

中国制剂药物市场：现状与前景

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# Outlook of China Drug Formulation Market



### **1.5 Product quality regulation in China: Current state of Chinese cGMP**

China has started implementing the cGMP policy for all Chinese pharma and drug-manufacturing companies since 2004. However, the original version of the Chinese cGMP standard was significantly different from the Western standards, either the US or the EU's version. Although it required Chinese drug companies upgrade their facilities including their quality control facility, there were no any specific requirements of to what extent their upgrading should reach, especially in the areas of the quality control staff's knowledge and skills. Nor were there any standard trainings provided to the professionals. Also, the law enforcement to enforce the implementation of the cGMP standard was weak. More significantly, in the past the certification process was not as strict as it should be (for example, there were cases reported in media in which the drug company's cGMP certificate was purchased without actual examination and/or inspection).

After a series of quality incidents, the Chinese government now starts paying attention to the quality of all products made by Chinese companies, including all pharmaceutical products. The Chinese government is also trying to unify China's cGMP standard with the Western standards.

For example, starting in late 2008 the SFDA implemented the stricter quality regulation (It was still based on the 2004 version but with numerous additions). In addition to the enforced improvement in quality control, all Chinese drug companies were required to use the electronic record for all their manufacturing activities including the information of all raw materials used in their production. Those that failed to make significant improvements are forced to close. The SFDA also increased the inspections on production process and facility.

On February 12, 2011, the SFDA announced the official launch of the new version of the Chinese cGMP standard (called GMP 2010 as its draft was released for discussion in 2010). The new version has adopted the regulations of the FDA, the EMEA and even the WHO; but it is closer to that implemented by the EMEA as it more emphasizes the importance and requirement of "Quality Management Responsible Person" for product quality in all pharma companies. It is the first time in the history of the Chinese product quality regulation. The Responsible Person is authorized to share the quality control responsibility with the authorized persons such as company executives, managers of manufacturing and quality control. Besides, it also adds the requirements on reporting adverse drug events, more detailed classification of clean area for sterile product manufacturing (also closer to the EMEA's regulation) and more specific requirements on production documentation (such as detailed SOPs and procedure records). More

importantly, it also requires the complete documentation of raw material supply including the records of supplier audit.

The new cGMP policy has been formally implemented starting from March 1, 2011. The SFDA expects to fully implement it in five years. For those new facilities that are currently under construction or to be built in the future, they must follow the new cGMP standard. For those existing facilities, they are given a five-year grace time to finish upgrading and make them in full compliance. The implementation of the new cGMP represents the determination of the Chinese government to improve the drug (and food) product quality. It is thus expected that after five years the quality management of most Chinese drug companies will be significantly improved.

## **1.6 Key and fast rising players in Chinese drug formulation industry**

Although at present the majority of Chinese drug companies are still lack of capability to market their finished drug products in the well regulated market, it is not a question that there are a few technically capable Chinese companies that offer good quality products that are accepted by the Western countries. Many Chinese drug companies are aggressively upgrading their techniques and facilities, just trying to make their capability reach or close to their Western counterparts. In fact, some of them are now able to market their dosage form drugs in the Western countries (though the number of such Chinese drug companies is still very small at present).

Through providing the OEM (Original Equipment Manufacturing) or contract manufacturing service to the Western drug companies, a number of the Chinese drug companies have gradually gained knowledge and experience of producing formulated drugs according to the Western standards. The practice has actually laid the foundation for these pioneer Chinese drug companies to enter the well regulated market later on.

### **Case Study 4 Zhejiang Hisun Pharmaceutical Co. Ltd.**