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## SFDA Plans to Implement New GMP Regulations in 2006

The State Food and Drug Administration (SFDA) has made Good Manufacturing Practice (GMP) certification for medical devices a priority for 2006. The SFDA plans to implement the General Rules on Good Manufacturing Practice (GMP) for Medical Devices and the Implementation Guidelines for Disposable Sterile Medical Devices and Implanted Medical Devices within the next year. Under these regulations, companies that manufacture any of the above types of medical devices will need to successfully pass the GMP inspection before obtaining a Medical Device Manufacturing Enterprise License. Companies will be required to pass the GMP inspection when they first begin manufacturing as well as when they renew their manufacturing licenses.

According to the SFDA, medical device GMP certification will be implemented in three stages. The SFDA will first implement GMP certification for companies that manufacture blood bags, orthopaedic internal fixation appliances, biological filling materials, MRIs and CT scanners. These manufacturers will require GMP certification two years after the regulation is passed. GMP certification for companies that manufacture ultrasound equipment will be completed in the second implementation stage. For companies that manufacture other regular medical devices designated by the SFDA, GMP certification will be completed in the third implementation stage within three to four years after the regulation is passed. Although manufacturing certain medical devices such as hospital stretchers will not require medical device GMP certification, the manufacturing will need to be done in accordance with the Provisions on Medical Device Manufacturing Supervision and Administration.

Since 1998, the SFDA has been taking steps to implement GMP guidelines in China. Until now, the SFDA has followed ISO 9000 standards for medical companies in China. With this new regulation, the SFDA will base GMP regulations for medical devices on ISO 13485.

Currently, there are about 10,400 medical device manufacturing companies in China. However, the industry is still relatively small and many domestic medical device manufacturing companies do not use advanced equipment or technology. Throughout 2005,

the SFDA established new Centers for Technology Evaluation and Testing for medical devices in preparation for the new medical device GMP certification. As the SFDA implements the new regulations for GMP certification, manufacturing conditions should improve dramatically. The new regulations will be beneficial because companies will be required to minimize manufacturing errors and ensure greater safety in manufacturing medical devices. If a medical device manufacturing company fails to comply with these new regulations, the SFDA will impose fines or other penalties.

Since many different materials can be used to manufacture medical devices, the SFDA will also issue guidelines on medical device GMP for specific manufacturing materials. Finally, these new regulations will only cover GMP for medical devices; there are separate pharmaceutical GMP regulations.

This article is excerpted with permission from *The China Medical Newsletter*, available by subscription from Pacific Bridge Medical. *The China Medical Newsletter* is intended to provide important updates and discussion of the Chinese medical device and pharmaceutical regulations, as well as coverage of market developments in China's rapidly growing medical industry.

*Ames Gross is President of Pacific Bridge Medical (PBM), an independent consulting firm dedicated to assisting medical companies in Asia. Since 1988, PBM has helped over 150 medical companies with business development and regulatory issues. To learn more about medical device GMP certification, attend Ames Gross' presentation at OMTEC 2006. (See information included in this issue.) Ames Gross can be reached at [adgross@pacificbridgemedical.com](mailto:adgross@pacificbridgemedical.com).*

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