IMDRF International Medical Device Regulators Forum

# Update on China regulatory

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**NMPA**

**Regulations on medical device supervision and administration**

✓On December 21, 2020, the State Council Executive Meeting approved the revised version of the regulations on medical device supervision and administration, which was signed by the premier on February 9. Now it is waiting for the official publish.

✓To cooperate with the implementation of the regulations, NMPA has made a plan to revise some corresponding provisions and Normative documents of the Regulations.

The Provisions…..

- The provisions for the medical device registration
- The provisions for the IVD registration
- The provisions for the supervision and administration of medical device production

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The Normative documents……

Requirements for medical device registration application materials and format of the approval certificate

Standard operation procedure for review and approval

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1.According to the reformation requirements of the state, encourage industry innovation and development

For example:

Optimize the approval procedure and simplify the approval materials

2. Fully implement medical device MAH system, Strengthen the responsibilities and obligations of MAH

The MAH responsible for the safety and effectiveness of medical devices in the life cycle of development, production, sale and use according to the regulation.

3.improve the supervision efficiency

Establish professional inspector system, use UDI system to realize the traceability of products, and so on.

- **Covid-19 Epidemic prevention and control**

- Up to now, NMPA had approved 56 COVID-19 IVD kits for 38 manufacturer, including 26 nucleic acid IVD kits, 27 antibody IVD kits and 3 antigen IVD kits.

- NMPA will continue to strengthen the cooperation with WHO and other regulators， provide information on time.

- **Optimize the licensing matters related to the production of imported medical devices in domestic enterprises**

In order to further implement the Opinions on the Reform of Review and Approval System for Drugs and Medical Devices issued by the State Council and the Opinions on Deepening the Reform of Review and Approval System to Encourage Innovation of Drugs and Medical Devices issued jointly by the General Office of the CPC Central Committee and the General Office of the State Council

- under the premise that the main raw materials and production process do not change, and the quality management system is consistent, the NMPA and provincial Regulatory Authority will recognize part of the original declaration data for the registration of domestic products, which will be beneficial to the development of China's medical device industry In order to save resources, improve the efficiency of review and approval, promote the rapid development of China's medical device industry, and better meet the needs of the people.

- **Technical guidelines for clinical evaluation of medical devices using real world data**

The main contents include real world data and evidence, advantages and limitations of real world research, common real world data sources, quality evaluation, common types of real world research design and statistical analysis methods, and real world evidence can be considered for clinical evaluation of medical devices.

NMPA has approved two products that use real world data as the part of clinical evidence.

This year, NMPA plan to hold Real world data research conference in Hainan, to discuss the hot topic further with experts from all over the world

- **Guidance for On-Site Inspections of SaMD GMP Appendix**
- To strengthen the supervision and inspection over medical device manufacturers' implementation of the Good Manufacturing Practice for Medical Devices and its appendix for SaMD, and guide the regulatory authority to better carry out on-site inspections, NMPA issued on June 4, 2020 the Guidance for On-Site Inspections of SaMD GMP Appendix
- The main contents include requirements for organization and personnel, premises and facilities, equipments, document management, design and development, quality control, etc.

- **Connection with the world wide regulation or standard**

- As a member of IMDRF, China actively promotes the implementation of the IMDRF guidelines in China. Up to now, among the 31 IMDRF guidelines, the 14 guidelines had been fully implemented in china, and 14 guidelines had been partly implemented in china.

- NMPA will continue to strengthen cooperation with IMDRF and contribute to the work of IMDRF, and now, NMPA will propose some new work items need to harmonize, according to the strategic 2020-2025, hope to submit the application in future.

# Thank you

1. The Regulation on medical device supervision and administration had been approved, waiting for the official publish.
2. Serve for Covid-19 Epidemic prevention and control
3. Optimize the licensing matters related to the production of imported medical devices in domestic enterprises
4. Promote the real world evidence operation
5. Guidance for On-Site Inspections of SaMD GMP Appendix