Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Regulatory Updates on Medical Devices in the Republic of Korea

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Digital Medical Products Act (Jan 2025)

Enactment (Jan 2024) ➔ Advance Notice of Proposed Rulemaking(Jul - Sep 2024) ➔ Implementation(Jan 2025)

Clinical Investigation

- Simplifying procedure of clinical trials which use data set
- Specifying decentralized clinical trials& digital biomarkers

Review & Approval

- TPLC evaluation for development, use and upgrade

  1) Utilize Real World Evidence for pre-/post-marketing evaluation

  2) Simplify Change Procedures of AI/ML-enabled MD (including PCCP)

  3) Focus on companies' responsibility & product management system

  ➔ Difficulties in evaluating products itself (e.g., Generative AI-based MD)

Digital Medical Products Act (Jan 2025)

Post-market Management

- Software & AI/ML-specific QM regulation (considering GMLP), National Cybersecurity Guidance, Electronic Labeling / Distributions

Combination Products

- Evaluation system for Combination Products (Pharmaceuticals/Digital Medical Devices/Digital Medical · Health Supporting Devices)

Impact Assessment (Public Health & Social Cost)

- Supporting Intellectual property rights protection
- Preliminary Performance Evaluation System for digital medical product components such as Sensors and AI algorithms

Expanded Scope for the Utilization of MDSAP Audit Results

Before	After
Submission of MDSAP Audit Reports • **On-site inspection** is mandatory for an initial audit	Submission of MDSAP Audit Reports • **On-site inspection** can be replaced by **doucument review** for an initial audit (Dec 2023)

Increasing cases of MDSAP certification for manufacturing sites in Korea

- approximately a **26% increase** in 2023 compared to 2022
- about 213 sites

Clinical Investigation Regulation

1. Streamlined path to clinical trial plan approval for low-risk devices

- Clinical trials conducted according to established standards
- Clinical trials using devices that simply measure and display biological signals
- Clinical trials for research purpose only

2. Involvement of non-clinical trial institutes in clinical trials

- For clinical trials using fixed medical devices
- For specific infectious diasease, patients are allowed to participate in the clinical trial
- Under the supervision of clinical trial institues

Newly Published Guidance Documents

- **Guidance on Adverse Event Reporting for Medical Devices**
  - Revised in May 2024
- **Guidance on Usability for GMP of Medical Devices**
  - Developed in June 2024
- **Guidance on Expedited Review of Medical Products**
  - Developed in July 2024
- **Guidance on Performance Evaluation of IVD Reagents for High risk Infectious Diseases**
  - Revised in August 2024
- **Guidance on AI-based IVD MD Software for Digital Pathology**
  - Revised in August 2024
- **Guidance on Medical Device Cybersecurity**
  - Revised in November 2024
- **Guidance on Clinical Trial Design for Digital Therapeutics**
  - Developed in December 2024

Ministry of Food and Drug Safety

Thank you

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