

中国原料药及合同生产新趋势



**The New Trend of API Sourcing
and
Contract Manufacturing in China**

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Report Description

For years China has been one of the main places for global drug companies to source APIs and pharma intermediates or contract out the manufacturing work of such compounds. Almost all world major pharma companies have sourced a variety of APIs and pharma intermediates in the country.

However, the fast growth of this Chinese industry experienced significant growth slowdown in the last one year or so. The financial crisis, which occurred coincidentally as the Chinese industry experienced the sharp decrease in API demand, is only one of the factors to blame. The quality incident in supply chain that involves Chinese companies has directly led to the apparent change in the raw material sourcing pattern of global drug companies in China.

Driven by the severe reality, a series of improvements have recently been made within the industry since the quality incident, including the revision of the current cGMP standard. Meanwhile, a number of foreign companies possessing specialty in quality control also rushed to China to help Chinese companies upgrade their quality control system and management. As a result of all these efforts, at present a fairly large number of drug companies from all over the world are still sourcing APIs in China or outsourcing the manufacturing work to the Chinese companies.

The report “**The New Trend of API Sourcing and Contract Manufacturing in China**” published by JZMed summarizes the latest developments in the Chinese API and CMO industry including the current industry and market size, service and manufacturing capability and capacity, the latest improvements made by both Chinese companies and government in product quality control and management, and the latest API sourcing pattern of global drug companies in China.

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 API supply and contract manufacturing in China or learning how the Chinese industry has been performing under the severe situation and how it will likely develop in the near future. 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.

Key Findings of the Report

- ❖ Chinese API industry experienced significant growth slowdown in 2009. The financial crisis is only one of the factors to blame. It was the quality incident in the supply chain involving Chinese companies that has woken up drug companies and consequently changed their sourcing patterns in China. Governments in the Western countries have also been tightening up the regulations for drugs (including APIs) imported from other countries.
- ❖ The total annual output of the combined Chinese API manufacturers reached close to \$31 B in 2009, representing a 3% decrease over 2008. Of which, about half (\$16 B) was marketed overseas, but the export value decreased 8% compared to 2008. The main drop in the export value occurred in the well regulated Western markets, which is in accordance with the current API sourcing practice of the Western pharma companies in China. In contrast, the Chinese-made APIs marketed in the emerging and other developing countries increased 20% during the same time period.
- ❖ China currently can make about three fourths of the world total API products. There are about 1,300 registered API makers in China. The industry is highly fragmented at present. About 70% of them have small molecule synthetic API products marketed overseas; but only about 13% of them have the export value exceeding \$1 M. About 11% of companies have APIs registered with the internationally recognized regulatory agencies.
- ❖ China's current total API production capacity is around 800,000 metric tons a year. It is the world largest API producer of penicillin, amoxicillin and a number of other antibiotics with the total production capacity of close to 200,000 metric tons a year. China is also the world largest producer of APIs of vitamins, accounting for about 60% of the global output of vitamin APIs, with the annual production capacity close to 300,000 metric tons.
- ❖ At present most contract manufacturing work outsourced to China has been centered on small molecule APIs. Outsourcing of APIs for macro compound-based drugs is still very rare in China. The outsourcing demands for multi-kilogram scale manufacturing of APIs of developmental drugs is also low in China. The market size of this type of outsourcing has been small. Most professional Chinese CMOs presently still do not have the FDA- or EMEA-certified cGMP production facilities to manufacture APIs to support drug development although they possess the strong capability in chemical process research and development and scale-up synthesis.
- ❖ At present the Chinese API manufacturing industry is still a huge mix. There are many cases in which a large number of companies manufacture the same products; but their product quality and after-sales service are significantly different. The majority of them have been serving only the domestic customers. On the other hand,

there are indeed a number of Chinese API suppliers that are technically sufficiently strong.

- ❖ The widely accepted API quality control standards such as the US Pharmacopeia (USP), the European Pharmacopeia (EUP) and the International Conference of Harmonization (ICHQ7) are currently being followed by many Chinese companies. The internationally recognized API quality certificates such as DMF, EDMF, CEP or COS are also common in those top tier API suppliers.
- ❖ Even though the quality incident has retarded many drug companies sourcing APIs in China, the current severe financial crisis has made the country still considerably attractive as achieving as much cost reduction as possible has never become so critical to all drug companies around the world.
- ❖ These factors will thus drive the further development of the Chinese API industry in the near future. The on-going nationwide healthcare reform in China will also further drive up the demands for high quality API products in the domestic market.
- ❖ Considering all these factors, coupled with the series of actions taken to correct the drawbacks, it is expected that the Chinese API industry will perform better in 2010. The total market value of the Chinese API industry is believed to reach \$32-33 B by the end of 2010, a growth of about 5-8% over 2009. In the following five years after 2010, the industry is expected to continue to grow in around 15% each year (CAGR) and its total output could reach as much as \$65 B by the end of 2015.
- ❖ Similarly, in 2010 the Chinese-made APIs marketed overseas will likely return to the positive growth territory with a predicted growth rate of around 2-4%. The market value of the exported Chinese-made APIs could reach close to \$17 B by the end of 2010. In the five years after 2010 the growth rate of this sector could maintain at around 13% (CAGR) and the total market value could reach \$30 B by 2015.
- ❖ Along with its future growth, the Chinese industry will still face a number of challenges including the fast rise of labor cost, constantly raised standards of product quality and environment protection and the competitions from other developing countries.

Key Features of the Report

- ❖ The Report is focused on the quality issue of the Chinese API industry. It analyzes the historical and cultural reasons that cause the quality incident. It also describes what improvements have been made within the industry since the quality incident.
- ❖ The Report is thus not designed to tell API seekers what China has. Rather, it is designed to tell them who are the best ones in China at present, who have had the most improvements so far in manufacturing technology and quality control, what new regulations have been added into quality control by Chinese government, etc.
- ❖ The Report also well summarized the latest developments in the Chinese API industry after it was double hit by the quality incident and the global financial crisis.
- ❖ The Report is the first time ever that describes from a variety of angles the current industry and market sizes and manufacturing capability and capacity of the Chinese API industry, including the detailed analysis of its positions in the same industry of Asia and the world.
- ❖ The Report also presents the detailed discussions on the common technical weakness of Chinese API makers, the cultural features of Chinese enterprises and the mindset of their executives. It also made detailed comparisons of the differences in business principles and conduct between the East and the West. A complete package of practical strategies of how to overcome the barriers and effectively conduct API sourcing and outsourcing in China is also included.
- ❖ The Report also provides our in-depth analysis of the future development potentials of the Chinese API and CMO industries including their future growth drivers and resistors.
- ❖ The Report also included the detailed company profiles of fifteen top tier players in the Chinese API and contract manufacturing industries. For each company, a variety of areas are examined including their technical capability, manufacturing facility and capacity, quality control system, product list, DMF/EDMF filing status, global presence, service history and experience and detailed contact information, etc.

Your Questions Are Answered

The Report provides the detailed answers to a variety of questions that you must want to know:

- ❖ What has happened to the Chinese API industry after the quality incident?
- ❖ How do Chinese companies manage product quality? What are the differences between their approaches and those practiced by the Western drug companies?
- ❖ What is the current status of the cGMP regulation in China? How is it different from those in the Western countries? What to expect in the new Chinese cGMP standard?
- ❖ What are the key criteria of choosing a Chinese CMO or API maker? How to differentiate the best vendors from a large pool of similar ones? How to avoid the quality issue in API sourcing or outsourcing in China?
- ❖ Who have the best quality control management system in China? What quality grades/certificates do they have? Who owns the most DMFs/EDMFs?
- ❖ How about the technical competence of Chinese API makers or CMOs compared with their counterparts in the world? What are the weak points of Chinese companies?
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About the Author

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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).

About JZMed, Inc.

JZMed, Inc. (www.jzmedi.com) is a leading market research and consulting company that specializes in the Chinese pharmaceutical, biotechnology and pharmaceutical outsourcing industries. The company's primary focus is to provide intelligence and market research services to global pharmaceutical and biotech companies to help them tap the resources in the Chinese pharmaceutical industry and explore the opportunities in the Chinese pharmaceutical market. Meanwhile, it also provides assistance to these companies to facilitate their entrance into the Chinese pharmaceutical market or collaborations with Chinese companies. The company has provided this type of services to a variety of companies worldwide including the world major pharma companies and investment firms/banks. It also has a network of preferred pharma and biotech companies in China.

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