



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

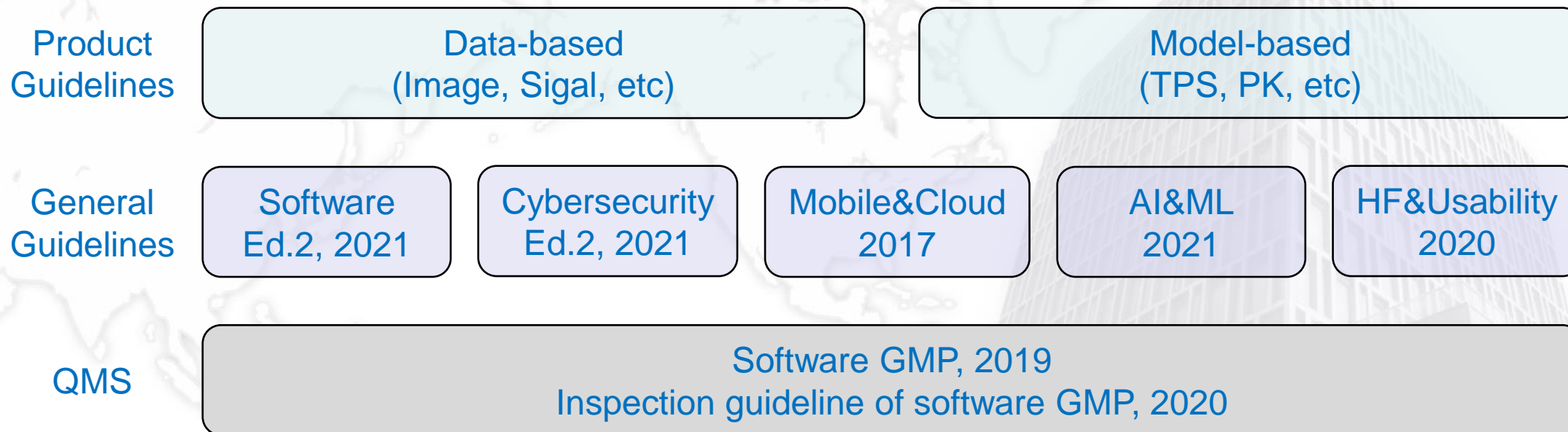
# Regulatory Progress of Digital Health in CHINA

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



- 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

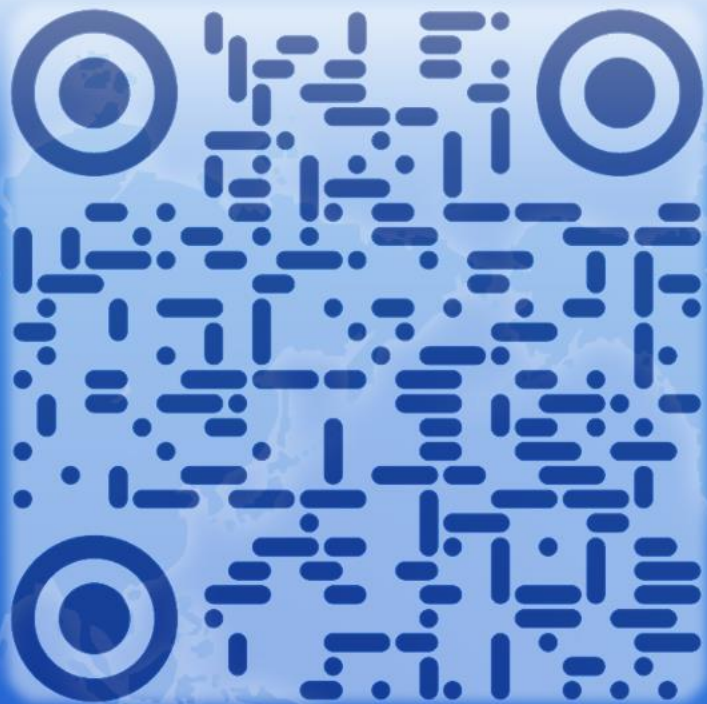
- Applied to SaMD and SiMD, including OTS software
- Based on cybersecurity feature, software safety class, and total lifecycle quality control
- Highlight the requirements of electronic interface, cybersecurity capabilities, incident response, vulnerability assessment, cybersecurity change, tracability,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

- 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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