



Pharma Outsourcing in China

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Despite the global economic downturn in 2009, outsourcing activity remains strong.
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While China currently still possesses numerous advantages in pharma outsourcing, there are a number of factors that could affect the future development of this industry.

Based on the analysis of the impact of the financial crisis on the outsourcing demands by global pharma and biotech industries, this article looks at how these changes are likely to affect the Chinese pharma outsourcing industry in 2010 and the near future.

The year 2009 was a challenging one for various industries worldwide. The financial crisis has significantly altered both the pharmaceutical and biotechnology industries on a global scale. The pharma outsourcing industry, both internationally and in China, has also been significantly affected. However, although a significant decrease in outsourcing demand was seen in almost every service sector of the Chinese pharma outsourcing industry, its growth rate was still significant.



Although having performed relatively well in 2009 compared to many of its counterparts worldwide, the Chinese pharma outsourcing industry experienced a significant slowdown during the crisis. (Source: Beijing JOINN Laboratories)

Industry Performance

The most affected sectors were the drug discovery and preclinical research services as almost all financially troubled biotech companies cut their programs in these two areas. Most major pharma companies also temporarily scaled down their budgets and efforts in early stage drug R&D - after the former gained more late stage drug candidates from

smaller financially troubled biotech companies.

The demand for contract manufacturing services also decreased mainly due to the quality incidents that occurred in 2008. Outsourcing demand of clinical research services was less affected as cash-rich major drug companies still outsourced a major portion of their development work.

Although having performed relatively well in 2009 compared to many of its counterparts worldwide, the Chinese pharma outsourcing industry experienced a significant slowdown during the crisis. The most affected sectors have been drug discovery and contract manufacturing; all are chemistry-focused services.

Each had a growth rate of only about 10- 12 percent in 2009 (compared to more than 30 percent before 2008). The growth rates of the preclinical and clinical research service sectors were maintained at around 30 percent and 35 percent, respectively (still much lower than the previous years).

The entire industry grew at only about 17 percent over 2008 (35 percent in 2008) and its current market value is estimated to be US\$1.67 billion. Three factors contributed to the continued growth of the Chinese pharma outsourcing industry in 2009:

- An increase in the number of R&D-focused small biotech companies that have entered China to look for outsourcing services;
- Increased outsourcing demand by foreign drug companies that have R&D centers/divisions in China;
- Growth in outsourcing demand by the domestic Chinese drug companies.

Industry-wide, the financial crisis has directly caused a reduction in R&D spending, which in turn resulted in the decrease in the demand for outsourcing. However, a more significant decline occurred in the R&D-focused biotech industry; whereas outsourcing demand from major pharma companies did not decrease significantly.



The entrance of various types of drug companies into China is likely to enhance outsourcing opportunities for Chinese service providers. (Source: Beijing JOINN Laboratories)

Strategic Realignment

What has changed in demand by major pharma companies is their research focus. As they now have more drug products in late development stages, their outsourcing focus has been on further developing these products. As a result, current outsourcing demand by the major companies for lead discovery and/or early stage development services has fallen.

The overall outsourcing demand by the major pharma companies has however, not decreased significantly compared to pre-crisis levels.

As many of these major pharma companies have been running at low productivity levels for a number of years, they have been constantly looking for outsourcing opportunities in many aspects of their operations in order to address low efficiency and productivity. What has been changing is their outsourcing patterns.

They now prefer to outsource an entire block of research work (lead discovery, preclinical research or early stage clinical development) to those preferred service providers who not only have a broad scope of service that spans the desired research areas, but who also possess the strong capabilities in these areas.

These pharma companies also look for Contract Research Organizations (CROs)/Contract Manufacturing organizations (CMOs) that possess specialty techniques such as the quick detection and effective reduction of cytotoxicity; bio-imaging; new drug delivery, etc. In short, they have now become more selective in choosing their preferred service providers.

To improve R&D productivity, pharma and biotech companies are restructuring their R&D divisions into smaller organizations. For example, Pfizer is planning to reorganize its R&D divisions into numerous smaller R&D centers, each focusing on only one therapeutic area and housing 100-150 researchers.

Pharma companies appear to be increasingly implementing the Networked Partnership (NP) R&D model. For example, Eli Lilly has set up an independent operation group called "Chorus" in its Indianapolis headquarters, specifically focusing on handling collaborations with its partners worldwide. It also has a similar operation group in its Shanghai R&D center, though much smaller in size.

To speed up their drug R&D progress, both major pharma and small biotech companies need to have more accurate therapeutic targets and a better understanding of the Mechanism of Action (MOA) of a drug compound. They also need to quickly identify lead compounds and get them optimized, and obtain the efficacy and safety testing results from their preclinical and clinical trials. All these operations must be organized in an efficient way. They also need to address the manufacturing costs for both developmental and marketed drugs.

For the realization of these goals, drug companies need to conduct broader and more extensive research on genomics and proteomics - including the development of disease/animal models, more effective diagnostic and imaging methods and better biomarkers. They will require large, readily available compound libraries that possess special structural features for screening against selected targets.



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They will also need to rely on faster, more accurate highthroughput screening systems to screen the compound libraries. A large portion of such heavy research work is likely to be fulfilled in the manner of collaborations with either academic research institutions (for target identification/validation and elucidation of action mechanism) or professional service providers (for discovery, development and manufacturing).

On the other hand, drug companies also want to have more control over late stage development and drug registration. Table 1 summarizes the analysis of outsourcing demands in the near future by the global pharma and biotech industries.

Outsourcing demand should remain strong in following areas:

- Research services in genomics and proteomics;
- Custom synthesis of compound libraries with special, diverse, or more natural product-like molecular structures;
- Preclinical research services such as animal/disease models, in vivo bio-imaging techniques, molecular diagnostic tools;
- Contract manufacturing services for small molecule drugs, both in development and on market (including generics).

Outsourcing demand may become softer in following areas:

- **Drug discovery and potency optimization** – As this type of work is considered the core component of drug R&D and is also Intellectual Property (IP)-sensitive, most major pharma companies are likely to conduct a major portion of this in-house. Due to the financial crisis, many small R&D-focused biotechs may have a weaker focus in this area;
- **Late-stage (such as phase III) clinical trials** – Since this stage is critical in the lengthy process of drug R&D, major pharma companies would prefer to have greater control over it; whereas most small biotech companies rely financially on the larger companies to co-develop the former's late-stage drug candidates;
- **Formulation for commercialized drugs** – As this is the tech-rich stage in a drug manufacturing process and also the last stage that is directly related to product quality, most major pharma companies are likely to keep it in-house.

Table 1: Analysis of outsourcing demands by global pharma and biotech industries

Outsourcing Development

Outsourcing lies further downstream in the value chain. How the future landscape of the Chinese pharma outsourcing industry is likely to develop,

will be dependent upon the strategic changes that are implemented by the pharma and biotech industries. However, even though many major pharma companies have been scaling down their operations in various aspects, it seems that their activities in China have not been affected. At present, many are accelerating their investments in the country.

For example, Novartis has announced an investment of US\$1.25 billion to expand its R&D center in Shanghai and to construct a process R&D and manufacturing facility in Changshu (Jiangsu Province), where it currently has a multi-kilogram batch manufacturing facility. Similar to the Novartis' move, other major pharma companies including Bayer Schering, Merck, Boehringer Ingelheim, Eli Lilly, and Pfizer are also planning to expand their R&D centers and other operations in China in the following years.

Also investing are smaller, R&D-focused biotech companies. An example is Forma Therapeutics, a Cambridge, Massachusetts-based startup biotech company that has announced the establishment of its R&D lab in Beijing. Partly because of the financial crisis, a growing number of small biotech companies now also prefer to conduct R&D in China.

The entrance of various types of drug companies into China is likely to enhance outsourcing opportunities for local service providers. For example, Eli Lilly is currently seeking greater collaboration with local Chinese companies. AlphaRx, a Canadian biotech company that set up its Asian headquarters in Shanghai Zhangjiang Hi-Tech Park, has been looking for a partnership with local companies.

In addition to outsourcing demand from the foreign drug companies, outsourcing demand by the local domestic Chinese drug companies is also expected to grow. Encouraged by the government and fueled by the growing availability of R&D funding and venture capital, more Chinese pharma and biotech companies are investing heavily in innovative drug R&D.

As many of them currently still do not have the full capability and capacity to conduct all the tasks of drug R&D on their own, they are likely to turn to the local CROs/CMOs for help as these service companies have readily available facilities and experience.

Looking at 2010 and beyond, cost reduction looks likely to be a main area of focus for pharma companies worldwide. For many small R&D-focused biotech companies, the shrinkage of the availability of venture capital caused by the financial crisis, could still be the main threat to their continual operation.

The challenges that are faced by the global pharma industry, coupled with the advantages that China still possesses over many of its counterparts, should sustain the demand for Chinese outsourcing services by the global pharma/biotech companies. All these factors contribute to a positive outlook of the Chinese pharma outsourcing industry in 2010. It is predicted that this industry is likely to expand by 20 to 25 percent this year, and its market value could exceed US\$2.0 billion.