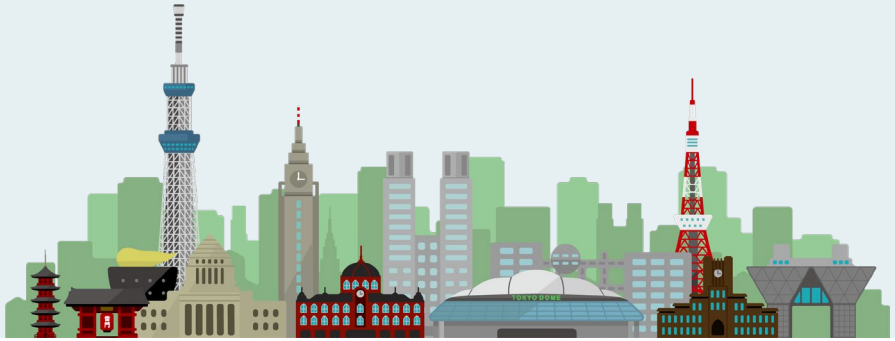
IMDRF International Medical Device Regulators Forum



Regulatory Update on Medical Devices in the Republic of Korea

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Enforcement of the Digital Medical Products Act

❖ **The "Digital Medical Products Act" came into force on 24 January 2025**

- Regulatory system was established to reflect the characteristics of digital products including digital medical devices, digital combination products (pharmaceuticals incorporating digital technologies), digital health support devices, and converged products combining these technologies in the era of AI and data-driven digital health.

❖ **Main contents of the regulatory system for digital medical devices**

① Reflecting **IMDRF's latest regulatory considerations** (SaMD risk considerations, PCCP and GMLP, etc.) and embracing the evolving nature of digital technologies

② Introducing the **flexible system** that can continuously evaluate the safety in the post-market phase, strengthening corporate self-responsibility

③ Establishing various **infrastructure to provide regulatory support**

* Recognizing the certification agencies, the regulatory support center and the training institutions for training experts in regulations

Regulations under the Digital Medical Products Act

❖ Major changes to the regulations of Digital Medical Devices under the "Digital Medical Products Act"

As-Is	To-Be
AI-applied products are subject to the classification of traditional medical products(hardware, software)	Criteria for classification of AI-applied products by digital technology to be established
Clinical trials on human patients only are acceptable	Various health data (including RWE, performance evaluation of components) to be acceptable
Any changes are required to make post-market changes as predetermined	Major changes are required to make post-market changes as predetermined
Performance evaluation for cybersecurity design in the pre-market phase is required	Total life cycle management of cybersecurity to be required
QMS requirements	Software and AI-specific requirements

New Guidance under the Digital Medical Product Act

❖ **32 subordinate guidance established, applicable to the Digital Medical Products Act**

- **Development or revision of the following 3 guidance documents under the law:**

❖ **Guidance on Review and Approval for Generative Artificial Intelligence-enabled Medical Devices (January 2025)**

- Provides case studies and guidance about how to draft application and submissions for GenAI medical devices

(Main content)
* Scope of GenAI medical devices and case studies
* Risk management analysis throughout total product life cycle and performance evaluation

New Guidance under the Digital Medical Product Act

❖ **Guidance on Review and Approval for Usability of Software as a Medical Device (January 2025)**

- Provides detailed explanation for criteria and guidance on how to draft applications and summaries

(Main content)
* Explanation for criteria and guidance on how to draft applications and summaries (with examples)
* Which cases are required to make post-market changes as predetermined
* How to collect risk information on usability

❖ **Revision of Guidance on Review and Approval for Cybersecurity of Medical Devices (November 2024)**

- To include requirements in international standards for cybersecurity (15→ 35, fragmentation and specification)

and in line with those of the U.S., the EU, etc.

Major Updates to the Medical Devices Act

❖ **Establishment of a legal basis for long-term tracking of implantable medical devices**

- To continuously collect, analyze and evaluate various information (on products, procedures, adverse events and other information) through voluntary participation (registration) of patients for implantable medical devices-focused management

❖ **Establishment of a legal basis for promoting safe use, improving convenience and increasing the use of the visually impaired or the hearing impaired**

- Regulation on medical devices recommended to include labelling with braille labelling or voice-to-sign language conversion codes for effective use by the visually impaired or the hearing impaired

* (Target medical devices) Blood pressure monitors, glucose analyzers, combination simulators and other medical devices intended for self-use to manage hypertension, diabetes or other chronic diseases

- Reduced user fee for manufacturing permission, import permission, review of technical documents for providers of medical devices including labelling with braille labelling or voice-to-sign conversion codes

Newly Published Guidance Documents

Developed Guidance Documents	Revised Guidance Documents
Guidance on Safety Performance Evaluation and Clinical Trial Plan for Digital Therapeutics for Mild Cognitive Therapy	Guidance on Performance Evaluation of NGS IVD
Guidance on Clinical Performance Testing Plans and Reports for IVD	Guidance on Review and Approval for PTCA & PTA Balloon Catheter
Guidance on Selection on Representative Models for Performance Testing of Orthopedic Medical Devices	Frequently Asked Questions on Vascular stent & catheter
Guidance on Clinical Trials Design of Digital Therapeutics	Guidance on Review and Approval for Virus Inactivation of Medical Devices Containing Materials Derived from Animal Sources
Guidance on Review and Approval for Selection of Representative Powered Exoskeleton Devices	
Guidance on Review and Approval for Medical Devices Manufactured Using 3D Printers	

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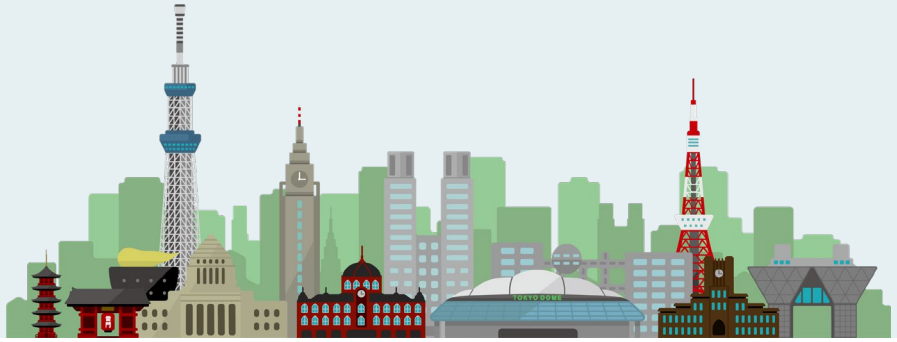

Thank you/Questions

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