

## China Introduces New Medical Device GMP and GSP Rules

In December 2014, China's Food and Drug Administration ("CFDA") revised the existing provisional Good Manufacturing Practices for medical devices ("New GMP"), and issued the country's first Good Supply Practices for medical devices ("GSP"). The New GMP rules will become effective on March 1, 2015, and the GSP rules immediately came into effect as of December 12, 2014. These rules serve as minimum standards for the quality management systems of device manufacturing and distribution in China. They form an important part of China's new device regulatory regime, which was substantially transformed since the promulgation of the *Regulation for the Supervision and Administration of Medical Devices* (also known as State Council Order No. 650) on June 1, 2014.

The New GMP and GSP rules adopt the following guiding principles:

- End-to-End Risk Management

The New GMP rules require legal manufacturers to manage risks throughout the entire product life cycle, i.e. from product design and development, manufacturing, and sales to after-sales services. Likewise, the GSP rules require distributors to manage risks throughout the entire supply chain, i.e., from procurement, delivery acceptance, storage, sales, and transportation to after-sales services. The design and implementation of the quality management system should reflect products' risk profiles. For example, distributors of Class 3 devices must build an IT infrastructure to enable sound implementation of the quality management system, whereas distributors of Class 1 and 2 devices are not subject to the same obligation.

The New GMP and GSP rules also introduce several new requirements to avoid adverse impacts on product quality in each of the product transfers. Manufacturers and distributors must qualify and audit their upstream suppliers and enter into quality agreements with these suppliers. Manufacturers should also promptly inform users or consumers of any product changes or updates.

- Traceability

The New GMP and GSP rules require manufacturers and distributors to retain complete documentation throughout the product life cycle and supply chain to ensure traceability. The documentation includes records for product design and development, production records, testing records, purchasing records, sales records, and after-sale services records. Records relating to delivery acceptance and sales of implants must be retained permanently.

- Detailed Requirements for Workshops and Equipment

The New GMP enhances the standards for the manufacturing environment, which must be fit for production and must not adversely affect product quality. Manufacturers must maintain appropriate production, testing, and warehousing space. They must fit the workshops with the necessary production, testing, and measuring equipment based on product attributes and manufacturing needs. Manufacturers need to follow protocols for the operation, cleaning, and maintenance of the manufacturing equipment, which must be evidenced in relevant records.

The CFDA expects all device companies to comply with the New GMP and GSP rules as long as they intend to sell the products in China. The CFDA, like its foreign counterparts, plans to exercise its jurisdiction over foreign legal manufacturers and may arrange overseas GMP inspections in the future. Companies that plan to introduce their devices to China are recommended to carefully review the New GMP and the GSP rules and timely address any potential discrepancy in their operations.

If you would like to discuss the foregoing or any other related matter, please contact [Katherine Wang](#) or your usual Ropes & Gray advisor.