IMDRF International Medical Device Regulators Forum | 26th Session

# Regulatory Updates on Medical Devices in the Republic of Korea

**Dr. Hye-won Roh**

Director General, Medical Device Evaluation Department

Ministry of Food and Drug Safety (MFDS), Republic of Korea

# Table of Contents

# 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)

**Postmarket 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<br>• **On-site inspection** is mandatory for an initial audit | Submission of MDSAP Audit Reports<br>• **On-site inspection** can be replaced by **doucument review** for an initial audit (Dec 2023) |

**Increasing cases of MDSAP certification for manufacuring 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 Clinical Trial Design for Digital Therapeutics**
  - Receiving internal feedbacks until the end of August 2024
- **Guidance on Medical Device Cybersecurity**
  - Receiving internal feedbacks until the end of August 2024


FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

# THANK YOU