

CROs in China: Only the Beginning

WHETHER IT IS PART OF A GLOBALIZATION STRATEGY OR MARKET ENTRY INTO CHINA, CHINA'S CRO INDUSTRY IS POISED TO CLAIM ITS PLACE IN THIS GLOBAL INDUSTRY.

YING LIU AND MICHAEL CHU OF ASIABIZCO LLC, A CROSS-PACIFIC CONSULTING FIRM FOCUSED ON THE LIFE-SCIENCES INDUSTRY IN THE UNITED STATES AND GREATER CHINA, PROVIDE EXPERT INSIGHT INTO THE CRO INDUSTRY IN CHINA.

According to these two experts, the CRO industry in China as a whole is still young and fragmented, but they anticipate a quick ramp up toward standardization and global competitiveness. Within two to five years, the Chinese CRO industry will offer serious competition to other Asian countries such as India. The Chinese domestic pharmaceutical sector is expected to continue double-digit growth for the next decade and become the fifth-largest pharmaceutical market in the world.

Ms. Liu and Mr. Chu say the current Chinese CRO market can be divided into three groups — foreign CROs, joint-venture companies, and local CROs.

FOREIGN CROS

Although there are only a handful of foreign CROs, their presence in China marked the beginning of a new industry. Leading the way was Quintiles Transnational, which opened its Beijing office in 1997.

"Before Quintiles, no one in China really knew too much about CROs," says Jianguang Ye, CEO of MedSept, a local Chinese CRO.

Multinational CROs have pioneered a new industry in China. Working with pharmaceutical companies, the regulators, and the clinical-trial professionals, they are carving out a place in China and the international marketplace for Chinese CROs.

JOINT-VENTURE COMPANIES

Joint-venture companies, of which there

are very few, serve as extensions of their prospective parent companies and, in some cases, take on specific tasks from the parent company much like a subcontractor.

KendleWits was formed by the American company Kendle International and Chinese Acer/Wits. With a team that has a strong medical background, KendleWits offers high-quality, efficient work to its parent company in clinical data entry, coding, and processing.

Ever Progressing Systems (EPS) China was formed between Japan's EPS and a Chinese group. EPS China operates in a similar manner, with almost 90% of its clients coming from its parent Japanese company. Dr. Pihua Jin, a well-known biostatistics professor at Shanghai Medical University who has been involved in CRO work since the 1940s, heads the China-based office.

Medium-sized pharmaceutical companies could do well with this type of CRO for clinical trials or to farm out specific work, such as data processing and analysis. One main advantage is the tight adherence to SOP and attention to quality at a reasonable cost. Also, medium-sized international CROs can consider this method to locate a partner to access the China market and offer lower cost, shorter time, and quality clinical data to their clients.

LOCAL CROS

There are an estimated 100 local CROs in China. This group varies in size, quality of offerings, and management capabilities. Their customers tend to be local Chinese and foreign pharmaceutical companies that are either already set up in China or looking for entry into China.

ExcelChina is perhaps the largest CRO in this category; 70% of its clients are multinational pharmaceutical companies. Mark Engel, an American expatriate, teamed up with a Chinese partner and started ExcelChina in 1999.

A formal partnership arrangement with Covance Inc. earlier this year provides the company with all of Covance's China projects. With offices

throughout China, Excel is able to monitor cases for large-scale projects.

Another local CRO company is VenturePharm CRO in Beijing. Sister companies to VenturePharm are focused on drug development, pilot research, and biotechnology.

In Shanghai, a professionally managed local Chinese company, Shanghai NewSummit Biopharma Co. Ltd., was formed in 2001 with strength in preclinical trials.

There also are smaller companies. Beijing MedSept Medical Consulting Co. is one such company, with fewer than 20 people. Started by CEO and President Mr. Ye, MedSept works with mostly smaller Chinese pharmaceutical companies and small- to medium-size companies from Korea, India, and other countries looking to sell their products in China.

An even smaller company, Shanghai Sunline Data Scientific Management Co., specializes in data management and statistical analysis.

For those pharmaceutical companies looking for drug approval from China's SFDA, teaming up with a Chinese CRO could be critical. A local CRO that has a good working relationship with SFDA can speed up approval, monitor the process, and resolve problematic areas without delay or even before they arise.

Whatever the category, China's CROs offer significant opportunities for global clinical R&D through world-class research and laboratory facilities, an abundant supply of internationally trained scientists and medical professionals, and access to large treatment-naïve patient populations.

Ms. Liu and Mr. Chu suggest that when working with Chinese CROs, companies need to consider localized business processes and approaches. China's unique regulatory environment and business culture require foreign companies to adapt.

Source: AsiaBizCo LLC, San Francisco. For more information, visit asiabizco.com.



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