Introduction on KMDICA

Supporting manufacturer for Regulatory Response

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1. Business Overview

2. Work scope of KMDICA
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   2-2. Capacity Building
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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

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

- **Expanding Domestic Market**

**Work Scope**
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