

中国临床前和毒性研究外包:现状分析与前景预测

# Future Outlook of China Preclinical and Toxicology Outsourcing Market



## Report Description

It has been well recognized in the global pharmaceutical industry that the R&D productivity of discovering a new medicine has been low. The high failure rate in various development stages has been the main factor that drives up the overall cost of drug discovery effort; whereas the severe toxicity and safety concerns have been the major causes of the high development failure. As all drug companies are vigorously controlling the R&D cost, the high failure rate has become a controlling factor for them to improve the efficiency and productivity of drug discovery and development. To reduce the overall cost of drug development, eliminating un-developable drug candidates and avoiding them being unnecessarily advanced to any late development stage have become critical to all drug companies. As such, all drug companies are now conducting extensive toxicology and safety pharmacology research for any drug candidates.

Although relatively young, the service capability of Chinese CROs in preclinical and toxicology research has been significantly improved in the recent years. As China possesses a number of advantages in preclinical and toxicology research, many drug companies are attracted by the significant benefits of conducting this type of research in the country.

To help these drug companies better understand the current state of this Chinese industry, the report “**Future Outlook of China Preclinical and Toxicology Outsourcing Market**” published by JZMed, Inc, a world renowned market research firm specialized in Chinese pharmaceutical industry, provides them with the unique insights into the current service capability and capacity of the Chinese preclinical and toxicology outsourcing industry.

The report revealed the current structural composition and the latest developments of the Chinese industry. By comparing the service capability and market size of the Chinese industry with its counterparts in the world, the report also provides a clear picture of where the Chinese industry currently stands in the global preclinical and toxicology outsourcing industry.

More importantly, by analyzing both growth drivers and resistors of the future development of the Chinese industry and the competitive landscape of the world preclinical and toxicology outsourcing industry, the report also provides the clear picture of the future development potential of this Chinese industry.

The report is a must-read book to all professionals in the industries of pharmaceutical, biotechnology, financial investment and outsourcing service that are interested in the China’s pharmaceutical outsourcing industry. It is also a valuable reference book to drug regulatory agencies and other government agencies that are involved in strategic planning for development of pharmaceutical industry in their own countries.

## Scope of the Report

It has been well recognized in the global pharmaceutical industry that the R&D productivity of discovering a new medicine has been low. The high failure rate in various development stages has been the main factor that drives up the overall cost of drug discovery effort; whereas the severe toxicity and safety concerns have been the major causes of the high development failure. As all drug companies are vigorously controlling the R&D cost, the high failure rate has become a controlling factor for them to improve the efficiency and productivity of drug discovery and development. To reduce the overall cost of drug development, eliminating un-developable drug candidates and avoiding them being moved to any late development stage have become critical to all drug companies. As such, all drug companies are now conducting extensive toxicology and safety pharmacology research for any drug candidates.

Although relatively young, the service capability of Chinese CROs in preclinical and toxicology research has been significantly improved in the recent years. As China still possesses a number of advantages in preclinical and toxicology research, many drug companies are attracted to and become interested in conducting this type of research in the country. To help these drug companies better understand the current state of this Chinese industry, the report described this Chinese industry from four different aspects.

Chapter One analyzed in depth why toxicology and safety studies have become so important in the modern drug discovery and development, what drug companies' desire to improve their R&D efficiency and productivity and what the outsourcing service providers are doing to meet the requirements of the drug companies.

Chapter Two analyzed why it is the time to recognize China also as a favored outsourcing destination for preclinical and toxicology research and, based on the analysis, pointed out that preclinical and toxicology outsourcing might be the next hot wave in China following the current widespread small molecule drug discovery outsourcing in the country.

In Chapter Three, detailed description was provided to drug companies about what China currently has and what Chinese CROs currently can do in terms of their service capability and capacity.

In the Fourth Chapter, an in-depth analysis was conducted about all major drivers and resistors determining the future growth of the Chinese industry. Based on the analysis, the report then forecasted the market growth pace of the Chinese industry between 2010 and 2015 and the possible market value it could reach by 2015.

The report is a must-read book to all professionals in the industries of pharmaceutical, biotechnology, financial investment and outsourcing service that are interested in the China's pharmaceutical outsourcing industry.

## About the Author

### **Jim J. Zhang, Ph. D.**

Jim J. Zhang currently is president and managing director of JZMed, Inc., a leading market research company that specializes in the Chinese pharmaceutical, biotechnology and pharmaceutical outsourcing industries. Before founding the company, Jim worked for nine years with Albany Molecular Research, Inc. (AMRI), a US-based and currently one of the world largest CROs. During his tenure at AMRI Jim was responsible for managing and overseeing multiple drug R&D projects that involved the international cooperation of AMRI's multiple sites (USA, Singapore and Hungary). He played key roles in helping numerous pharma and biotech companies discover and develop a series of drug candidates that later entered preclinical and clinical development including advanced clinical trials. He was also the key contributor to the development of chemical production process for several developmental drugs. Prior to pursuing his Ph.D. program in the US, Jim worked for six years in a China-based CMO as process engineer and developed production process for a number of pharma products.

Jim's technical expertise spans from chemical process research and development to drug discovery and development for viral infection, cancer, chronic obstructive pulmonary disease (COPD) and cystic fibrosis. Currently he holds 18 patents. He is also the principal author of 12 peer-reviewed research articles.

Jim has authored a series of research reports about Chinese pharmaceutical outsourcing industry. He was also invited by a number of market research firms such as Business Insights to author/co-author industry reports.

Jim received his master's degree in Chemical Engineering from East China University of Science & Technology (Shanghai), and his Ph.D. degree in Synthetic Organic Chemistry from the University of Iowa. He also received additional trainings in Medicinal Chemistry through working at Research Triangle Institute (Research Triangle Park, North Carolina).

## Key Findings of the Report

- ◆ The Chinese pharmaceutical outsourcing industry has been growing in an exponential rate in the past decade. Most early established Chinese CROs almost all started with chemistry service only. However, after having practiced for a few years, a number of them have now also gained sufficient experience and skills in preclinical and toxicology research.
- ◆ The rapid development and growth of the Chinese preclinical and toxicology outsourcing industry is, to a large extent, contributed by the entrance of a number of multinational CROs that are attracted by the fast growth history and still huge future growth potential of the Chinese industry. Their presence has greatly enhanced the overall service capability of the Chinese industry.
- ◆ Currently, there have been about 65 CROs in total, including the China divisions/branches of those multinational CROs, in the Chinese preclinical and toxicology outsourcing service industry. Combined together, they provide a wide spectrum of services covering almost all areas of the preclinical and toxicology research. One of the key features of the Chinese service industry is that most Chinese CROs have non-human primates for *in vivo* efficacy testing and other pharmacological property studies, which have become more and more important in the modern preclinical and toxicology research.
- ◆ Most China-based CROs have brand new, state-of-the-art preclinical research facilities including animal vivaria. Currently, China has a capacity of more than one million square-foot animal space. About another one million square-foot animal facility is under construction.
- ◆ China has started implementing the GLP standard for preclinical and toxicology research since 2007, including the regulations on the use of animals in medical research. As the FDA gradually recognizes the Chinese GLP standard, more and more data generated in the laboratories of Chinese CROs are now accepted by the agency.
- ◆ Responding to the improvements, a large number of drug companies, both major pharma and small biotech, have outsourced their preclinical and toxicology research to China. After conducting drug discovery research in China for several years, the China R&D centers of many major pharma companies have generated a number of lead compounds in their pipelines which are ready to enter the next development stage. They are currently expanding their R&D focus in China along the value chain, from originally only discovery-focused research to now also including early development.
- ◆ Although the current outsourcing demands for preclinical and toxicology research service are still relatively soft in China (and in the globe as well) compared with those years before the financial crisis, in long term, these demands will be still strong. A

number of positive drivers, both globally and regionally and both internally and externally, all determine the anticipated fast future growth of the Chinese industry.

- ◆ Globally, as more major pharma companies will be implementing the strategy of networked partnership and as a key stage of drug development, outsourcing demands for preclinical and toxicology research will only become stronger and stronger. Similarly, outsourcing demands by small biotech companies will also become stronger as more and more of them now pursue virtual operation model, which determines that they will mostly rely on CROs to fulfill their R&D work.
- ◆ Regionally, as China will still possess a number of advantages even five to seven years from now in preclinical and toxicology research over many of its competitors in the world, drug companies from around the world will be attracted to conduct this type of research in the country.
- ◆ Internally, continually working with experienced multinational companies is steadily improving the skills and experience of Chinese CROs, which will in turn attract more drug companies to outsource to the country. The outsourcing service demand by the local domestic Chinese drug companies is also expected to grow rapidly in the near future as more and more Chinese drug companies are now embarked on innovative drug research.
- ◆ Externally, as many pharma companies have now recognized the power and usefulness of the large talent pool in China, conducting drug R&D directly in China can enhance their productivity. The fast development of the Chinese industry will also attract more multinational CROs to enter the Chinese market in the near future, which will further accelerate the development and growth of the Chinese industry.
- ◆ In the past several years China has been recognized as one of the best places in the world for small molecule drug discovery research. The country is currently also emerging as one of the most favored places for preclinical and toxicology research as well. It is therefore expected that the outsourcing service of preclinical and toxicology research will be the next wave in China. Major pharma companies will be looking for outsourcing or collaboration opportunities in China. They will also be implementing the networked partnership strategy in China through partnering with preferred local companies or research organizations.
- ◆ JZMed thus forecasted that the Chinese preclinical and toxicology outsourcing industry will likely grow in a CAGR of 27% for five years after 2010 and its market value will likely reach more than \$760 M by 2015.
- ◆ As the fast growth of the Chinese industry attracts more multinational CROs to enter the Chinese market, the current industry landscape of the Chinese preclinical and toxicology service sector will soon be changed as the competition will rise rapidly. For Chinese CROs to survive the anticipated competition, it is expected that more consolidations within the Chinese industry will take place in the very near future.

## Key Features of the Report

- ◆ The report analyzed in depth and described in detail the current structural composition of the Chinese preclinical and toxicology outsourcing industry. Based on the broad and in-depth analysis, it is the first time ever that the report revealed the influence of the multinational service providers on the development and growth of the Chinese preclinical and toxicology outsourcing industry.
- ◆ It is also the first time that the report described in detail the current service capability and capacity of the Chinese industry including the successful identification of the best players of the Chinese industry, China-based CROs that are certified for GLP compliance or accredited by the international organizations for their facilities.
- ◆ It is the first time that the report provided a guide to world pharmaceutical and biotech companies that are interested in outsourcing to China of what China currently has and what Chinese CROs can do at this moment.
- ◆ It is also the first time that the report analyzed in depth the R&D activities of major pharma companies in China and the driving factors that attract them to China as well as the outsourcing strategies they are implementing in the country. Based on these analyses, the report then pointed out what the next outsourcing steps these major pharma companies will likely take in the Chinese market.
- ◆ The report analyzed and provided a detailed description of the latest development trends in the world preclinical and toxicology outsourcing industry with focus on the latest development of technologies, drug companies' new desires and the evolving services offered by global major CROs in the preclinical and toxicology outsourcing industry.
- ◆ The report also performed comparisons of the Chinese industry with its global counterparts in terms of their service capability and industry and market sizes. It provides a clear picture of where the Chinese industry currently stands in the world industry.
- ◆ By analyzing both in detail and in depth a series of drivers and resistors, the report also revealed how the Chinese industry will likely develop and grow in the near future and what market size it could reach as well as its possible market share in the global industry.
- ◆ One of the key features of the report is that it includes the detailed company profiles of the top 30 best players in the Chinese preclinical and toxicology outsourcing industry, including the detailed description of their service capability, features and experience. Besides, the company profile also contains the detailed information of their animal space capacity, features of their facilities and the disease models offered, in addition to their detailed contact information.

## **Your Questions Are Answered**

The report provides detailed answers to a variety of questions many professionals are constantly asking about the Chinese preclinical and toxicology outsourcing industry:

- ◆ Why does toxicology study now become so important? How drug companies allocate their R&D budget to this part? How much is the current global toxicology research spending? How much of that is currently outsourced? How much toxicology outsourcing is from major pharma and how much from small biotech?
- ◆ What is the current market size of global preclinical and toxicology outsourcing? How much does Chinese market account in this global outsourcing sector?
- ◆ Why do pharma and biotech companies want to go to China for preclinical and toxicology outsourcing? What are their intentions of outsourcing to China?
- ◆ What advantages and disadvantages does China currently possess in preclinical and toxicology outsourcing? How to compare China's these advantages with its global counterparts? Will China still have such advantages in the following five to seven years?
- ◆ What are Chinese CROs' current service capability and capacity? Who are the best players in the Chinese industry? How do the world major CROs influence the development of this Chinese industry both in the past and in the future?
- ◆ Who are the Western CROs that provide this type of outsourcing service in China? How will their presence in China impact the development of the local Chinese CROs? How will this trend affect the future development path of this Chinese industry?
- ◆ Who are those world drug companies that are currently outsourcing preclinical and toxicology research to China? Why is it the right time to recognize China also as a favored outsourcing destination for preclinical and toxicology research?
- ◆ How will the Chinese preclinical and toxicology outsourcing market develop in the next five to seven years? How to compare it with the global preclinical and toxicology market in the same time period? How to compare the market size and service capability of the Chinese CROs in this sector with their global competitors including both Western CROs and Indian CROs?