Korea regulatory framework for Medical Device

2015. 11

MINISTRY OF
FOOD AND DRUG SAFETY

MFDS organization and Responsibilites

Vision of MFDS

Vision

Safe Food and Drugs, **Healthy Nation**, **Well-being of Society**

Purpose

1. **Ensuring safety of the people** to improve quality of life
2. **Consumer-based** safety management from Farm to Table
3. Realization of safer and **healthier lives** of the people
4. Beyond safety, **providing assurance** to the people

Core Strategies

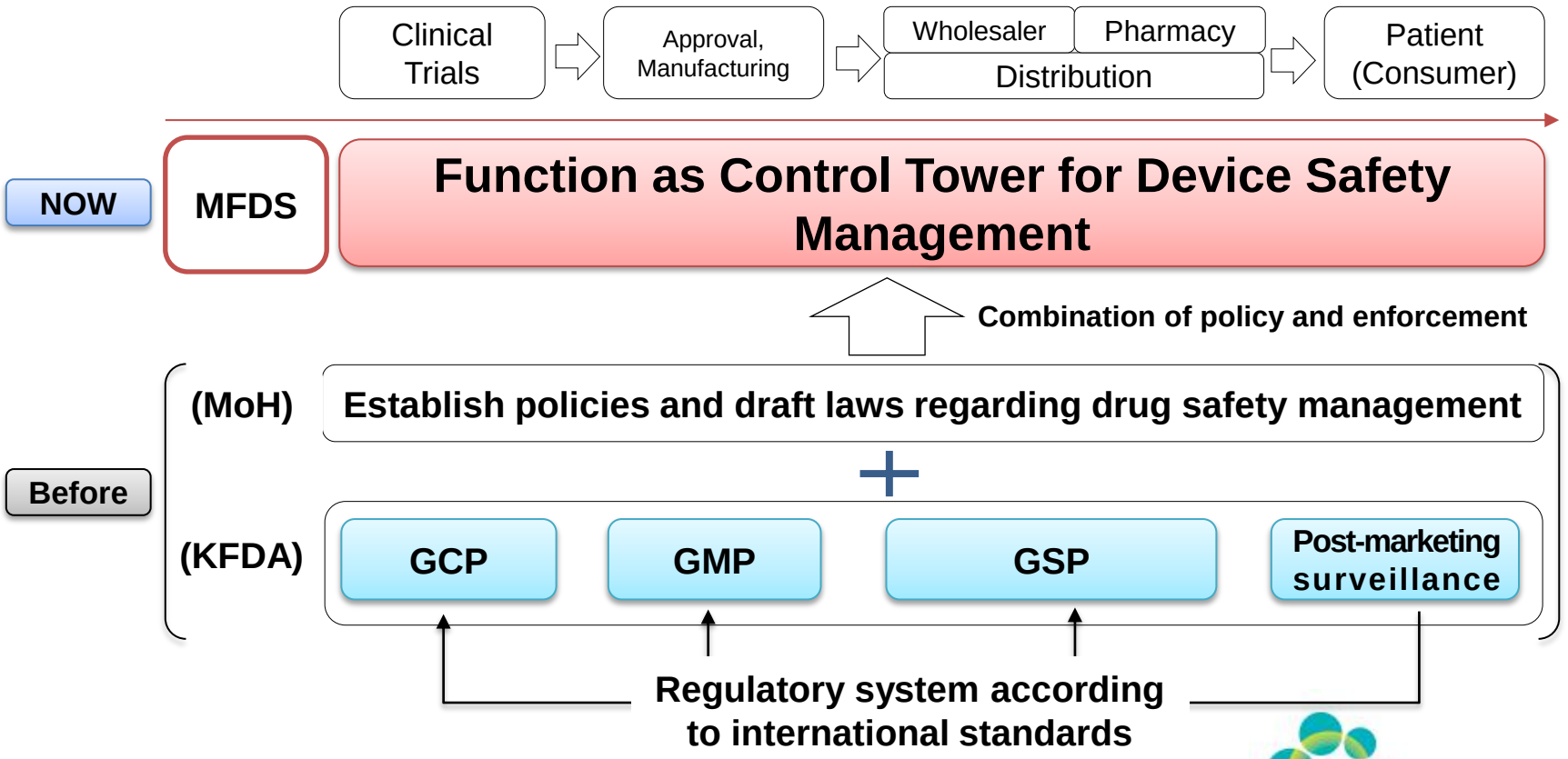
- Eradication of adultered foods
- Coherent safety management from Farm to Table
- Promotion of comsumer participation and increase in consumer awareness for safety
- Creation of job opportunities
- Rapid release of medical products

Virtuous circle of safety and industrial development

Close collaboration with healthcare policy

Ministry of Food and Drug Safety(MFDS)[former KFDA]

- **To function as the "Control Tower" of medical device safety management by combining enforcement duties regarding clinical trials , drug approval · manufacturing, distribution, post-marketing surveillance etc. with related policy matters such as legislation and system improvement**



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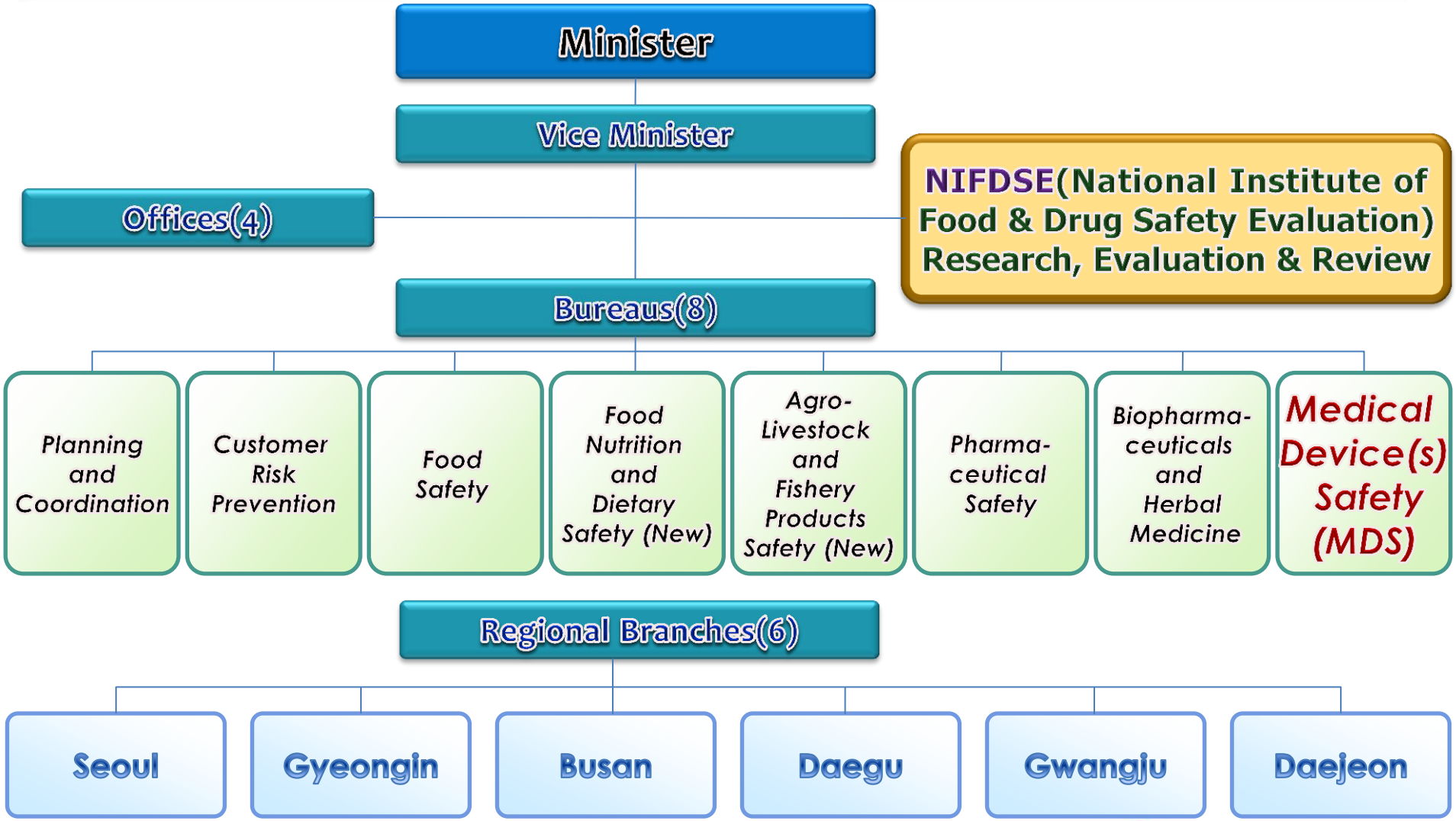
Organization of MFDS



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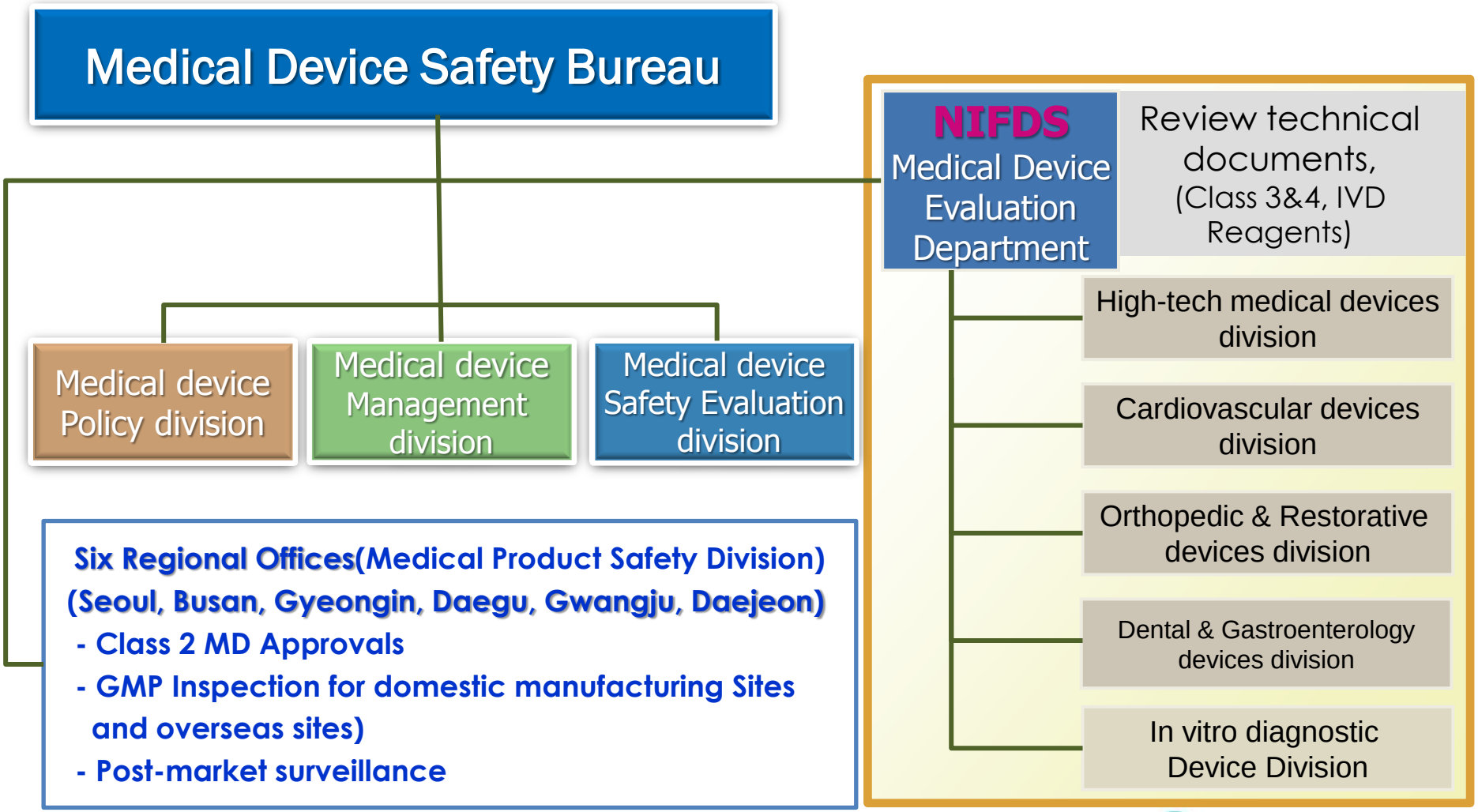
Organization of MDS Bureau



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Other Related Organizations

Subsidiary Organization

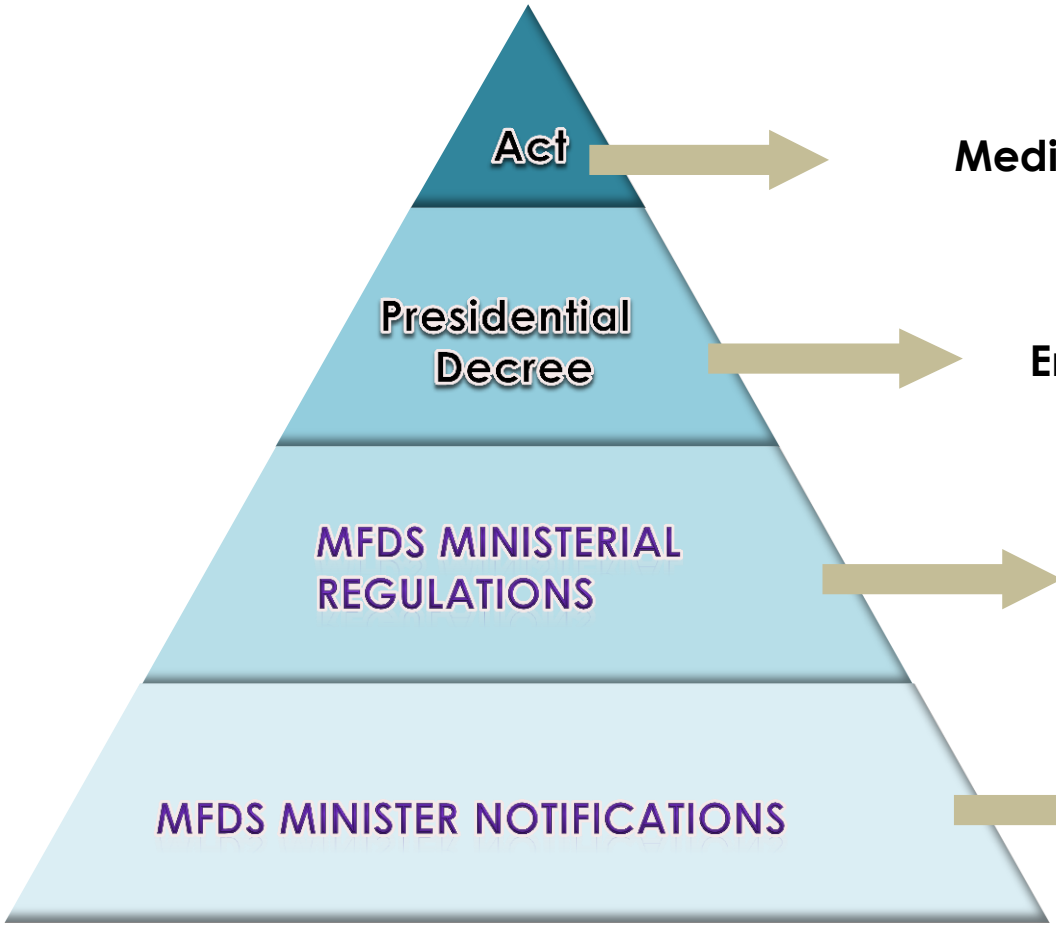
Medical Device Information & Technology Assistance Center (MDITAC)	Legal entity established by Medical Device Act Supports and provide information regarding clinical investigations, standards, safety, training, etc. (established June , 2012)

Collaborating Third-party Organization

Medical device Testing Laboratories	Test labs for medical devices (14 labs)
Medical device QMS Audit Institutions	Quality Management System(GMP) audit & issue certificate with MFDS (4 Institutes)
Technical Document Review Agency	Review of Technical Documents on Class 2 devices (7 Institutes)
Medical device Clinical Trial Centers	Hospitals accredited by MFDS for Medical device clinical trials (total 142 Hospitals)
Korea Medical Device Industry Association	Industry association approved by MFDS Advertisement review, Performance reports, Customs prediction report, Representatives of Medical Device Industry

Medical Device Regulation Overview

Structure of MFDS Medical Device Regulations



Medical Device Act (MDA)

Enforcement Regulations of MDA

Enforcement Decree of MDA

MFDS Notifications of MDA
- Notifications for detailed requirements supporting Act and Ministerial Regulations

MFDS Guidelines and example documents on specific requirements

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Definition of Medical Devices

- **any instrument, machine, contrivance, material or similar article that is used on human beings or animals either alone or in combination with other devices and that falls under any of the following Items provided below.**

  - Articles used for the purpose of diagnosis, cure, alleviation, treatment, or prevention of illness;

  - Articles used for the purpose of diagnosis, cure or alleviation of or compensation for an injury or disability;

  - Articles used for the purpose of test, replacement, or modification of the structure or functions [of the body]; or

  - Articles used for the purpose of control of conception

Classification of Medical Devices

- Risk Based regulation : Classification of medical devices

  4 classes based on potential risk to human health and purpose of use Harmonized with GHTF/IMDRF rules

  2,218 items are designated by current Ministerial Notification

Class	Risk Levels & Purpose of Use	Device Examples	Numbers of classified devices
I	Little Risk	Forceps for medical use, Mechanical Stethoscope	594
II	Low Risk	Syringe, Infusion pump	1,023
III	Moderate Risk	Silk Suture, Contact Lens	343
IV	High Risk	Coronary stent,	256
I~IV			2
Total			2,218

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Overview of Medical Device Regulations

- **Based on life span of a medical device**

Conception Development	Manufacture	Package Labeling	Adverting	Sale	Use	Disposal
Manufacturer/ Importer			Vendor		User	
			Manufacturer/ Importer			

Pre-Market

- **Device Business Licenses**
  - Manufacturing, Importing, Repairing, Distributing, Rental Business)
- **Product Notification/Approval**
  - Class I (Notification)
  - Class II(Certification, Approval)
  - Class III, IV(Approval)
- **Clinical Investigation Plan Approval**
  - Good Clinical Practices
- **GMP requirements**(ISO13485)

Post-Market

- QMS Requirements
- Labeling requirements
- Review of advertisement
- Tracking and control
- Adverse event & safety alert reporting
- Re-evaluation
- Re-examination
- Recall & removal
- Inspections and audits

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Major Changes in Medical Device Law

On the Contract for Class I and Class II MD

Background

- Need fast certification for Low risk and Low Hazard Medical Device
- Government concentrate on High Risk and Hazard Medical Device

  to enforce Safety and Review ability

Changes

- Commissioned to MDITAC* for Class I Notification and Class II Certification Medical Device (Only for noticed MD by MFDS)
  (* Medical Device Information and Technology Assistance Center)

Adoption

- 6 month later after proclaim(2015. 7. 29.)

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Adoption of GMP before MD approval

Background

- Current : MD approval -> GMP certification -> Sell
- Problem : Selling product without GMP certification

Changes

- Adoption of GMP : Before selling MD → Before Approval of MD

※ During Approval process, facility, manufacturing and QMS data should be provided

Adoption

- 1 year later after proclaim (16.1.29.)

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Change on Approval to Manufacturer certificate

Background

- Current : Certification on every factory even the same company
- Burden to company if they expand their factory

※ Number of Manufacturer with multiple factory : 52 site (as of 14.11.4)

Changes

- Approval by every factory -> Approval by company(listing)

Adoption

- 6 month later after proclaim(2015. 7. 29.)

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Directions for Changes

Directions for Regulation Changes

Reinforce Risk-based scientific regulation

- **Streamline regulatory process for lower-class devices or devices of established safety**
- **Focus on high risk devices**

Strengthen post market regulation

- **Improve compliance to adverse event reporting and recalls**
- **Expand of Re-examination, Re-evaluation**

Enhancing Expertise of Reviewers

- **Train and education of reviewers**
- **Outside expert participatory review**

Accelerate international harmonization

- **Expand acceptance of international standards**
- **Adopt international practices in device regulations or review practices**

Thank you for your attention!

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