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Trend Report : R&D in China: Outsourcing or offshoring? – that is the question!

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- China offers significant advantages for R&D-intensive industries
- Contract research organisations and contract manufacturers are open to foreign customers
- Many companies prefer offshoring over outsourcing for strategic reasons

R&D of new drugs is a systematic, difficult task that requires a great amount of time, knowledge and money. Whereas functions like IT or accounting, that are considered to be operative rather than strategic, have for some time been outsourced to low-cost countries, many companies have been reluctant to do the same with strategic business units like R&D. The fear of relinquishing control of vital intellectual property has outweighed the need to reduce costs.

The first country to profit from the emerging trend to outsource at least tactical (as opposed to strategic) R&D was India. Tactical outsourcing means buying certain resources or expertise, while retaining in-house capacities that represent the major, core parts of the necessary resources.

Strong arguments for R&D outsourcing

Nevertheless, despite the general reluctancy, there are strong arguments in favor of R&D outsourcing. Besides increasing cost awareness, the same considerations hold for R&D as for other functions: different companies may have different strengths along the R&D value chain, and few companies succeed in maintaining constant quality in all stages. Apart from reducing costs, outsourcing may also be attractive because it can reduce time-to-market, give access to specific expertise, utilise automated technology and create the large amounts of data associated with clinical approval processes. This is why more and more companies are thinking about extending their R&D outsourcing. According to PhRMA (Pharmaceutical Research and Manufacturers of America) data, domestic R&D spending of US companies increased from US\$ 21.4 billion to US\$ 38.4 billion, a rise of 80%, from 2000 to 2008,

while offshore R&D expenditure grew by 151% from US\$ 4.7 to 11.8 billion over the same period.

Thus, a company might decide to keep a strategic R&D unit that focuses on developing new IP, while outsourcing as much experimentation as possible to a specialized provider. Research in most pharmaceutical companies is done in the “classical” way: a huge amount of manual work is performed serially and mainly on a trial and error basis. If a specialized contract research organization (CRO) can offer microscale, parallel and largely automated experimentation technology, the advantages in terms of cost and speed are obvious.

One factor that also pushes the trend to R&D outsourcing is the shift from “hard chemistry”, in which pharmaceutically active molecules are synthesized, towards biotechnological production of pharmaceuticals. The processes in this kind of research differ significantly from those in “traditional” research and require different skills and technology.

The Chinese CRO market is maturing

The development of CROs started in the 1970s and gathered momentum during the 1990s. The recent economic crisis has given them a considerable stimulus, as pharma companies struggle to save costs. Experts believe that the annual revenue of Chinese CROs amounts to US\$ 145 million, occupying less than 2% of the global CRO market. The increase rate of the Chinese CRO market is estimated at 18%, and market volume is expected to reach US\$ 240 million in 2012. Analysis by Shanghai Modular R&D Consult Company shows that there are at least 138 CROs in China, and the competition is fierce.

While Chinese CROs originally focused on low-profit steps like compound screening in pre-clinical trials, today more and more CROs are entering the high-profit field of R&D, consisting of areas like toxicology research, animal trials and human pharmacokinetic studies. Modern CROs cover all steps of pharmaceutical R&D from compound screening to animal testing and even to expensive clinical tests involving hundreds or thousands of patients. Most of the CROs active in the pre-clinical trial field are still small or medium-sized enterprises, and only a few companies like Wuxi Pharmatech and Venture Pharm are listed on the stock exchange. WuXi, a Shanghai-based firm founded in 2001 that employed 2,900 scientists in 2009, was recently acquired by Charles River Laboratories, a US-based global R&D outsourcing specialist, for US\$ 1.6 billion.

The outsourcing of clinical trials to China is especially attractive. Similar to India, China has a giant population pool, meaning that the time for recruiting patients is significantly shorter than in other countries, which is a significant cost advantage.

“Time is money” is especially relevant when it comes to the launch of new drugs where a delay can cost a sponsor as much as US\$ 8 million per day.

Secondly, highly qualified personnel are much cheaper in China than in Western countries. According to statistics, at R&D centers in Western countries a biotechnology PhD graduate costs US\$ 80,000-100,000 per annum, whereas in China the cost will not exceed a quarter of that amount. In China, the cost of investigator grants, lab tests and CRO charges is at least 30-40% lower than in Western countries. At the same time, both the experience of the investigators and the quality of the trials have improved significantly.

Based on the above advantages, leading global CROs, such as Quintiles, PPD, Covance, and Parexel, have entered the Chinese market. In November 2009, Covance announced its acquisition of Excel, the largest domestic CRO in China. In consequence of the rising international activity, the number of clinical trial applications to the Chinese State Food and Drug Administration, SFDA, has soared over the past few years.

Outsourcing manufacturing is also an option

However, the opportunities that China offers in the pharmaceutical sector are not restricted to R&D outsourcing.

Following GMP transformation, many pharmaceutical companies have dramatically increased their production capacity. Statistics of China’s Pharmaceutical Enterprises Management Association in July 2005 show that the equipment utilization rate of Chinese pharmaceutical manufacturers is only 55.3%, with injection equipment showing the highest utilization rate of still only 71.5%. The equipment utilization rate of oral liquid production facilities is only 38.3%. In order to solve the problem of idle capacity, the Chinese government is encouraging manufacturers to offer outsourcing production opportunities to foreign companies.

Since some experts believe that the development of China’s pharmaceutical industry can be divided into four stages – generics, partial innovation based on generics, outsourcing manufacturing, and drug innovation – outsourcing manufacturing could become the main means of solving the problem of idle capacity, and it may also represent an ideal opportunity for Chinese manufacturers to export drugs to the international markets. The Chinese pharmaceutical industry, especially the API sector, has obvious advantages in terms of production outsourcing. Currently, over half of APIs produced, accounting for one quarter of global API trade, are exported. Zhejiang HaiZheng Pharmaceutical Company and SuZhou LiDa Pharmaceutical Company conduct production outsourcing for Merck and Wyeth respectively. Dozens

of companies, such as Sinochem Ningbo Group, ShanDong LuKang Group and XinHua Pharmaceutical Company, specialize in production outsourcing.

Hot investment: setting up an R&D center in China

Even given the advantages offered by R&D outsourcing listed above, many companies, especially in the pharmaceutical sector, shy away from relinquishing control of such sensitive areas. However, this is not the only means of profiting from China's R&D capacities: an increasing number of global pharmaceuticals are beginning to set up R&D centers in China, preferring off-shoring over outsourcing. In 2002, Novo Nordisk opened the first global R&D center in China. Since then, Roche, AstraZeneca, Eli Lilly, Novartis, GSK and Pfizer have all set up local or global R&D centers there. Initially, R&D centers in China accounted for only part of the global research of their mother companies. For example, the Pfizer center in China was mainly responsible for its global trial design, data management, statistics analysis and report writing, while Lilly's center focused on early drug development, drug synthesis and screening, and Novartis' center specialized in oncology research. This situation changed recently when GSK and Roche established the first drug discovery centers in China.

In contrast to R&D outsourcing, setting up an integrated R&D center offers the advantages of the Chinese conditions, while not jeopardizing IP. Moreover, since the Chinese pharmaceutical market is one of the most attractive markets in the world, it also enables a multinational company to get its foot in the door and expand operations from R&D and production to marketing and sales. The move of R&D to China has probably only just started.

R&D centers of multinational companies in China

Company	R&D center
Novo Nordisk	In 2002 , the first international pharmaceutical company to set up an R&D center in China.
AstraZeneca	In 2002 , the East Asia clinical trial center was established in Shanghai. In 2007 , the Innovation Center China (ICC) in Zhangjiang Hi-Tech Park in Shanghai opened its doors, with an investment of 750 million RMB
Eli Lilly	In 2002 , Eli Lilly & ChemExplorer Co. established diversified chemical platforms for novel pharmaceuticals R&D in China. In 2007 , Hutchison MediPharma (HMPL) signed a landmark strategic partnership agreement with Eli Lilly, a joint cooperation to research and develop new drugs.
Roche	In 2007 , Roche launched its Pharmaceutical Development Center in China (PDCC), one of Roche's 3 global R&D centers.
Pfizer	In 2005 , Pfizer opened its China R & D Center in Shanghai.
Sanofi-Aventis	In 2005 , Sanofi-Aventis established an R&D center in China. In 2008 , it enlarged its R&D center in China.
GSK	In 2007 , GSK announced set-up of its 32nd global research center in Shanghai to carry out fully- integrated drug development, with an annual investment of US\$ 40 million.
Novartis	In 2006 , Novartis established its R&D center in Shanghai. In Nov. 2009 , Novartis announced investment of US\$ 1 billion in China in the next 5 years in order to increase R&D activities in China, including expansion of its Shanghai R&D center to be one of the top 3 in the world.
Wyeth	In 2006 , Wyeth set up the Early Clinical Development Center in Beijing. In 2006 , Wyeth announced relocation of its Asia-Pacific clinical research center from Austria to Shanghai
Bayer	In 2009 , Bayer announced investment of 100 million euros to establish its R&D center in Beijing.
Boehringer-Ingelheim	In 2009 , Boehringer-Ingelheim announced investment of 100 million euros in China to expand production plants and establish a chemical R&D center.
Merck Serono	In Nov. 2009 , Merck announced set-up of a global R&D center in China with an investment of 1.5 billion RMB.

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(This trend report was put together by a team of experts and international trade journalists on behalf of DECHEMA. DECHEMA does not accept any responsibility for incomplete or incorrect information.)