Overview & Amendments of Medical Device Regulations in Korea

Medical Device Evaluation Department
National Institute of Food & Drug Safety Evaluation
Ministry of Food & Drug Safety, Korea

Ministry of Food and Drug Safety

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1. Introduction of MFDS Organization

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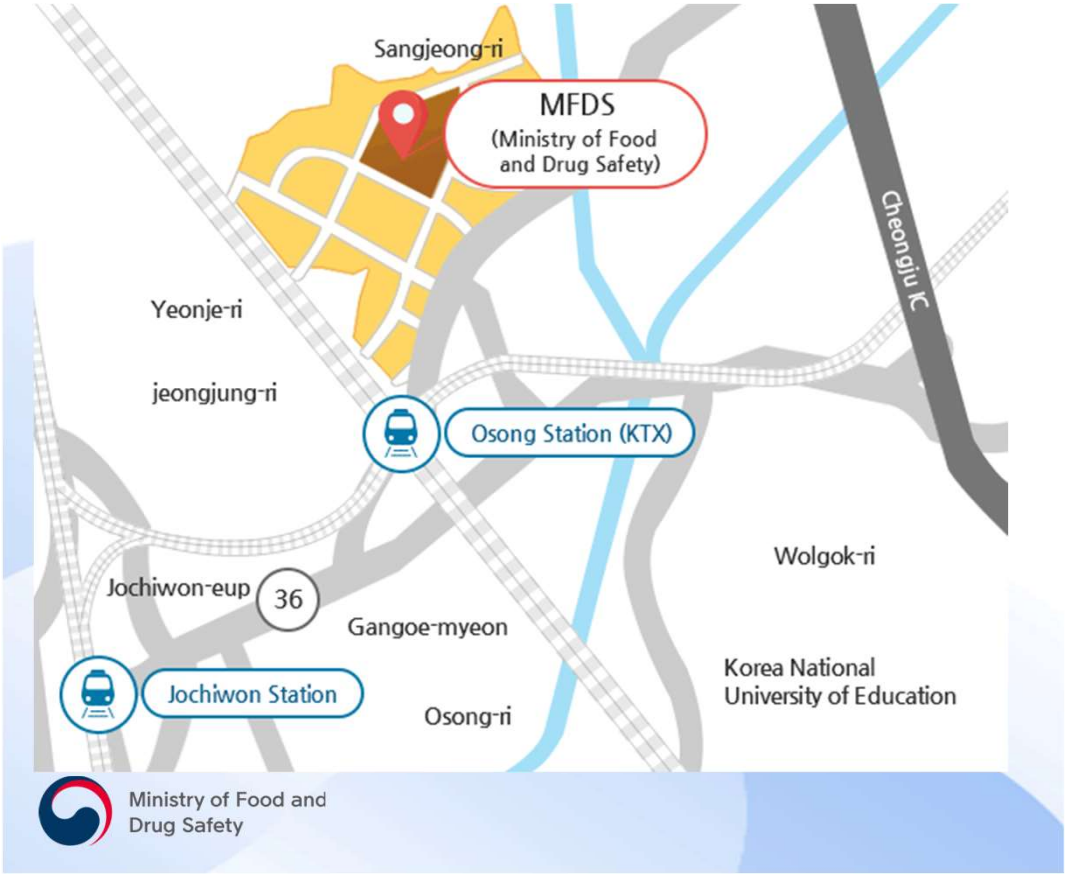
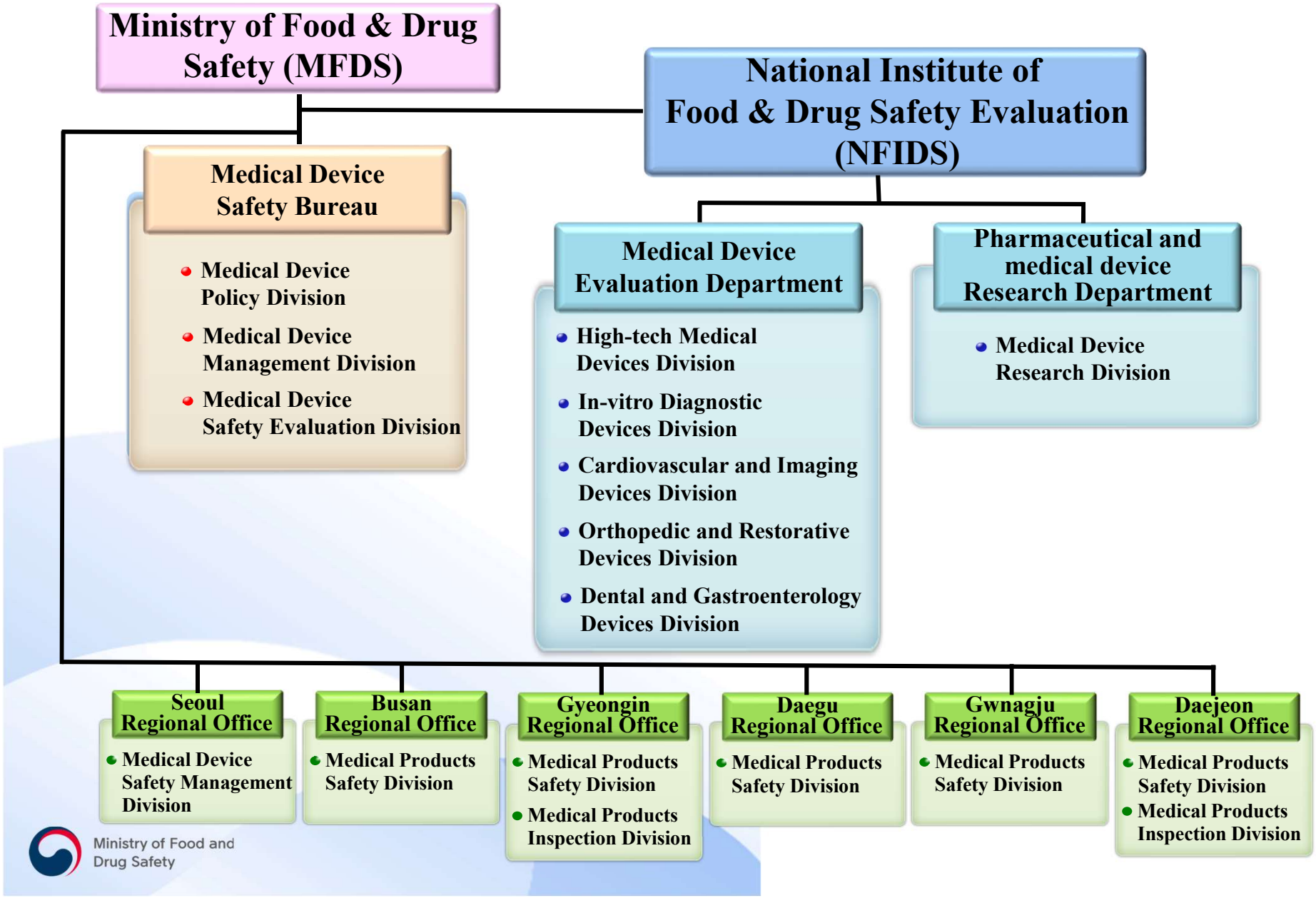
Ministry of Food and Drug Safety (MFDS)

Ministry of Food and Drug Safety(MFDS)
Headquarter is located in O-Song
http://www.mfds.go.kr



Organization Structure for Medical Devices



Other Related Organizations

Subsidiary Organization

National Institute of Medical Device Safety Information (NIDS)	· Legal entity established by Medical Device Act · Supports and provide information regarding clinical investigations, standards, safety, training, etc. (established June , 2012)

Collaborating Third-party Organization

Medical Device Testing Laboratories	· Test labs for medical devices (13 labs)
Medical Device QMS Audit Institutions	· Quality management system(QMS) audit & issue certificate with MFDS (4 Institutes)
Technical Document Review Agency	· Review of technical documents on class 2 devices (8 Institutes)
Medical Device Clinical Trial Centers	· Hospitals accredited by MFDS for medical device clinical trials (total 198 Hospitals)
Korea Medical Device Industry Association	· Industry association approved by MFDS · Advertisement review, Performance reports, Customs prediction report, Representatives of medical device industry

2. Medical Device Regulations for Approval

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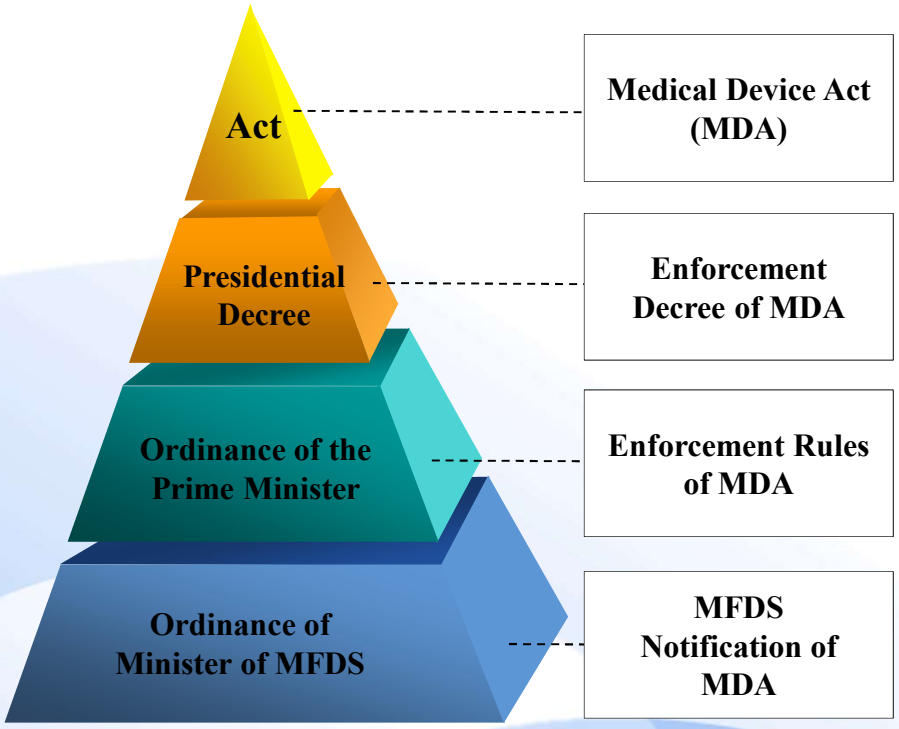
Regulations at four hierarchical orders

- **Korea regulatory systems, harmonized with the global regulations, allow MFDS to manage the medical devices more effectively.**

Medical Device Regulations



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MD Regulatory System and its Operation

- **Developed regulatory system by legislating Medical Device Act in 2003**
- **Established risk-based Medical Device Classifications in 2003**
  - I~IV Classed based on GHTF/IMDRF principles
  - Designation of 2,419 items
- **Introduced QMS for medical device in 2004**
  - harmonized with ISO 13485
- **Established Clinical trial for medical devices in 2005**
  - Harmonized with ISO 14155

Classification of Medical Devices

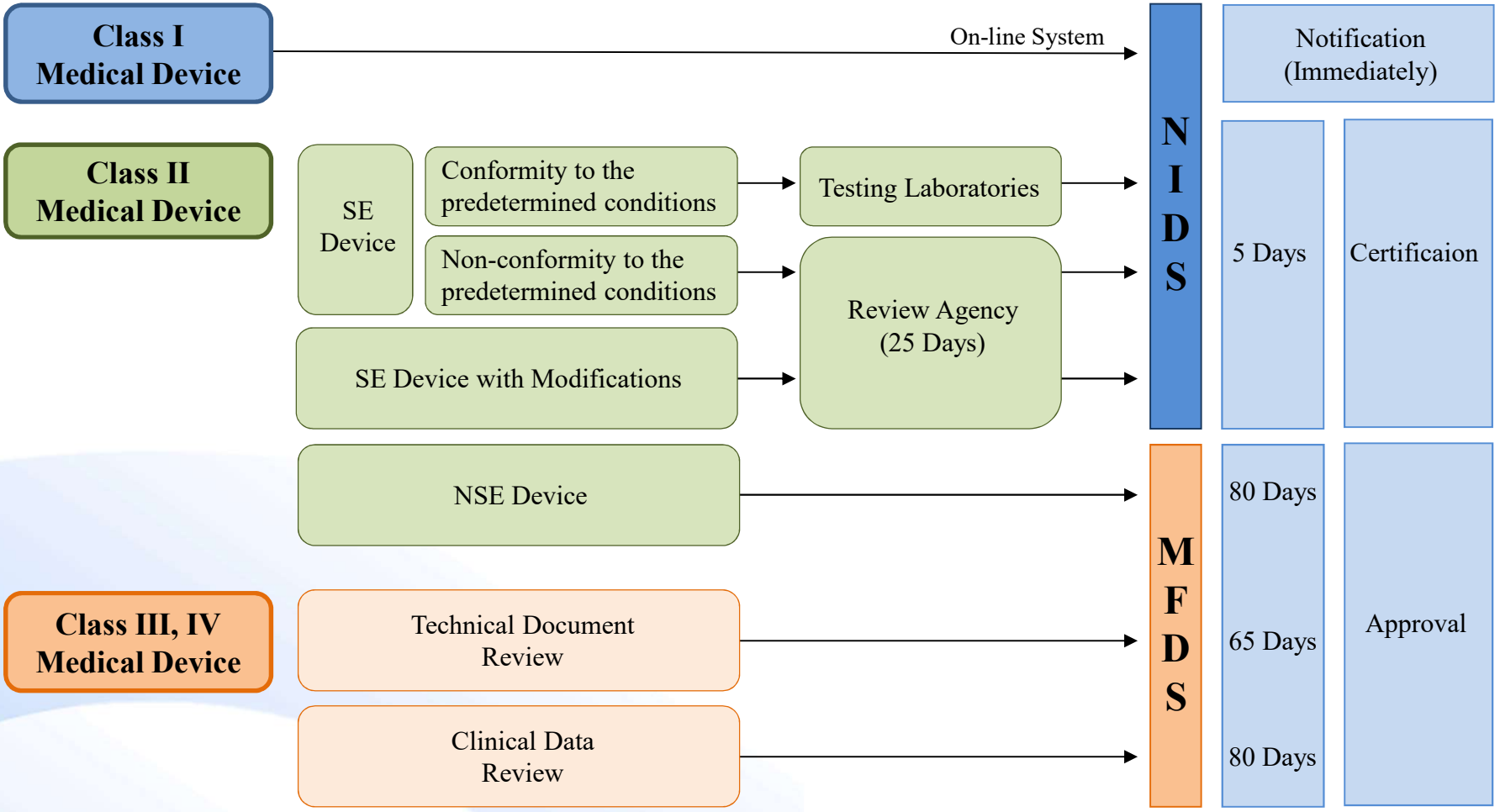
- **4 Classes based on potential risk to human health and purpose of use harmonized with GHTF/IMDRF rules**

Class	Risk level	Medical Device except IVD		IVD	
		Examples	Num.	Examples	Num.
I	Very Low	Ophthalmic microscope, Radiation shielding glove, Operation table, Stethoscope, etc.	526	IVD reagents for extracting nucleic acids, Specimen transport media, Blood type(automation) analyzer, etc.	93
II	Low	MRI, Pulse oximeter, Sterilizer, Electroencephalograph, etc.	1,083	IVD regents for urine chemistry, IVD reagents for vitamin test, IVD reagents for allergy test, etc.	74
III	Moderate	Cryosurgical(mechanical) system, Anaesthesia(gas) system, Silk suture, Condom, etc.	332	IVD strip for glucose self test, IVD reagents for infectious disease marker(immunological method), IVD reagents for infectious disease marker(molecular diagnostics), etc.	48
IV	High	Implantable cardiac defibrillator, Coronary stent, Biodegradable spine disc, Intraocular lens, etc.	253	IVD reagents for diagnosis of HIV/HBV,HCV,HTLV(immunological method), IVD reagents for ABO phD blood typing(red cell agglutination), IVD reagents for diagnosis of HVI/HBV/HCV/HTLV(molecular diagnostics), etc.	10
		Total	**2,194**	**Total**	**225**

Overview of Regulations

Overall Medical Device Regulations			Relevant Tasks	
Pre-Market	QMS Conformity		Conformity Assessment	Manufacturing Class 2 to 4 Importing Class 2 to 4
	Business License		Business License for Manufacturing and Importing Medical Devices	
	Item Approval Certification Notification	Notification (class 1)	Notifications of Item (immediately notified at the submission of application) ※ Exemption of QMS inspection	
		Certification-Approval (Class 2 to 4)	Approval for Clinical Investigation Plan (If needed)	
			Technical Documents Review	Class 2 Class 3&4
			Certification	Class 2
			Approval	Class 3&4
Distribution	Selling-Renting-Repairing		Selling & Renting Business Notification Repairing Business Notification	
Post-Market	Post-Market Safety Management		Inspection of QMS Compliance	
			Recall	
			Adverse Event Reporting	
			Management of Labeling and Advertising	
			Tracking of High Risk Medical Devices	
			Administrative Disposition and Punishment (penalty, fine)	

Predictable Approval System



※ Substantially Equivalent (SE), Non Substantially Equivalent (NSE)

※ National Institute of Medical Device Safety Information (NIDS)

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Approval for Clinical Trial Plan

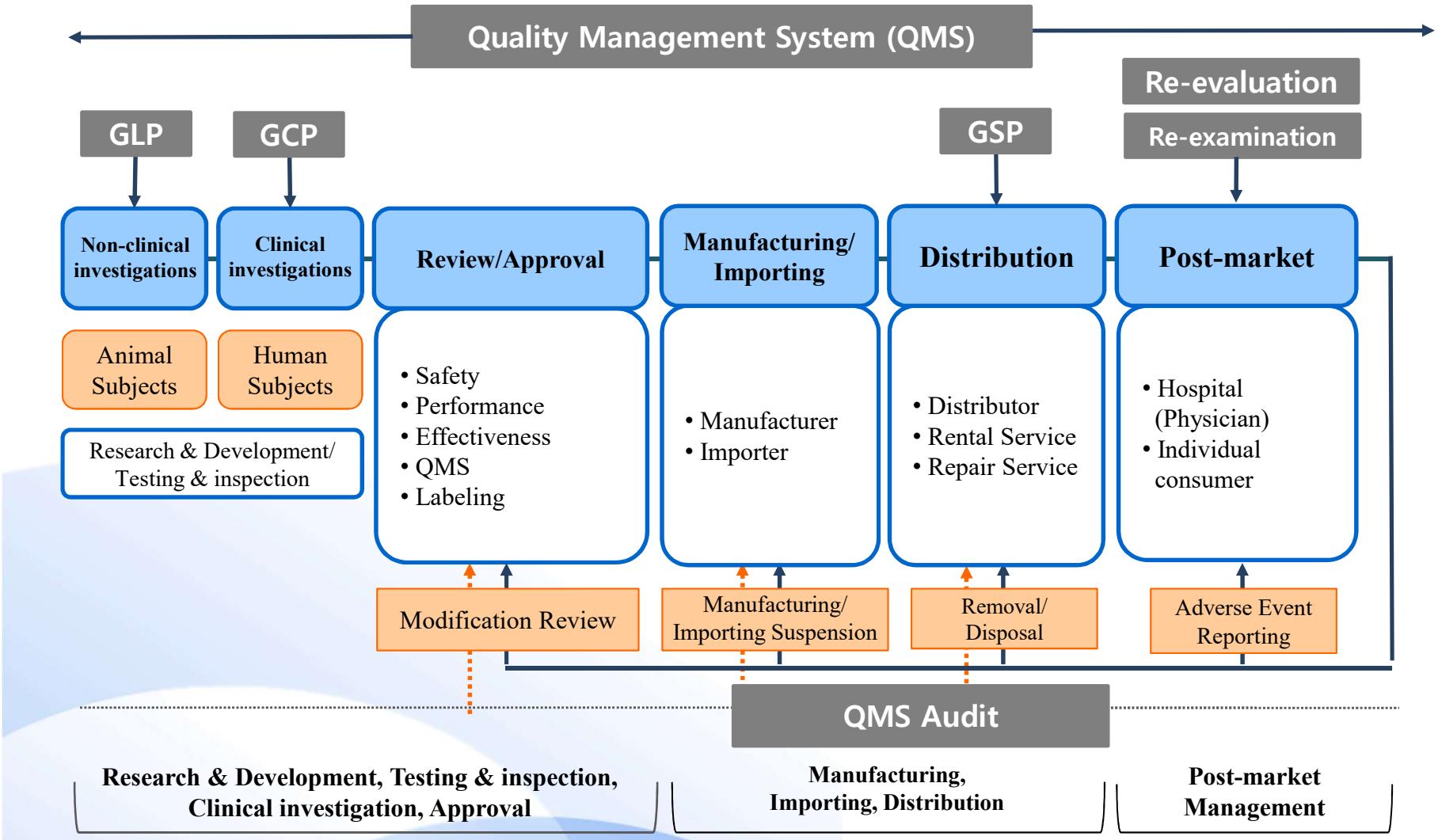
Approval process

Application	Review & Approval	Clinical trial
· Plan(protocol) · Technical document · Manufacturing site description (QMS)	· Submission review (30 days)	-

- **Who must apply**
  - A person who intends to conduct clinical studies with medical devices

- **When to apply**
  - Prior to initiation of studies

Quality Management System Regulations



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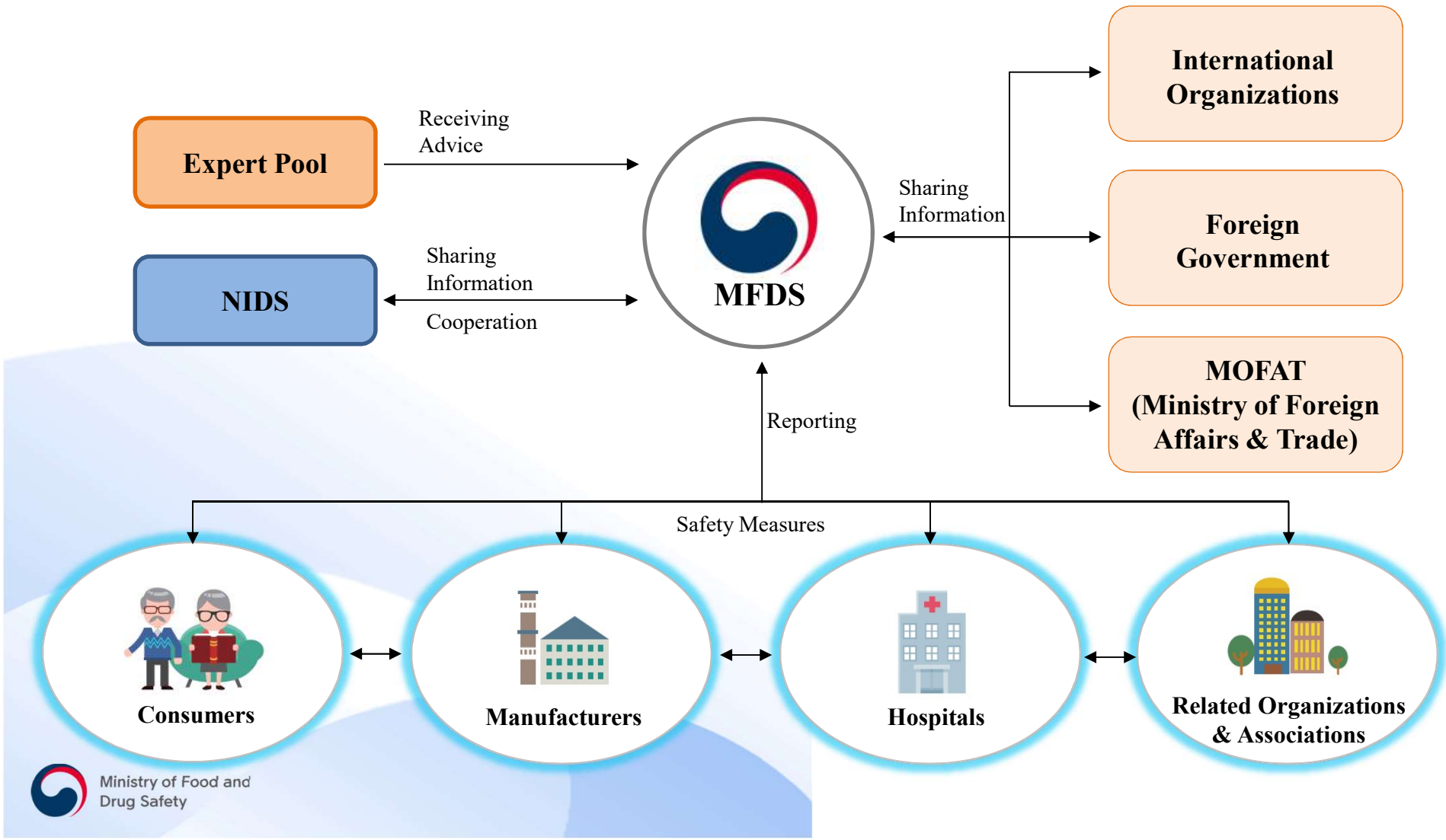
Adverse Event Reporting

● Medical Device Adverse Event Reporting and Management System



International Harmonization

● UDI Regulations on Medical Devices

Process in Law Reforms

As of Dec 2 2016,
- Placing UDI based on the Medical Device Act
- Building legal basis for mandatory reporting of distribution records

As of Dec 31 2018,
- Stating the implementation dates of placing UDI for Class 4 devices following revised Enforcement Regulations of the Act

As of Dec 31 2018,
- Developed Regulations on obtaining and placing UDI

As of June 12 2019,
- Developed Regulations on UDI database

Plans

- Expanding devices subject to obligations* of placing UDI barcodes and submitting UDI data to the DB

  * by July 1 2019 for Class 4 devices and by July 1 2020 for Class 3

Class 4 (since July 1, 2019) » Class 3 (by July 1, 2020) » Class 2 (by July 1, 2021) » Class 1 (by July 1, 2022)

- Expanding training on placing the Unique Device Identifiers for better understanding of the regulation

3. Amendments to Regulations

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Act on Innovative Medical Devices

1. Certifying and Supporting Innovative Device Manufacturers

- **(Pre-certification Program)** application procedure and the requirements, **valid in 3 years**, rules for certification withdrawals
- **(Supporting the manufacturers)** **preferential government-initiated R&D**, tax exemption, a special exception for **constructing research facilities**

2. Designation and Supporting Innovative Device Groups

- **(Innovative devices groups)** valid in 3 years for the **recognized groups** for breakthrough improvement of the therapy and treatment for rare or intractable diseases
- **(Designating Innovative devices)** **designate innovative devices** that are applicable to the recognized group
- **(Supporting approval of Innovative devices)** **exempt business license, modular review process and priority review**
- **(Post-market surveillance)** **less than 5-year period of follow up surveillance** required when needed a follow up for its clinical efficacy and adverse events observation

3. Special Exception for Innovative Software Devices

- **(Pre-certification program)** **exemption of some submission requirements** for the **pre-certified software manufacturers** by appraising the organization and personnel
- **(Modification approval)** **amendment approvals required for major changes** and **report for other changes**
- **(Clinical trial)** clinical trials for innovative software medical devices with **IRB approvals**
- **(GMP/QMS)** Good Management Practice established for software medial devices

4. Support for the Technology

- **(R&D)** R&D initiatives, necessary information sharing, establishing basis for rewarding outstanding developers
- **(Clinical investigations)** support for clinical researches and clinical trials for conducting such investigations by MFDS and MOHW(Ministry of Health and Welfare)

Act on In-Vitro Diagnostic Medical Devices

Main contents of the Act

- **(Scope)** Definitions, classifications and designation of IVD devices
- **(Pre-market approval)** Procedures to obtain manufacturing license or certification or to file a manufacturing report, etc.
- **(Clinical performance test)** Approvals of plans for clinical performance tests and criteria to designate the testing institutions, etc.
- **(QMS)** facilities and manufacturing and quality management system, etc.
- **(Labeling)** Labeling on containers and information in package insert, etc.
- **(Management)** Revocation of approvals, suspension of business and imposition of administrative sanction fines and negligence fines, etc.
- **(Experts committee)** Establishing and operating, etc. an experts committee for IVD devices

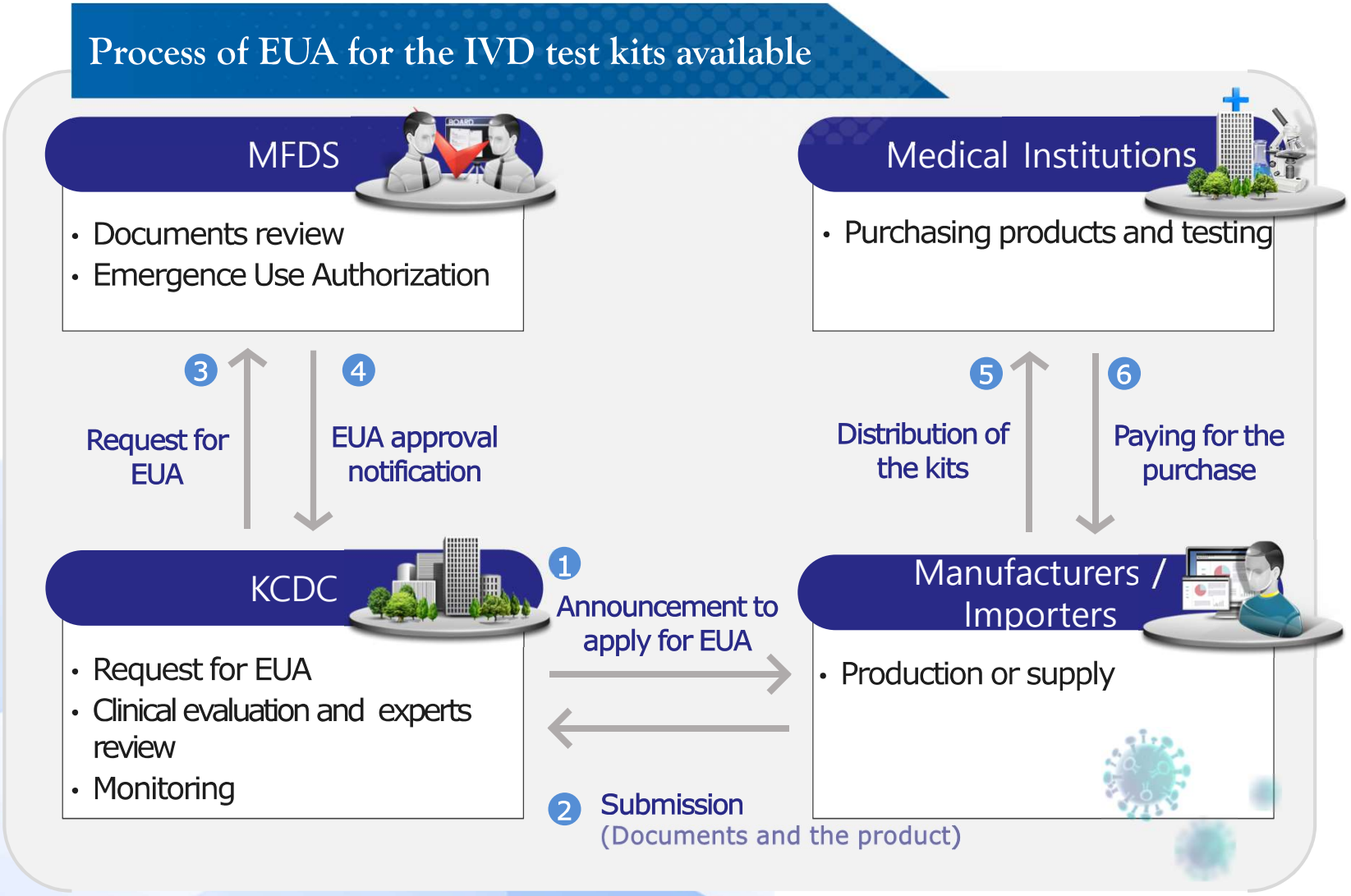
Expectations of the Act

- **(Obligations)** Obligations of Manufacturers/ importers/quality managers, etc.
- **(MFDS-recognized establishment)** Designating technical document review bodies and quality management inspection bodies for medical devices
- **(Approval)** Restrictions on manufacturing licenses, etc., conditional approvals and pre-application reviews, etc.
- **(Device handlers)** Report of repair/sales business and obligations of sellers
- **(Advertisements)** Precautions for labeling, prohibitions, etc. of labeling and advertisements and deliberation of advertisements, etc.
- **(Reports on distribution)** Report of medical device supply information, etc. and establishment of medical device information consolidation system, etc.
- **(Orders)** Inspection orders, orders for recall/destroy and public announcement, etc., orders of stop using, etc., corrective order, etc.

The Act stipulates regulations only for IVD devices separately, and the other matters are regulated under the Medical Devices Act.

EUA Regulation for COVID19

Process of EUA for the IVD test kits available



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Chairmanship of 2021 IMDRF

IMDRF MC members

- Korea serves as the chairpersonship of 2021 IMDRF
- As of December, 2017, Korea officially joined IMDRF as a 10th MC Member of International Medical Device Regulators Forum (IMDRF)
- MFDS operates the domestic IMDRF steering committee which is composed of experts group from other regulatory authorities, industry, academia or research organizations.
- MFDS is also actively participating in various work items of IMDRF including MDC, MDCE, RPS, UDI, Standards, AE, GRRP, and PMD

Thank you !

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