



Introduction on KMDICA

*Supporting manufacturer
for Regulatory Response*

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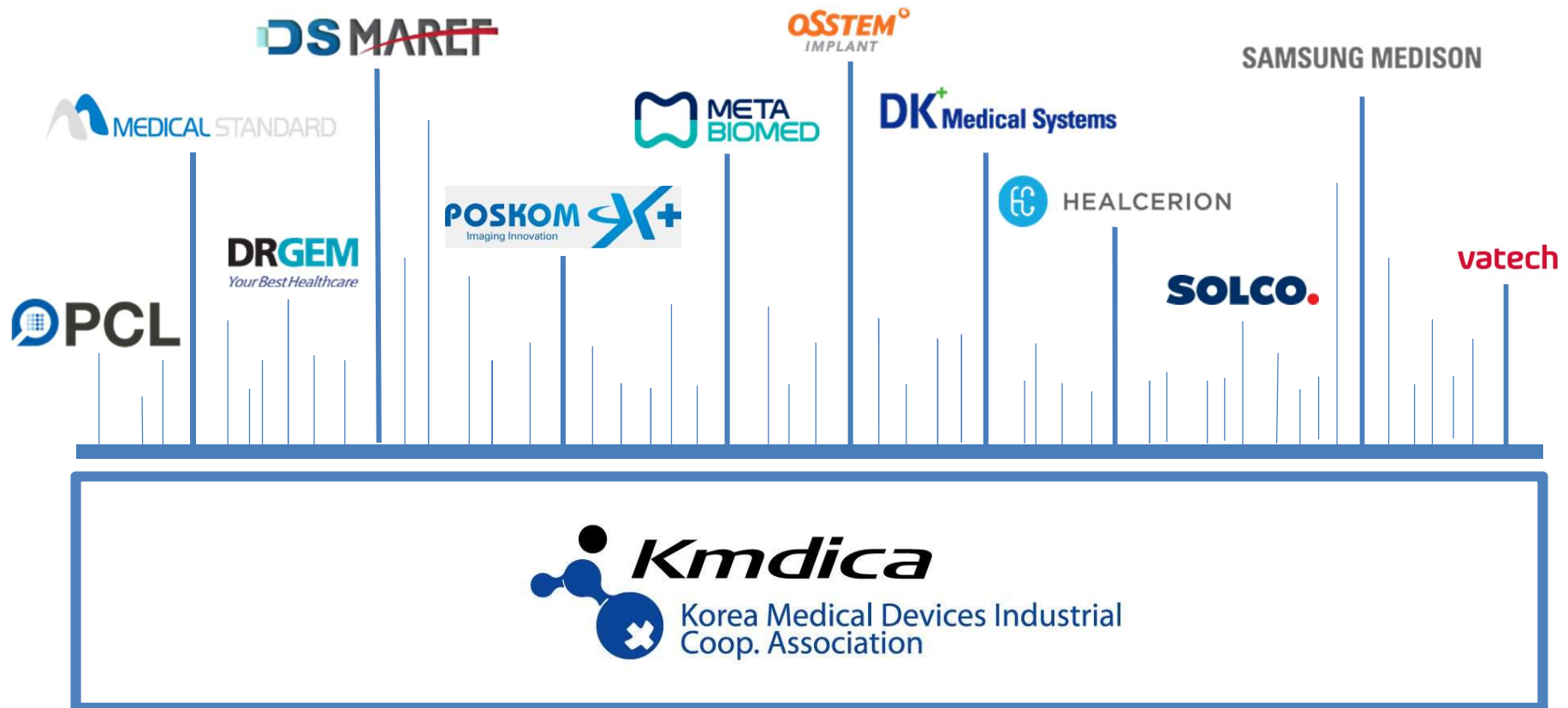
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1. Business Overview

THE PLATFORM OF MEDICAL DEVICE MANUFACTURERS

[With about 650 member companies]



* Membership qualification : Manufacturer of medical instruments and devices approved by Ministry of Food & Drug Safety of ROK

1. Business Overview

Business Domain of KMDICA

Policy Development

Cooperation with MFDS Korea

Capacity Building

Regulatory Response Support

Work
Scope

Export Support &
Local Center Business
(Asia-Pacific Region)

Expanding
Domestic Market

2. Work scope of KMDICA

2-1. Policy Development

Cooperation with MFDS(Ministry of Food and Drug Safety) Korea

- Strengthening the network between MFDS and Medical Device Industries, such as operating 'Government-Industry consultative body'
- Participate in establishment & revision of regulation such as 'Medical Device Item Renewal System'
- Inform guidance on Regulation Establishment to industries.
- Collect opinions of Industries on regulatory enactment

2. Work scope of KMDICA

2-2. Capacity Building

Regulatory Response Support for Industries

- Coaching service
(Guidance to establish regulatory response strategy)
 - Establish regulation approval strategies for each medical device development process
 - Establish roadmap for medical device certification
 - Provide manufacturer-customized training
- Training & Education Service
 - Provide latest regulatory response information and training to improve regulatory response capabilities for medical device manufacturers

2. Work scope of KMDICA

2-2. Capacity Building

Regulatory Response Support for Industries

- Others
 - Support surveillance test for Prototype
 - Guidance for design review
 - Support for preparing clinical evaluation report

2. Introduction on Detail task of KMDICA

2-3. Export Support & Local Center Business

- Export Support
 - : Leading Korean Pavilion for each major international exhibition and support overseas market entry
 - Arab Health (UAE), Western Vet Conference (USA), Hospitalar (Brazil), Medical Fair Asia (Singapore), CMEF(China), Hospital Expo (Indonesia), MEDICA (Germany)

2. Work scope of KMDICA

2-3. Export Support & Local Center Business

- Operate Local business Center in Asia-pacific region : Indonesia, Vietnam, China
 - Product Registration & License Holding support
 - Localization Assistance
 - Maintenance & Repair Service
 - PR Service
 - Show Room Service, etc.

2. Work scope of KMDICA

2-4. Expanding Domestic Market

- Holding domestic exhibition (*KIMES 2021 Mar 18-21 COEX*)
: Vitalize domestic market
 - Securing new marketplaces and new business models
for manufacturers
 - Support for promoting outstanding medical device manufacturers



Thank You

