MINISTRY OF
FOOD AND DRUG SAFETY

Overview & Amendments of Medical Device Regulations for Approval in Korea

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Contents

I. Introduction of MFDS Organization

Ministry of Food and Drug Safety (MFDS)

March 22, 2013
KFDA was elevated to the
Ministry of Food and Drug Safety (MFDS)
Headquarter is located in O-Song
http://www.mfds.go.kr

Korea Food & Drug Administration

MINISTRY OF
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MINISTRY OF
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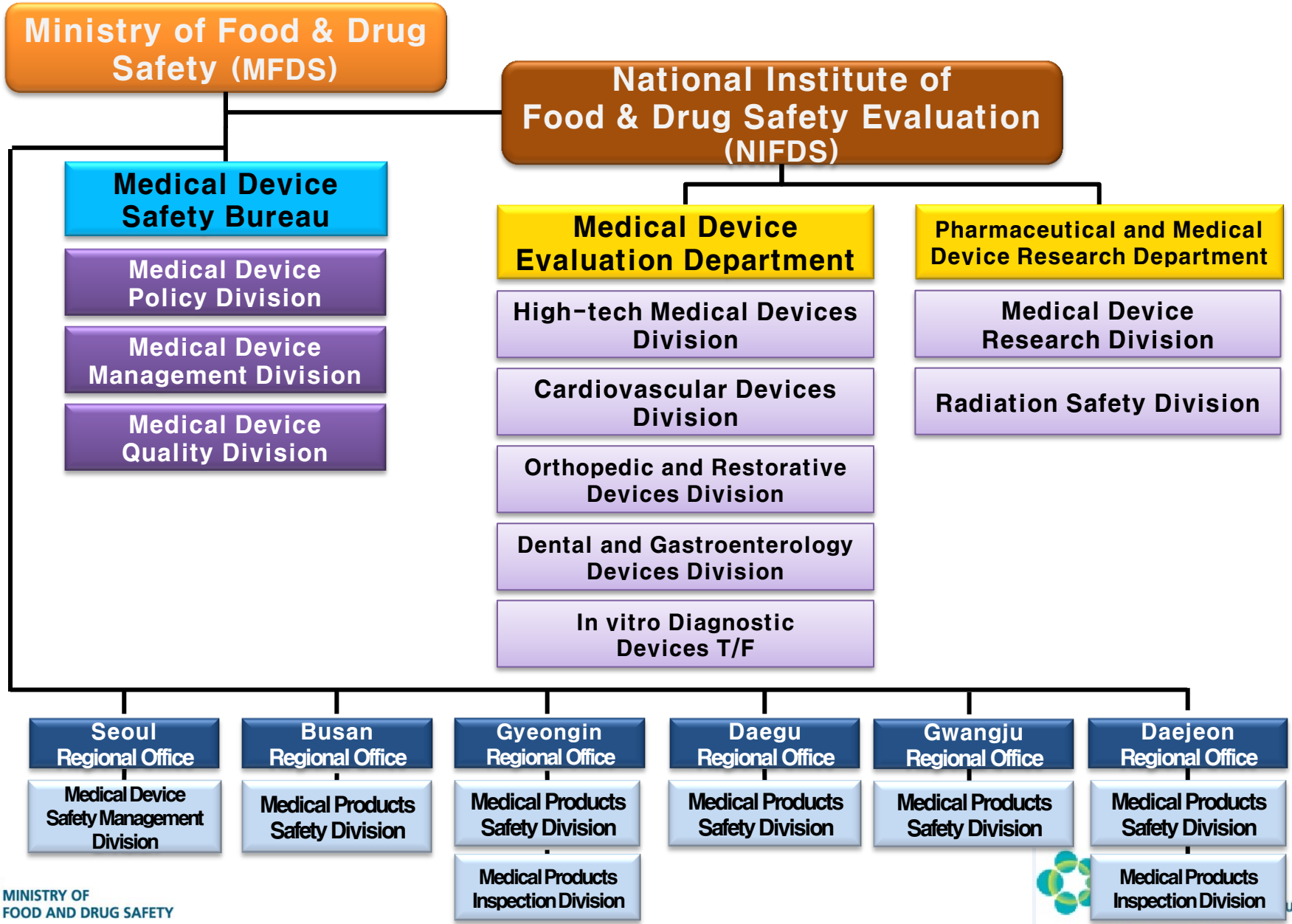
NATIONAL INSTITUTE OF
FOOD AND DRUG SAFETY EVALUATION

Organization Structure for Medical Devices



Other Related Organizations

Subsidiary Organization

Medical Device Information & Technology Assistance Center (MDITAC)	• Legal entity established by MFDS • Supports and provides information regarding international & domestic standards, training QMS managers, etc

Collaborating Third-party Organization

Medical Device Testing Laboratories	• Test labs for medical devices (14 labs)
Medical Device QMS Audit Institutes	• Audit Quality Management System (QMS) & issue certificates (4 Institutes)
Technical Document Review Agencies	• Review Technical Documents on Class II devices (7 Agencies)
Medical device Clinical Trial Centers	• Hospitals accredited by MFDS for clinical trials on medical devices (137 centers)

II. Medical Device Regulations for Approval

Classification of Medical Devices

▪ Risk-based Classification of Medical Devices

- Four classes : based on potential risk to human health and intended use
- Harmonized with GHTF/IMDRF rules
- Designated 2,206 items (2014. 4. 8.)

Class	Risk level	Device Examples	Number of Devices
I	Very low Risk	Tongue depressor, Splint	601
II	Low Risk	Medication syringe, Hearing aid	1,009
III	Moderate Risk	Laser surgical unit, Knee prosthesis	340
IV	High Risk	Vascular stent, Implantable cardiac pacemaker	254
I ~ IV		IVD reagents for Other tests	2
Total			2,206

Overview of Premarket Regulations

		Regulatory System	
		Relevant Tasks	Regulatory Body
Business License		• Manufacturing - Importing License	MFDS Regional Offices
Device Notification or Approval	**Notification** (Class Ⅰ)	• Notification & Listing of **Class Ⅰ** in the e-system of MFDS	MFDS Regional Offices
	Approval (Class **Ⅱ, Ⅲ, Ⅳ**)	• Approval of Clinical Trial Plan (if needed)	MFDS (NIFDS)
		• Review of Technical Document — **Class Ⅱ**	Third party
		• Review of Technical Document — **Class Ⅲ · Ⅳ**	MFDS (NIFDS)
		• Approval — **Class Ⅱ**	MFDS Regional Offices
		• Approval — **Class Ⅲ · Ⅳ**	MFDS (NIFDS)
QMS Inspection		• Inspection (Initial inspection of imported device) — **Class Ⅱ**	Third party
		• Inspection (Initial inspection of imported device) — **Class Ⅲ · Ⅳ**	MFDS/ Third party

International Harmonization of STED

STED is required for Class IV (except IVDD)

- effective as of Jan. 1, 2014
- optional for other Classes

Technical Document

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Annexed Documents on
- Comparison
- Intended use
- Principles of operation
- Test report
- Clinical trial report, etc.

Technical Document

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Summary Technical Documentation
- **Essential principles**
- **Risk management file**
- **Design validation file, etc.**

- Comparison
- Intended use
- Principles of operation
- Test report
- Clinical trial report, etc.

Approval for Clinical Trial Plan

Approval process

Application

- Plan (protocol)
- Technical Document
- Manufacturing site description (GMP)

Review & Approval

Submission Review (30 days)

Clinical trial

- 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

- **Scope**
  - Apply to every manufacturer of medical devices
- **Inspection Team**
  - Inspector of MFDS and Quality Management Review Institutes
- **Harmonized with ISO 13485**

- Initial Inspection for the 1st manufactured Medical Device
- Additional Inspection to add new product group (26 product groups)
- Modified Inspection for changed manufacturing site
- Periodic Inspection for re-certification within 3-year period

III. Amendments to Regulations

Regulatory System for IVD reagents

Background

- Integrating management system for IVD reagents by classifying as medical devices

Amendment

PAST	Amended
- IVDD : medical devices or pharmaceutical products	All IVDD : to be regulated as medical devices (Nov. 10, 2014)

Regulation Updates on Raw Materials

Background

- Recent discussion on controversial chemicals

Amendment

- Limitation on approval & notification
  - Mercury (from the effective date of Minamata Convention)
  - Asbestos (Jan. 1, 2015)
  - Phthalate (DEHP, DBP, BBP)-containing I.V. administration set (July. 1, 2015)

Implementation of International Standards

- Integrating 「Medical electrical equipment - Part1: General requirements for basic safety and essential performance (IEC 60601-1 ed. 3.0)」 & other attendant standards into the approval process (May 30, 2014)
  - Collateral Standards (IEC 60601-1-3, 6, 8, 10)
  - Electrical equipment for measurement, control, and laboratory use (IEC 61010-1)
  - Active implantable medical devices (ISO 14708-1)
- Implementation dates vary depending on the medical device class.

THANK YOU !