IMDRF International Medical Device Regulators Forum

Regulatory Update on Medical Devices in the Republic of Korea

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IMDRF International Medical Device Regulators Forum

< Table of Contents >

- Korean Medical Devices Regulatory Framework
- Legal Framework of Medical Devices in Korea
- Key Updates
  - Medical Devices Act
  - Digital Medical Products Act and Regulations
  - Act on the Nurturing of Medical Device Industry and Support for Innovative Medical Devices

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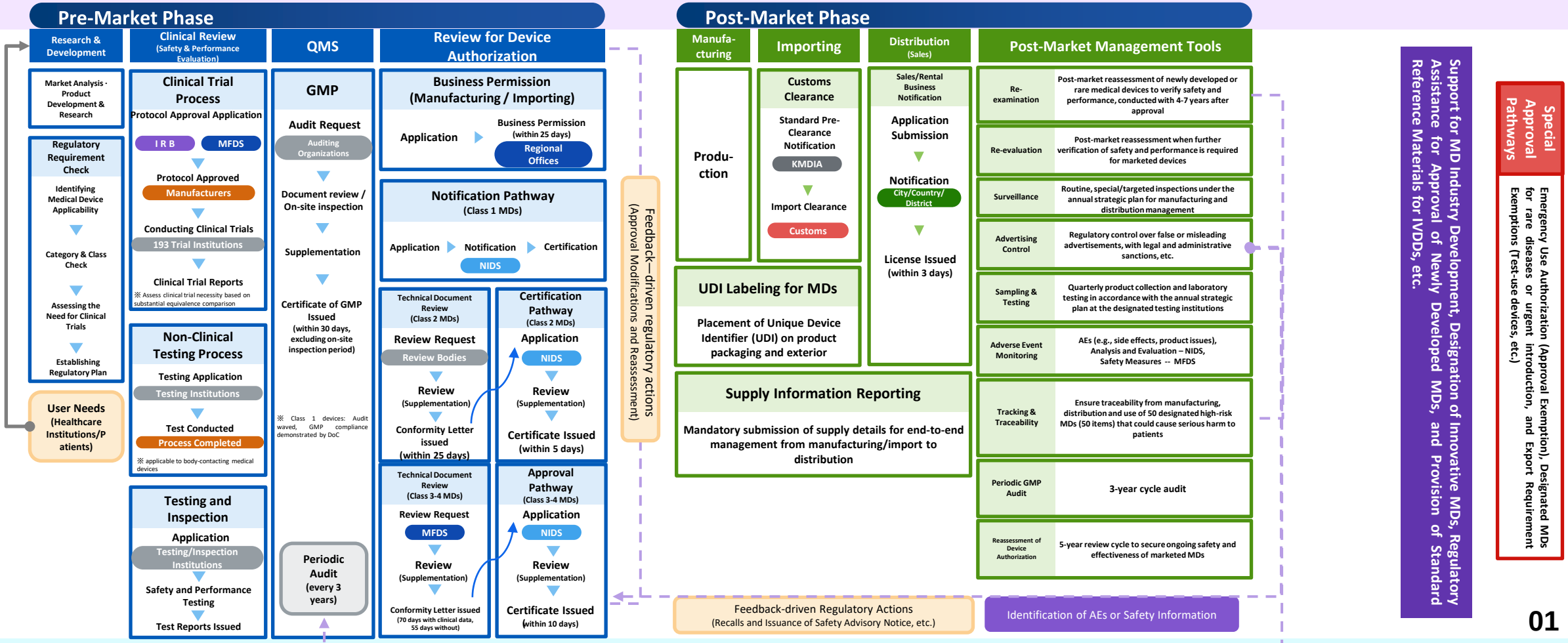
Korean Medical Devices Regulatory Framework

: Medical Devices Lifecycle Safety Management



Support for MD Industry Development, Designation of Innovative MDs, Regulatory Assistance for Approval of Newly Developed MDs, and Provision of Standard Reference Materials for IVDs, etc.

Special Approval Pathways

Emergency Use Authorization (Approval Exemption), Designated MDs for rare diseases or urgent introduction, and Export Requirement Exemptions (Test-use devices, etc.)

Legal Framework for Medical Devices in Korea

Pharmaceutical Affairs Act
(since 1953)

Medical Devices Act
(May 2004)
(applies to general medical devices and IVDDs)

* Including Software (SW)

In Vitro Diagnostic Medical Devices Act
(May 2020)

Digital Medical Products Act
(January 2025)

Act on the Nurturing of the Medical Device Industry and Support for Innovative Medical Devices
(May 2020)

Special Act on the Promotion of Development and Emergency Supply of Medical Products for Public Health Crisis
(March 2021)

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Key Updates

▣ Medical Devices Act and Regulations

❖ Strengthening Post-Market Surveillance: Long-term Follow-up of Implantable Medical Devices

- **Legal basis**: effective Jan 31, 2025
- Decision Criteria

  1) Whether adverse events during use of the device occurred at least once a year

  2) Whether the device may cause death or serious incurable adverse effects after implantation

- **Amendments to subordinate regulations**: **Processing sensitive information**

  ✓ **legal basis**: effective Aug 1, 2025

  ✓ collection & analysis of **real-world data**

Key Updates

▣ QMS Regulations

❖ Introduction of KGMP & MDSAP Combined Audits (April 7, 2025)

- **(As-Is) Separate audits** for KGMP and MDSAP
- **(To-Be) Combined audits** for export-oriented manufacturers
  - ✓ to reduce audit burden and encourage broader use of MDSAP
  - ✓ to provide incentives to MDSAP AOs in Korea

KGMP Certification Bodies & MDSAP AOs in Korea (2)

- **TÜV SÜD Korea (TSK)**
- **TÜV Rheinland Korea (TRK)**

Key Updates

▣ Use of MDSAP

❖ Status of MDSAP-Certified Manufacturers located in the Republic of Korea

Year	2021	2022	2023	2024	July 2025
Site	161	169	213	241	265

❖ Use of MDSAP in the Republic of Korea

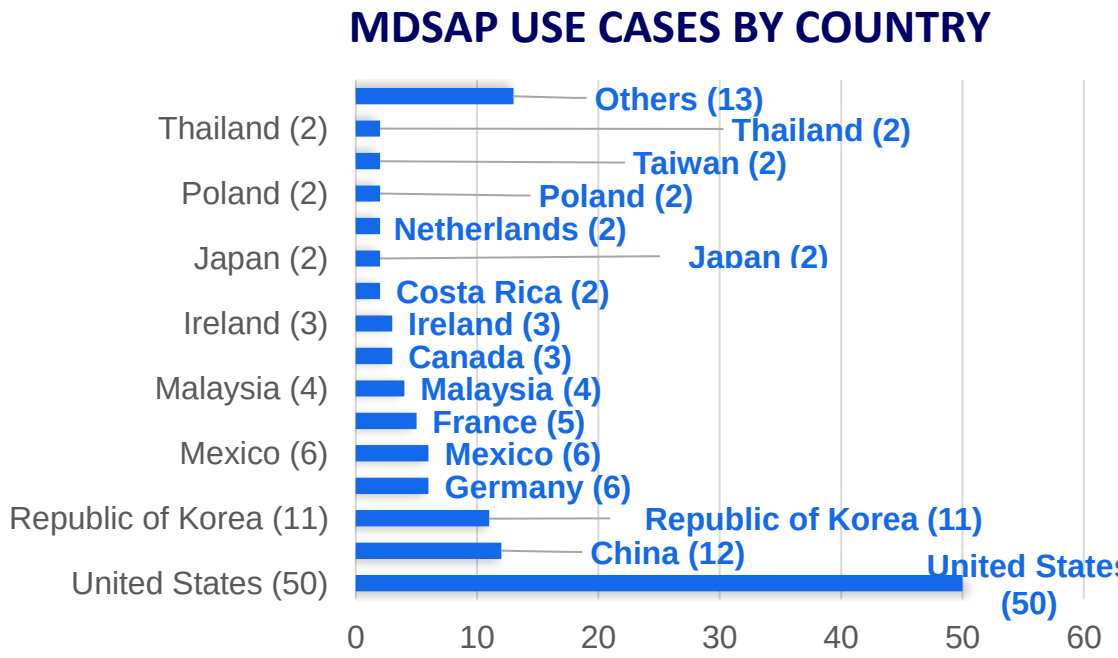
- 106 MDSAP reports (2024) and/or certificates were submitted as part of GMP inspection applications

  → Accepted as **mandatory documentation**

- **44** sites (as of August 2025) submitted valid MDSAP report

  → Qualified for **document review only**

  * 19 Sites in 2024



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(March 2021)

Key Updates

▣ Digital Medical Products Act and Regulations (effective Jan 24, 2025 / Jan 24, 2026)

Digital Medical Products Act

- Decree of the Digital Medical Products Act
- Rule of the Digital Medical Products Act

Guidelines

Subordinate Regulations (6)

① **(Classification)** Regulation on Classification and Designation of Digital Medical Products

② **(Authorization)** Regulation on Approval/Certification/Notification/Evaluation of Digital Medical Products

③ **(QMS)** Good Manufacturing Practice for Digital Medical Devices

④ **(Clinical Investigation)** Regulation on Protocol Approval & Conduct & Management of Clinical Trials for Digital Medical Devices

⑤ **(Cyber Security)** Regulation on Cybersecurity for Digital Medical Devices

⑥ **(Special Provisions)** Regulation on Certification Criteria for Excellent Governance Systems

Guidelines (New / Revised) (6)

① **(New)** Guideline on Authorization Review of Digital Medical Devices Software

② **(Revised)** Guideline on Clinical Trial Design Methods for Digital Medical Devices Applying AI Technology

③ **(Revised)** Guideline on Authorization Review of Medical Devices Software

④ **(Revised)** Guideline on Authorization Review of Digital Medical Devices Applying AI Technology

⑤ **(Revised)** Guideline on Authorization Review of Digital Medical Devices Applying Virtual Convergence Technology

⑥ **(Revised)** Guideline on Authorization Review of Digital Therapeutics

Key Updates

▣ Digital Medical Products Act and Regulations (effective Jan 24, 2025)

① (Classification) Regulation on Classification and Designation of Digital Medical Products

- Classification system reflecting the development and risk considerations of AI/SW-based products
  - ✓ Aligned with IMDRF /SaMD WG/ N12, N81

② (Authorization) Regulation on Approval/Certification/Notification/Review and Evaluation of Digital Medical Products

- Introduction of software usability evaluation and Pre-determined Change Control Plan (PCCP)
- Exemption conditions established for certain Clinical Decision Support System (CDSS)
- Enhanced disclosure requirements to improve transparency of AI medical devices (SW-Labeling with AI related information)
- Established evaluation framework for Digital Health Technologies (DHTs) combined with pharmaceuticals and devices
  - ✓ Aligned with IMDRF /AIML WG/ N67, N88
  - ✓ Aligned with IMDRF /SaMD WG/ N41

③ (QMS) Good Manufacturing Practice (GMP) for Digital Medical Devices

- Based on ISO 13485, reflecting characteristics of SW (IEC 62304) and AI-specific Control Measures

Key Updates

▣ Digital Medical Products Act and Regulations (effective Jan 24, 2025 / Jan 24, 2026)

④ **(Clinical Investigation) Regulation on Protocol Approval & Conduct & Management of Clinical Trials for Digital MDs**

- Simplified procedures for data-driven trials
- Facilitated Decentralized Clinical Trials (DCT) and use of real-world evidence

⑤ **(Cybersecurity) Regulation on Cybersecurity for Digital Medical Devices**

- Cybersecurity requirements covering AI/SW lifecycle
  - ✓ Aligned with IMDRF /CYBER WG/ N60, N70, and N73

⑥ **(Special Provisions) Regulation on Certification Criteria for Excellent Governance Systems**

- Designating firms with proven AI governance & AI cybersecurity capacity
- Allows “use first, evaluate later” for AI products difficult to assess individually
  - ✓similar to a conditional regulatory sandbox

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(March 2021)

Digital Medical Products Act Updates

AI Act
(January 2026)

Key Updates

▣ Digital Medical Products Act & AI Act in Korea

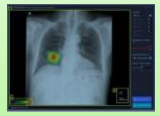
Medical Devices Act

In Vitro Diagnostic Medical Devices Act

AI MD / SaMD

"Digital Health"

Digital Medical Products Act



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Digital(AI·SW) Pharmaceuticals / Digital(AI·SW) Health Technology

AI Act

High-impact(High-Risk) AI based MD

DMP Act + AI Act

Overlapping Requirements are deemed fulfilled when compliance with the DMP Act is demonstrated

AI Act (Basic Act)

Digital Medical Products Act

Key Updates

▣ Act on the Nurturing of MD Industry & Support for Innovative MDs (established Apr 30, 2019)

➢ **To support rapid productization and promote public health**

✓ designation of "**Innovative Medical Devices**"

✓ applying to technologies significantly improving safety and performance

❖ **Special authorization pathways** applied to designated innovative devices

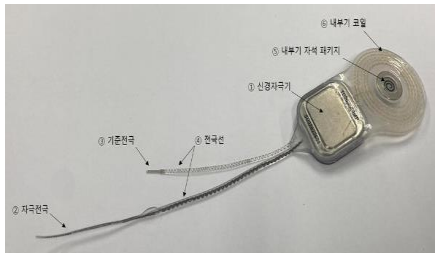
- Priority review, Stepwise review, etc.
- To support timely market entry and patient access
- 111 innovative medical devices designated (as of Aug 2025)

❖ **Ongoing activities:**

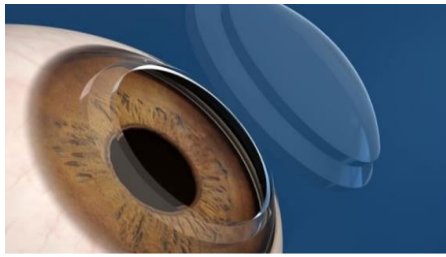
- Training specialized personnel
- Full lifecycle technical support
- Collecting & Providing R&D information domestically/internationally

Fundus Image Reading Solution

Electrosurgical System for Hypertension



Implantable Cochlear Hearing Device



Corneal Prosthesis

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Thank you/Questions

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