Your Vision, Our Future

Korean Medical Device
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.

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>
</tr>
<tr>
<td>3</td>
<td>Soft Contact Lens</td>
</tr>
<tr>
<td>4</td>
<td>Biomaterial Graft/Prosthesis</td>
</tr>
<tr>
<td>5</td>
<td>Medical Image Processing System</td>
</tr>
<tr>
<td>6</td>
<td>IVD Reagents for Testing of the Immune System</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>
</tr>
</tbody>
</table>
Based on ISO 14155 and due to expedited processing for clinical trials, diverse clinical researches are conducted in Korea.

There are a total of 153 clinical trial centers designated by Ministry of Food Drug Safety (MFDS), ensuring good clinical trial environments.
Korea comprehensively regulates medical devices with a well-organized legal system and clearly defined regulations.

MFDS has an efficient and well-balanced system to manage the total lifecycle of medical devices.
Strategic Operation based on Expertise & Efficacy

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

MFDS works cooperatively with other third party organizations to increase efficiency and expertise.
Predictable Approval System with Scientific Approach

Based on risk classification of medical devices, each classes of devices have different pathways for a marketing authorization.

<table>
<thead>
<tr>
<th>Class I Medical Device</th>
<th>On-line System</th>
<th>Notification (Immediately)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE Device</td>
<td>Conformity to the pre-determined conditions</td>
<td>Testing Laboratories Issue Conformity Notification</td>
</tr>
<tr>
<td>SE Device with Modifications</td>
<td>Non-conformity to the pre-determined conditions</td>
<td></td>
</tr>
<tr>
<td>NSE Device</td>
<td>SE Device with Modifications</td>
<td></td>
</tr>
<tr>
<td>Class III, IV Medical Device</td>
<td>Technical Document Review</td>
<td>MFDS</td>
</tr>
<tr>
<td>Class III, IV Medical Device</td>
<td>Clinical Data Review</td>
<td>MFDS</td>
</tr>
<tr>
<td>Class III, IV Medical Device</td>
<td>Classification Approval</td>
<td></td>
</tr>
</tbody>
</table>

* Substantially Equivalent (SE), Not Substantially Equivalent (NSE)
* Medical Device Information and Technology Assistance Center

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.

**Accessibility**
- Consultation for approval
- Provision of various guidelines

**Efficacy**
- Modular Review Process
- Expedited Review Process

**Expertise**
- A Pool of External Experts
  - Academy
  - Researcher
  - Industry
  - Physicians

**Evidence-Based Resources**
- Research & Development
  - Standards and Specifications
  - Evaluation methodology
- International Standards (IEC, ISO)
Korean QMS is harmonized with the international standard, ISO 13485.

QMS Audit Procedures for Medical Device

1. Manufacturer/Importer (including Overseas Manufacturing Site)
2. Application of QMS audit
3. Preparation of QMS audit
4. Receipt of application
   - Pre-review
   - Confirmation of third-party auditor and audit date
5. Notice for QMS audit schedule
6. Notifying to MFDS auditor about audit schedule
7. QMS Audit Institutions (3rd Party Organizations)
   - Correction
   - Minor-Nonconformity
   - Major-Nonconformity
8. Notice to applicant for prohibition of distribution
9. Issuing QMS certification
10. Correction request for identified deficiency

Ministry of Food and Drug Safety
Medical device manufacturers, importers and distributors are required to report any adverse events and keep those records.

- Life-threatening adverse events should be reported within 7 days, with additional report to be submitted within 8 days after the initial report.
- Other non-life-threatening adverse events should be reported within 30 days.

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 implantable and life-supporting medical devices, which are subject to tracking for patient safety.

MFDS collects information about devices and patients from manufacturers and importers to regulate the safe use of those devices and prevent medical incidents.
Types of Recall

▷ (Firm-initiated Recall) Recall made voluntarily by the firm after the discovery of safety issues or product defects that may have potential health risk to patients.

▷ (Government-initiated Recall) Recall order made by Minister of MFDS when the product is determined to be defective or potentially harmful.

Procedure for Government-initiated Recall

1. Product that is in violation of laws
   - Yes
   - Assessment of the product
   - Order of recall
   - Public warning about the product

2. No
   - Review of submission
     - Approval of a proposed recall strategy
     - Public notification about the Recall
     - Recall of product as planned
     - Effectiveness Checks
     - Approval of termination of a recall

3. Submission of a recall strategy
   - Submission of final report
   - Approval of termination of a recall
   - Termination of a recall

4. Discontinuation of market distributions
   - 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

International Cooperation Activities

Collaboration with International Organizations

Bilateral Cooperation

- ANVISA (Brazil)
- CFDA (China)
- DHMA (Denmark)
- MHRSA (England)
- MoH (Equador)
- NAMHP (France)
- NADFC (Indonesia)
- MHLW (Japan)
- COFEPRIS (Mexico)
- URPLWMiPB (Poland)
- HSA (Singapore)
- NDA (Uganda)