Overview & Amendments of Medical Device Regulations for Approval in Korea

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I. Introduction of MFDS Organization
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
## 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.)

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

**Total**: 2,206
### Overview of Premarket Regulations

#### Regulatory System

<table>
<thead>
<tr>
<th>Relevant Tasks</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business License</td>
<td></td>
</tr>
<tr>
<td>• Manufacturing - Importing License</td>
<td>MFDS Regional Offices</td>
</tr>
<tr>
<td>Notification (Class I)</td>
<td></td>
</tr>
<tr>
<td>• Notification &amp; Listing of <strong>Class I</strong> in the e-system of MFDS</td>
<td>MFDS Regional Offices</td>
</tr>
<tr>
<td>Approval (Class II, III, IV)</td>
<td></td>
</tr>
<tr>
<td>• Approval of Clinical Trial Plan (if needed)</td>
<td>MFDS (NIFDS)</td>
</tr>
<tr>
<td>• Review of Technical Document</td>
<td><strong>Class II</strong></td>
</tr>
<tr>
<td></td>
<td>Third party</td>
</tr>
<tr>
<td></td>
<td><strong>Class III · IV</strong></td>
</tr>
<tr>
<td></td>
<td>MFDS (NIFDS)</td>
</tr>
<tr>
<td>• Approval</td>
<td><strong>Class II</strong></td>
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<tr>
<td></td>
<td>MFDS Regional Offices</td>
</tr>
<tr>
<td></td>
<td><strong>Class III · IV</strong></td>
</tr>
<tr>
<td></td>
<td>MFDS (NIFDS)</td>
</tr>
<tr>
<td>QMS Inspection (Initial inspection of imported device)</td>
<td></td>
</tr>
<tr>
<td>• Inspection</td>
<td><strong>Class II</strong></td>
</tr>
<tr>
<td></td>
<td>Third party</td>
</tr>
<tr>
<td></td>
<td><strong>Class III · IV</strong></td>
</tr>
<tr>
<td></td>
<td>MFDS/ Third party</td>
</tr>
</tbody>
</table>

**Device Notification or Approval**

- **Notification (Class I)**
- **Approval (Class II, III, IV)**
- **QMS Inspection**
STED is required for Class IV (except IVDD)
- effective as of Jan. 1, 2014
- optional for other Classes

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

Technical Document
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

<table>
<thead>
<tr>
<th>PAST</th>
<th>Amended</th>
</tr>
</thead>
<tbody>
<tr>
<td>- IVDD : medical devices or</td>
<td>All IVDD : to be regulated as medical devices</td>
</tr>
<tr>
<td>pharmaceutical products</td>
<td>(Nov. 10, 2014)</td>
</tr>
</tbody>
</table>
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)
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!