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PRC Medical Device Good Manufacturing Practice Rules Issued

Early in 2006 the State Food and Drug Administration (SFDA) of the People's Republic of China, the regulatory body in charge of the manufacturing, distribution and use of medical devices, attempted to implement good manufacturing practice (GMP) for medical device products nationwide. By raising the standards for medical device manufacturing, the implementation of GMP was expected to benefit the health of the general public in China and increase the competitiveness of China-based medical device manufacturers in the global market. There was, however, no general GMP rule applicable to all kinds of medical devices until December 2009, when the SFDA issued a package of regulations addressing GMP for medical devices including the Regulation on Medical Device GMP (GMP Rules) and the Regulation on Examination of Medical Device GMP (GMP Exam Rules). Both the GMP Rules and the GMP Exam Rules will become effective as of January 1, 2011, leaving one year for medical device manufacturers to make improvements. Accordingly, it is reasonable to expect that 2011 will witness the official implementation of GMP for medical devices in China.

GMP Rules

The GMP Rules serve as a benchmark generally applicable to any medical device product. Given that the manufacturing of certain medical devices is subject to more specific requirements, the SFDA has issued, and will continue to issue, separate GMP implementation rules applicable to such medical devices. For instance,

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the GMP implementation rules for sterilized devices and implantable devices were issued by the SFDA on December 29, 2009.

Aiming to regulate a manufacturer's quality management system throughout the process — from design, development and manufacturing to sales and after-sale service — the GMP Rules set detailed requirements with respect to the management position, documentation and records, design and development, sourcing, manufacturing management, product monitoring and measurement, adverse effect monitoring, etc.

Under the GMP Rules, it is critical to create and maintain various types of documentation as evidence of a manufacturer's compliance with GMP. Specifically, the following requirements deserve close attention:

- A manufacturer is required to create a set of quality management rules including quality standards, product specifications, and standards for product manufacturing, testing, examination, installation and after-sale service.
- Early in the design stage, a manufacturer must fully document, after internal review, the anticipated function, usage and performance of its products, as well as any safety issues and risk control measures.
- With respect to the sourcing process, the manufacturer must establish standards for evaluation and selection of suppliers and record the evaluation process and results.
- In terms of the production process, a manufacturer must create and keep manufacturing records for each batch of products, which should specify the output and allow for product tracking.
- A manufacturer must establish written product monitoring and measurement procedures. Monitoring and measuring devices must be regularly calibrated, with the calibration records maintained. In the case of malfunction of any monitoring or measuring device, the reliability of the data previously collected from the device must be reevaluated and results recorded.
- A manufacturer must designate a department to receive, investigate, evaluate and handle customer complaints, and maintain complaint processing records. If a manufacturer decides not

to take any corrective or preventive action after receiving a complaint, the decision must be approved internally and the reasoning must be documented.

The GMP Rules also require a manufacturer to adopt document control procedures. The issuance of documents and any amendments thereto must be approved internally, and any amendment must be identified to ensure that the applicable version is available on the manufacturing site. For the purpose of product repair and product liability determination, the repealed document must be appropriately labeled and kept for a specified period. Unless otherwise stipulated in other laws or regulations, a manufacturer must keep its documents for a period equal to the life cycle of the relevant medical device product or two years from the date when the product is released, whichever is longer.

GMP Exam Rules

The GMP Exam Rules set forth procedures for the SFDA and its local branches to follow when conducting examinations and to verify whether a manufacturer meets the GMP requirements. A manufacturer of Class II or Class III medical devices must apply for a GMP exam after it establishes a quality management system in accordance with the GMP Rules, whereas a manufacturer of Class I medical devices is exempt from the GMP exam.

Though the GMP Exam Rules do not set a deadline for device manufacturers to submit the exam application, failure to apply for the exam will cause severe consequences for manufacturers of sterilized or implantable medical devices — i.e., starting on July 1, 2011, to register or re-register their products with the SFDA, those manufacturers must provide an SFDA-issued notice as evidence that they have passed the GMP exam.

According to the GMP Exam Rules, the SFDA is responsible for the GMP examination of high-risk Class III medical devices including cardiac pacemakers, artificial heart valves, blood stents and catheters, disposable plastic blood bags and animal-derived medical devices. The examination of Class II devices and non-high-risk Class III devices is under the authority of provincial-level SFDA branches.

As a portion of the GMP exam, the SFDA or its local branches will conduct an on-site investigation within 30 business days after a manufacturer submits all required application materials. A manufacturer will be given a

notice of the exam five business days in advance. The SFDA will select at least two inspectors to form an investigation committee, which will notify the manufacturer of the investigation's scope and agenda. The on-site investigation will be conducted in accordance with the examination standards applicable to the medical device concerned. By the end of 2009 the SFDA had issued the examination standards for sterilized devices and implantable devices. If a manufacturer has a different opinion regarding the investigation committee's conclusion, as indicated by the GMP Exam Rules, it will have a chance to request a review by providing written explanation.

Based on the conclusion of the investigation committee, the SFDA or its branches will give one of three decisions:

- Pending for correction — The manufacturer will have six months to make improvements and will receive a pass if it manages to meet the standard after the improvements have been made.
- Fail — The manufacturer will not be allowed to file another exam application for six months.
- Pass — The manufacturer will receive a pass notice, which will be valid for four years.

With the promulgation of the GMP Rules and GMP Exam Rules, medical device manufacturers should start to improve their quality management systems as soon as possible. As noted earlier, a critical step will be to create and maintain various documents evidencing the establishment of a comprehensive quality management system. Finally, it is not hard to envision that, sooner or later, the registration of any Class II or Class III medical device will require a manufacturer to pass the GMP examination.
