国家药品监督管理局医疗器械技术审评中心
CENTER FOR MEDICAL DEVICE EVALUATION , NMPA

Regulatory Progress of Digital Health in CHINA

PENG Liang, PhD

Center for Medical Device Evaluation, NMPA, CHINA

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General Considerations

- Digital Health
  - Cross fusion of information and communication technology(ICT) and medical devices(MD) based on computer technology
- Guideline system

Product Guidelines	Data-based (Image, Sigal, etc)	Model-based (TPS, PK, etc)
General Guidelines	Software Ed.2, 2021	Cybersecurity Ed.2, 2021	Mobile&Cloud 2017	AI&ML 2021	HF&Usability 2020
QMS	Software GMP, 2019 Inspection guideline of software GMP, 2020				

Guideline of MD Software Ed.2

- Applied to SaMD and SiMD, including OTS software
- Based on software feature, software safety class, and total lifecycle quality control
- Highlight the requirements of algorithm, function and intended use, software change and version control, software lifecycle process, tracablitiy, clinical evaluation principles, interoperability, measurement function, non-MD function, computing platform, and QMS software
- Refer to IMDRF N10、N12、N41

Guideline of MD Cybersecurity Ed.2

- Applied to SaMD and SiMD, including OTS software
- Based on cybersecurity feature, software safety class, and total lifecycle quality control
- Highlight the requirements of electronic interface, cybersecurity capabilities, incident response, vulnerability assessment, cybersecurity change, tracability, data cross border, remote service, and legacy device
- Refer to IMDRF N12、N60

Guideline of AI-MD

- Applied to AI-SaMD and AI-SiMD
- Based on the review point of deep learning software(2019)
- Focus on algorithm, data/model, and computing capability
- Highlight the requirements of AI-MD lifecycle process, algorithm change, third-party database, stress testing, adversarial testing, continuous learning/adaptive learning, algorithm programming framework, and AI chip
- Refer to IMDRF N12、N41、N67

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