This article will address the current climate for the pharmaceuticals industry in China, new trends in cross-Pacific outsourcing as well as strategic issues to be considered for Western pharmaceutical and biotech companies when picking their contract research organization partners.

### China's Role In The Pharmaceuticals World Market

With its explosive and sustained economic growth and increasing influence on world affairs, China has emerged at the dawn of the 21st century as one of the last remaining "superpowers" on the world stage. In the pharmaceutical industry, many experts predict that China will continue its rapid growth and eventually surpass the United States as the top pharmaceuticals market worldwide in the next two decades.

In recent years, all levels of the Chinese government have designated the life sciences industry as one of its "pillar" industries fueling future growth. Various incentive programs were created to attract overseas commercial entities to establish their China operations and entice highly experienced sea turtles to return to the homeland to launch their entrepreneurial endeavors. High-ranking government officials from top-notch life science parks throughout the country who represent different regional interests have gone on competitive "road shows" to pitch to talent pools at such U.S. biotech hotbeds as Boston, San Diego and San Francisco.

The central and regional government has invested heavily in numerous start-ups founded by Chinese overseas returnees that are clustered in a few dozen high-tech biotech parks. How bountiful a harvest that results from these efforts will depend on the quality and critical mass of these new companies, as well as the sustainability of the government support in assisting these start-ups to obtain sufficient financing, provide reliable infrastructure and recruit and retain top talent. San Diego represents one of the most frequently visited biotech hubs in the United States by top-tier Chinese life science park officials because of the high concentration of Chinese-American professionals and entrepreneurs in the biomedical and pharmaceutical industry.

The influential professional organization - the Sino-American Biomedical and Pharmaceutical Professionals Association (<http://www.sabpa.org/>) - which has grown to more than 1,500

members since its founding in 2002 by a handful of Chinese scientists in local pharmaceutical and biotech companies, also is based in San Diego. One of SABPA's flagship annual conferences, the Pacific Forum on cross-Pacific life sciences alliances, consistently has attracted influential speakers from the United States and China, elite corporate sponsors and roughly 300 attendees each year. The popularity of this conference demonstrates the burgeoning relationships being formed between China and other countries in the pharmaceuticals industry.

### **Outsourcing Outlook**

The Western pharmaceuticals industry currently is facing a crisis of unprecedented scale: the astronomical price tag of more than \$1 billion per approved drug, declining internal R&D efficiency, imminent patent expiration of multi-billion dollar blockbusters, not to mention the chaos from major drug safety problems and a deteriorating public image of the pharmaceutical industry.

Large pharma companies, as well as smaller and virtual biotech companies, increasingly have sought the helping hands of CROs, especially those in China and India, to drastically decrease the cost of R&D while still maintaining the quality of deliverables. Hundreds of Chinese CRO companies mushroomed during the past five to seven years as a result of the huge demand for research partners in China, with many CROs specializing in a niche area, such as chemistry, preclinical or clinical trials work.

The early phase of the Chinese CRO boom primarily was flooded with chemistry-based companies, due in large part to both the sizable and available chemist talent pool in China and to the clarity and ease with which Western customers can assess the quality of deliverables. As the chemistry-based CROs have become more saturated, new opportunities now exist for CROs that can provide preclinical, animal model, clinical trial support or a combination of such services.

Of course, the hurdles are higher here because of the complexity and higher level of difficulty in quality control and assurance. Big pharma and large biotech companies in the West have been more cautious in using these biology, preclinical and clinical services, but are likely to increase outsourcing in these areas after they get more comfortable with the quality and services provided.

Chinese companies with strong management teams, solid work experience in Western pharmaceutical and biotech companies and successful track records in serving these clients are the most attractive CRO partners to consider. (Looking into the future, the cost advantage of working with Chinese CROs could gradually erode as a result of the escalating cost of living and fierce competition for top talent in such cities as Shanghai and Beijing.)

### **CRO Success Stories**

As the demands of client service and the capabilities and experiences of Chinese CROs increase, leading Chinese CROs have adopted a few new strategic moves. First, they are expanding services beyond the original area of expertise via mergers and acquisitions or strategic partnerships. WuXi Pharmatech acquired Apptec Laboratory Services, a U.S.-based supplier of biology services and medical devices for \$163 million in January 2008 to gain an established customer base and instant access to valuable services beyond WuXi's core chemistry expertise (PharmAsia News, May 29, 2008).

Shanghai Medicilon announced the formation of a joint venture in Shanghai with U.S.-based MPI Research to provide good laboratory practices and non-GLP preclinical services to their combined customer base globally. The strategic advantage gained here was combining the GLP

capabilities of MPI with the cost-efficiency of conducting many services in China (PharmAsia News, Jan. 28, 2008).

In November 2007, Crown Biosciences, a Silicon Valley-headquartered oncology-focused preclinical CRO service company with wholly owned research centers in Beijing, acquired Kinasia, an Indianapolis-based contract service company specializing in protein expression and structural biology, with the goal of providing integrated service capability in cancer drug development, from lead-to-clinical efficacy.

Sundia MediTech, a Shanghai-based CRO, merged with Shanghai United PharmaTech in June 2007 after the two companies announced a CRO Service Alliance in May 2007 with HD BioSciences to integrate and expand their chemistry and biology expertise for the increased demands from their worldwide clients. In February 2008, NovaSecta, a European specialist R&D service provider for smaller to mid-sized pharmaceutical and biotech companies, joined the alliance to further integrate the alliance's work with European pharmaceutical and biotech companies. Most recently, Tigermed Consulting, a Chinese clinical trial service CRO, became the newest alliance partner in April 2008 (PharmAsia News, March 5, 2008).

Leading Chinese CROs such as WuXi are beginning to add new locales in second-tier inland cities to mitigate the higher costs in Shanghai and Beijing. Newer CRO companies are being formed in second- and third-tier cities where a more affordable cost of living and an availability of scientific talents will attract new investors and entrepreneurs.

Several leading CROs with strong financing are beginning to experiment with alternative ways of working with their pharma and biotech clients in the West, especially small biotech companies that have challenging financial situations but also have a promising pipeline and upside potential. Risk-sharing, milestones and equity participation options are being considered by some CROs to trade calculated risks for a potentially high future payoff. However, many CROs would rather keep risk-sharing to a manageable degree without involving royalties and equity participation out of concern for potential conflict of interest from other clients.

Finally, a number of leading Chinese CRO companies are starting to hire U.S.-based Chinese-American scientists to take on business development responsibilities. By leveraging the Chinese-American scientists' knowledge of drug discovery research and their bicultural experience, Chinese CROs hope to expand their client base, especially in biotech hubs such as San Diego, where many CROs compete for a variety of outsourcing services.

For example, among the scientists-turned-business-development professionals of Chinese origin, Charles Huang was hired by Shanghai-based Sundia MediTech Co., whose CEO and founder Xiaochuan Wang was Huang's supervisor at Neurocrine Biosciences in San Diego before she went back to China as an entrepreneur. Formerly a senior scientist at Neurocrine Biosciences whose main responsibility was to design and synthesize small molecule compounds with therapeutic potential, Huang also was in charge of managing Neurocrine's multiple outsourcing projects during the past four years.

"Having managed Chinese CRO service providers for years at Neurocrine gives me a clear perspective and understanding as to what a potential client's needs are for outsourcing services," Huang said.

### **The Art Of Working With CROs**

As the Chinese CRO industry continues to mature and prosper, more cross-Pacific and domestic

M&As and alliances are expected, with a handful of leading companies becoming dominant players through consolidation. The question remains: What role should Western pharma and biotech companies play in the dynamic Asia Pacific CRO field?

First of all, establishing a wide network of highly reputable CRO service providers is key to ensuring adequate risk diversification and smooth project management. Interruption of critical services due to corporate M&As or new alliances at a CRO service provider is not as likely if one chooses to work with more established companies with operational excellence and financial stability.

Effectively integrating CRO services with internal R&D efforts also is essential. The key to success here depends on establishing frequent and open communication routines, as well as managing expectations between customers and CRO service providers. Hiring and using bicultural and bilingual professionals who can better communicate cross-culturally to manage Asian CROs is a strategy increasingly adopted by Western pharma and biotech companies that work with Chinese and Indian CROs.

Although it is a "buyer's market" in terms of pricing due to the highly competitive CRO marketplace, price should not be the most important consideration. Timeliness, ease of communication, industry reputation, breadth of services, quality of deliverables and other factors should take a higher priority in choosing the right CRO partners.

In summary, the cross-Pacific life sciences trends in recent years demonstrate the vibrant and dynamic nature of the Chinese CRO industry, which is likely to go through major consolidation in the next few years with the stronger entities dominating the scene. These successful CROs will play an increasingly important role in reshaping the future of global drug discovery and development efforts. Western pharma and biotech companies will reap rewards by effectively choosing and working with their Chinese CRO partners as they navigate the frontier of the new life sciences "Silk Road."



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