China Update

IMDRF Open Stakeholder Forum
March 19th, 2019
Moscow

Overview

- Revision of special approval procedures for innovative medical devices
- The Catalogue of medical devices exempted from clinical trials
- Promoting the Pilot Work of MAH
- Provisions for medical device AE monitoring and re-evaluation
- Guidance on the administration of management representatives of Medical Device Manufacturers
- GMP Appendix for SaMD (draft for comments)

Revision of special approval procedures for innovative medical devices

- Issued in November, 2018
- Detailed patent review requirements
- Applicable to Class II and III
- 5 year valid period
- Termination of the review process
- 50 innovative products approved up to now

The Catalogue of medical devices exempted from clinical trials

- Issued in September, 2018
- 1254 types of medical devices (including IVD) exempted
- vast majority of Class II and 192 Class III products covered

Promoting the Pilot Work of MAH

- Pilots approved: Shanghai, Guangdong and Tianjin
- Shanghai: expanded to the whole city
  guidances issued and drafted
  4 manufacturers, 7 products approved
- Guangdong and Tianjin
- A practical foundation for future MAH system

Provisions for medical device AE monitoring and re-evaluation

- Jointly issued by SAMR and NHC on August 13th, 2018
- Decree 1, SAMR
- Came into force on January 1st, 2019
- Clearly stipulate the MAH responsibilities
  - MAH direct reporting system
  - Risk control
  - Improved re-evaluation system

Provisions for medical device AE monitoring and re-evaluation

- MAH direct reporting system
  - Establish a system of direct reporting of adverse events, to actively collect and timely report to the monitoring institution according to the defined time limit
  - Suitable internal organization and personnel
  - Monitoring information system
  - Communication with the ditributors and hospitals

Provisions for medical device AE monitoring and re-evaluation

- Improved re-evaluation system

  MAH shall

  - Conduct active re-evaluation according to the scientific progress and the assessment of adverse events
  - actively revoke the marketing approval and notify the public according the re-evaluation results

  The authority can withdraw the marketing approval when the MAH fails to apply for revoke.

Guidance on the administration of management representatives of Medical Device Manufacturers

- issued on September 29, 2018
- The 5th GMP guidance
- Originated from Notice 64 (China MD GMP) and 13485 regulatory requirements combined
- Purposes:
  - clarify and emphasize the roles and responsibilities of management rep
  - insure the reliable communication between the manufactures and the authorities

Appendix for SaMD of good manufacturing pratice

- Public consultation: January, 2019
- Based on:

  IMDRF/SaMD/N23
  IEC 62304/IEC 82304-1、GB/T 19003
  China guidances on SaMD evaluation and Cybersecurity
  FDA guidances
- whole lifecycle covered
- 5th GMP appendixes (sterile, implants, IVD, denture)
- 164 comments and suggestions received

Thank you!