ROPES & GRAY ALERT

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China FDA Announces Good Clinical Practices for Medical Devices

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On March 23, 2016, the China Food and Drug Administration ("CFDA") and the National Health and Family Planning Commission jointly promulgated the final revision to the 2004 *Medical Device Clinical Studies Rules* ("MDCSR"), the first ever revision in almost 12 years. The revision, titled *Good Clinical Practice for Medical Devices* ("Device GCP"), will become effective as of June 1, 2016.

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A medical device clinical study defined in this Device GCP only refers to registration studies intended for obtaining regulatory approvals. Notably, this Device GCP does not apply to in vitro diagnostic reagents that are classified as medical devices.

The revised Device GCP contains 11 chapters and 96 articles, significantly expanding the current MDCSR's 29 articles. It sets forth general principles, as well as guidance regarding preparation before the clinical study, protection of subjects' rights, the clinical trial protocol, responsibilities of ethics committees/sponsors/investigators/sites, retention and documentation of records and reports, management of the study device, and source document management. Highlights of the Device GCP are as follows:

- **Clarifying the Definition of Sponsors:** A sponsor refers to the party who is responsible for the initiation, management and monitoring of a clinical study. The current MDCSR defines a sponsor of a clinical study as the applicant who submits the device registration application, while the Device GCP clarifies that a sponsor shall be a device manufacturer. If the sponsor is a foreign entity, such sponsor shall designate a Chinese company as its agent.
- **Strengthening the Responsibilities of Sponsors:** Sponsors are responsible for monitoring the study and shall appoint qualified monitors to perform monitoring activities. In addition, if there is any information affecting the study, the sponsor is responsible for revising the investigator brochure, and obtaining an approval from the ethics committee for the revision.
- **Detailing the Requirements for Seeking Informed Consent:** The Device GCP specifies what types of information must be included in an informed consent form and how to obtain informed consent from study subjects. Any revised informed consent forms must be approved by the ethics committee prior to its communication with study subjects. As long as the revision can potentially affect the subjects' willingness to participate in the study, the sponsor must seek subjects' further consent.
- **Clarifying the Validity of the Registration Test Report:** The study device must pass the registration type test conducted by a qualified testing center, and such type test report must be issued within a year.
- **Specifying the Requirements for Multicenter Studies:** According to the Device GCP, a multicenter study is defined as a study conducted according to a single protocol but at more than three sites. The ethics committee of the lead site shall conduct an ethics review of the protocol on behalf of all study sites. The participating sites may review the feasibility of conducting the study within the site, but generally will not

propose any revisions to the protocol. The principal investigator of the lead site will become the coordinating investigator. In addition, both the coordinating investigator and the sponsor are responsible for the implementation of the entire study.

- **Imposing Stringent Records Retention Requirements:** The Device GCP stipulates that the study sites must keep all clinical data and materials for a period of ten years after the completion of the study. The sponsors must keep records of the study until all of the devices are no longer in use.
- **Reiterating the Study Recordation Requirements:** Reinforcing the *Regulations on the Supervision and Management of the Medical Device* (also known as the Order #650), the Device GCP stipulates that sponsors shall file for the recordation of their device studies with the local FDAs at the provincial level prior to launching any studies.

The Device GCP will strengthen the administration of device registration studies in China. Companies intended to launch new devices in China are advised to review their current practices and upgrade their compliance standards to the extent necessary.

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