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International Medical
Device Regulators Forum

Update on China Regulatory

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Provision for supervision and administration of medical device manufacturing

Revised, Decree No. 53 of the State Administration for Market Regulation (SAMR)

- published on March 10, 2022 and implemented as of May 1, 2022
- Include six chapters and 81 articles

Provision for supervision and administration of medical device distribution

Revised, Decree No. 54 of the State Administration for Market Regulation (SAMR)

- published on March 10, 2022 and implemented as of May 1, 2022
- Include 6 chapters and 73 articles



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- Implement the strictest regulatory requirements.
- Strengthen the supervision and management of medical device registrant, clarified the responsibilities of both registrants and entrusted manufacturers, incorporated the requirements related to entrusted production management into the QMS, and further improved the inspection responsibilities, inspection methods, results disposal, investigation and evidence collection and other regulatory requirements in the production process of medical devices.
- Improve the management requirements for sales, transportation, storage and other aspects of the distribution, and strengthen the quality and safety responsibility of registrants and filing entity for selling their registered and filed medical devices.



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- Consolidate the main responsibility of medical device production and distribution enterprises.
- Establish a medical device production report system, and specify the requirements for product variety report, production dynamic report, production condition change report and annual self inspection report of QMS operation.
- Optimize the licensing and filing process, adjust the requirements for distribution licensing and filing under the medical device registrant system,
- cancel the requirements for submitting business licenses and relevant supporting documents when licensing, further shortened the time limit for verification and approval, clarified the specific circumstances for exemption from submitting application materials and business filing, and simplified the procedural requirements for submission of materials for those who applied for licensing and filing at the same time.



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- Strengthen quality and safety risk control.
 - In combination with the actual supervision work, the requirements for hierarchical management, risk control and inspection of medical device production and distribution were further refined and improved.
 - Strengthen the control of quality and safety risks, clarify the key points of production and distribution supervision and inspection by classification, and clarify the quality responsibility and management requirements for providing transportation and storage services for medical device registrants, filing entity and distribution enterprises.



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GCP Revised

In 2016, the former SFDA (State Food and Drug Administration) and the former National Health Commission jointly issued the Good Clinical Practices for Medical Devices (Decree No. 25 of the State Food and Drug Administration)

According to the development of the medical device industry, the GCP for medical devices were revised, and the revised file (Decree No. 28 of 2022) implemented on May 1, 2022.



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- In China, activities related to clinical trials of medical devices for the purpose of applying for registration of medical devices (including in vitro diagnostic reagents) shall comply with the GCP requirements.
- The requirements covers the whole process of clinical trials of medical devices, including the scheme design, implementation, supervision, audit and inspection of clinical trials of medical devices, data collection, recording, storage, analysis, summary and report.
- The GCP has nine chapters and 66 articles, Compared with the 2016 document, there are the following major changes



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- Adjust the overall frame.
- Highlight the main responsibility of the sponsor, introduce the concept of risk management, and demand that the sponsor's quality management system should cover the whole process of clinical trials of medical devices;
- Strengthen the requirements of medical device clinical trial institutions, and clinical trial institutions shall establish the organizational structure and management system of clinical trial management;
- emphasize the responsibilities of researchers, who should carry out clinical trials of medical devices in accordance with the provisions of the code and relevant laws and regulations.
- include IVD GCP requirement



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- Simplify and optimize relevant requirements.
- deleted the requirement that "clinical trials of medical devices should be conducted in two or more clinical trial institutions of medical devices" ,allow carry out the clinical trials in one clinical trial institutions
- Absorb the requirements of the latest international regulatory.
- Absorbing the contents of IMDRF guidance N57, introduce the concept of multi regional clinical trials conducted in different countries or regions.
- Fully refer to international standards such as ISO 14155:2020 and ISO 20916:2019.



Adjust the contents of the medical device classification catalogue (No. 30, 2022)

- Adjust 27 categories of medical devices classification level or description

For example:

- Radio frequency therapy (non ablation) equipment, from II to III
- Add the category of implant wire for plastic surgery as the III category of medical device management
- Details show on the NMPA website:

<https://www.nmpa.gov.cn/ylqx/ylqxggtg/20220330144627167.html>



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- **Covid-19 Epidemic prevention and control**
- Up to now, NMPA had approved 111 COVID-19 IVD kits, including 39 nucleic acid IVD kits, 38 antibody IVD kits and 34 antigen IVD kits. including 11 fast IVD kits(30min-1hour)
- NMPA will continue to strengthen the cooperation with WHO and other regulators,provide information on time.



Thank you

1.revised the Provision on the supervision and administration of medical device production

2.revised the provision on the

3.revised the GCP

4.adjust 27 categories of medical devices classification level or description

5.continue to Serve for Covid-19 Epidemic prevention and control