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 distributors 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 practice

• 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!