Korea Medical Device Regulatory System

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Ministry of Food and Drug Safety
Your Vision, Our Future
Korean Medical Device

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- Emphasis on Quality: QMS
- Systematic network for patient safety and management
  - Adverse Event Reporting
  - Monitoring & Tracking System
  - Recalls
- Sustainable Effort & Commitment for International Cooperation
With a 5% average annual growth rate, the Korean medical device market was valued at approximately US$ 5.8 billion in 2016, making it the 9th largest market in the world.
### Current status of MedTech Industry in Korea

#### Major Exports of Korean Medical Devices in 2016

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Top 10 Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ultrasound Imaging System</td>
</tr>
<tr>
<td>2</td>
<td>Dental Implant</td>
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<tr>
<td>3</td>
<td>Soft Contact Lens</td>
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<tr>
<td>4</td>
<td>Biomaterial Graft/Prosthesis</td>
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<tr>
<td>5</td>
<td>Medical Image Processing System</td>
</tr>
<tr>
<td>6</td>
<td>IVD Reagents for Clinical</td>
</tr>
<tr>
<td>7</td>
<td>Probe for Medical Use</td>
</tr>
<tr>
<td>8</td>
<td>IVD Reagents for Infectious Disease</td>
</tr>
<tr>
<td>9</td>
<td>Laser Surgical Unit</td>
</tr>
<tr>
<td>10</td>
<td>X-ray System</td>
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</table>
Based on ISO 14155 and due to expedited processing for clinical trials, diverse clinical researches are conducted in Korea.
Korea comprehensively regulates medical devices with a well-organized legal system and clearly defined regulations.

**Medical Device Regulations**

- Act
- Presidential Decree
- Ordinance of the Prime Minister
- Ordinance of Minister of MFDS
- Medical Device Act (MDA)
- Enforcement Decree of MDA
- Enforcement Rules of MDA
- MFDS Notification of MDA

**Overall 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 Classes based on GHTF/IMDRF principles
  - Designation of 2,225 items
- Introduced QMS for medical device in 2004
  - Harmonized with ISO 13485
- Established Clinical trial for medical devices in 2005
  - Harmonized with ISO 14155
MFDS has an efficient and well-balanced system to manage the total lifecycle of medical devices.

<table>
<thead>
<tr>
<th>Overall Medical Device Regulations</th>
<th>Tasks</th>
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<tbody>
<tr>
<td><strong>Pre-Market</strong></td>
<td></td>
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<tr>
<td>QMS Conformity</td>
<td>Conformity Assessment</td>
</tr>
<tr>
<td>Business License</td>
<td>Manufacturing (Class II to IV) Importing (Class II to IV)</td>
</tr>
<tr>
<td>Clinical Trial</td>
<td>Approval of business license for manufacturing and importing</td>
</tr>
<tr>
<td>Marketing Authorization</td>
<td>Approval for Clinical Trial Plan (If required)</td>
</tr>
<tr>
<td>Notification (Class I)</td>
<td>Notifications of Item (Immediately notified at the submission of application)</td>
</tr>
<tr>
<td>Certification Approval (Class II to IV)</td>
<td>Exemption of QMS inspection</td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td></td>
</tr>
<tr>
<td>Selling-Renting-Repairing</td>
<td>Listing for Selling, Renting &amp; Repairing Businesses</td>
</tr>
<tr>
<td><strong>Post-Market</strong></td>
<td></td>
</tr>
<tr>
<td>Post-Market Safety Management</td>
<td>Re-Certification of QMS conformity</td>
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<tr>
<td></td>
<td>Management of Labeling and Advertising</td>
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<td></td>
<td>Adverse Event Reporting</td>
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<tr>
<td></td>
<td>Recall</td>
</tr>
<tr>
<td></td>
<td>Tracking of High Risk Medical Devices</td>
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<tr>
<td></td>
<td>Enforcement Actions (Fines/Restitution, etc)</td>
</tr>
</tbody>
</table>
Strategic Operation based on Expertise & Efficacy

With a systematic organizational structure, MFDS is strategically operated for an effective medical device management.

<table>
<thead>
<tr>
<th>Medical Device Safety Bureau</th>
<th>Medical Device Evaluation &amp; Research Department</th>
<th>6 Regional Branches</th>
</tr>
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<tbody>
<tr>
<td><strong>Divisions</strong></td>
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</tr>
<tr>
<td>- Medical Device Policy Division</td>
<td>- High-tech Medical Devices Division</td>
<td>- Seoul Regional Office of MFDS</td>
</tr>
<tr>
<td>- Medical Device Management Division</td>
<td>- Cardiovascular Devices Division</td>
<td>- Busan Regional Office of MFDS</td>
</tr>
<tr>
<td>- Medical Device Safety Evaluation Division</td>
<td>- Orthopedic &amp; Restorative Devices Division</td>
<td>- Gyeongin Regional Office of MFDS</td>
</tr>
<tr>
<td><strong>Main Tasks</strong></td>
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</tr>
<tr>
<td>- Establishing medical device-related policies</td>
<td>- Medical device approval</td>
<td>- QMS audit</td>
</tr>
<tr>
<td>- Establishing QMS Standards of Manufacturing site</td>
<td>- Supporting innovative medical device approval</td>
<td>- Issue of business license</td>
</tr>
<tr>
<td>- Processing and tracing management information on safety including adverse events</td>
<td>- Training technical document review agencies</td>
<td>- Post-market surveillance</td>
</tr>
</tbody>
</table>
MFDS works cooperatively with other third party organizations to increase efficiency and expertise.

**Affiliated Organization**

- Medical Device Information & Technology Assistance Center (MDITAC)
  - A legal entity established in 2012
  - Supports and provides information regarding clinical trials, standards, safety, training, etc.
  - Issues Notification of Class I devices & Certification of Class II devices

**Related Organizations designated by MFDS**

- Medical Device Testing Laboratories
  - Test medical devices (16 Labs)

- Medical Device QMS Audit Institutions
  - Conduct QMS audit and issuing certificates with MFDS (4 Institutions)

- Technical Document Review Agencies
  - Review technical documents on class II devices (7 Agencies)

- Medical Device Clinical Trial Centers
  - Hospitals designated by MFDS (153 Centers)
  - Conduct clinical trials for medical devices

(Total: about 1,552 experts)
Based on risk classification of medical devices, each classes of devices have different pathways for a marketing authorization.
For an easy access and better compliance of regulations, MFDS provides consultations and various guidelines for applicants. MFDS also gains additional scientific understanding from a pool of external experts as needed, and invests on various R&D projects to increase expertise in review and approval processes.
Korean QMS is harmonized with the international standard, ISO 13485.

QMS Audit Procedures for Medical Device

- Manufacturer/Importer (including Overseas Manufacturing Site)
  - Application of QMS audit
- QMS Audit Institutions (3rd Party Organizations)
  - Receipt of application
  - Pre-review
  - Confirmation of third-party auditor and audit date
  - Notice for QMS audit schedule
- Medical Device Quality Evaluation Institutions (3rd party organizations)
  - Notifying to MFDS auditor about audit schedule
  - MFDS auditor

Audit

- Conformity
  - Major-Nonconformity
  - Minor-Nonconformity
- Correction
- Correction request for identified deficiency
- Notice to applicant for prohibition of distribution

Issuing QMS certification
All of collected information regarding adverse event reports are being reviewed and analyzed to be used for field safety corrective actions.
MFDS has designated 52 high risk medical devices, which are subject to tracking for patient safety.
Procedure for Government-initiated Recall

**MFDS**
- Product that is in violation of laws
  - Yes
  - Assessment of the product
  - Order of recall
  - Public warning about the product
  - Review of submission
  - Approval of a proposed recall strategy
  - Effectiveness checks
  - Approval of termination of a recall

**Manufacturers/Importers**
- Discontinuation of market distributions
  - Submission of a recall strategy
  - Public notification about the recall
  - Recall of product as planned
  - Submission of final report
  - Termination of a recall

**Distributors/User facility**
- Notification: temporary discontinuation of market distributions
  - Return or removal of the product
  - Informing a patient about the recalled product
Sustainable Effort & Commitment for International Cooperation

Asian Harmonization Working Party (AHWP)

- MFDS, as a chair of AHWP, takes a leading role among 30 member economies from Asia, Middle east, South America and Africa.
- Publishes various AHWP guidelines for implementation in pre- and post-market management of medical devices.
- Provides Capacity Building workshops for low and middle income countries.

International Medical Device Regulators Forum (IMDRF)

- MFDS actively participates and cooperates with IMDRF working groups and the committee members.
- Member countries: EU, US, Canada, Japan, Australia, China, Russia, Brazil and Singapore.
Brochure for Korean medical Device
(Eng. ver.)

# Pdf file will be available on the following link
http://www.mfds.go.kr/eng
• 30 member economies as of June, 2017
• 6 new countries joined AHWP as member economies from 2015 to 2017
• Chair of AHWP : South Korea (2015 ~ 2017)
- Held on Nov 21st to 25th, 2016 in Cebu, Philippines
- About 300 Participants from 40 different countries
- 9 other international organizations’ representatives
- 66 speakers
- 12 main themes & 5 panel discussion sessions
- 4 new member economies
- 1 new industry liaison
AHWP handed out the certificates to all of 30 member economies as well as 3 liaison organizations, as part of our 20th anniversary celebrations.
AHWP Global Partnership

Collaborating International Organizations & International Associations of Industry

- WHO
- APEC
- PAHO
- ASEAN
- PAHWP
- OECD
- IEC/ISO
- IMDRF
- APACMED
- DITTA
- GS1
- GMTA
- RAPS
2016
Published 15 Guidance Documents

- Guidance for Minor Change Reporting
- Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representatives, etc

2017
Proposed 15 New Topics for Guidance Documents

- E-labeling as an Alternate Method for Compliance to Labeling Requirement
- Post-market Clinical Follow-up Studies
- Analysis of Global and Local AE Reporting, etc
AHWP Capacity Building Project

KICK OFF (2015)
Training Workshop
• AHWP Annual Meeting in Thailand

IMPLEMENTATION (2016)
• AHWP Annual Meeting in Thailand

GROWTH (2017~)

Training Workshop
• AHWP Annual Meeting in Thailand

In-country Training Plan
• Malaysia, Kazakhstan
• TBC

Training Workshop
• AHWP Annual Meeting in India

Future Plan: Phase II
• Build Curricula
• Develop Competency Assessment Tools

In-country Training
• Indonesia
• Vietnam

Training Workshop
• AHWP Annual Meeting in Philippines
• To enhance the effectiveness & user-friendliness of AHWP website
• To communicate & exchange information with members and stakeholders
Upcoming 22nd AHWP Annual Meeting in Delhi, India

Dec 4th-8th, 2017

All of IMDRF members are cordially invited to 22nd AHWP annual meeting!
Thank you