

Korea IMDRF WGs

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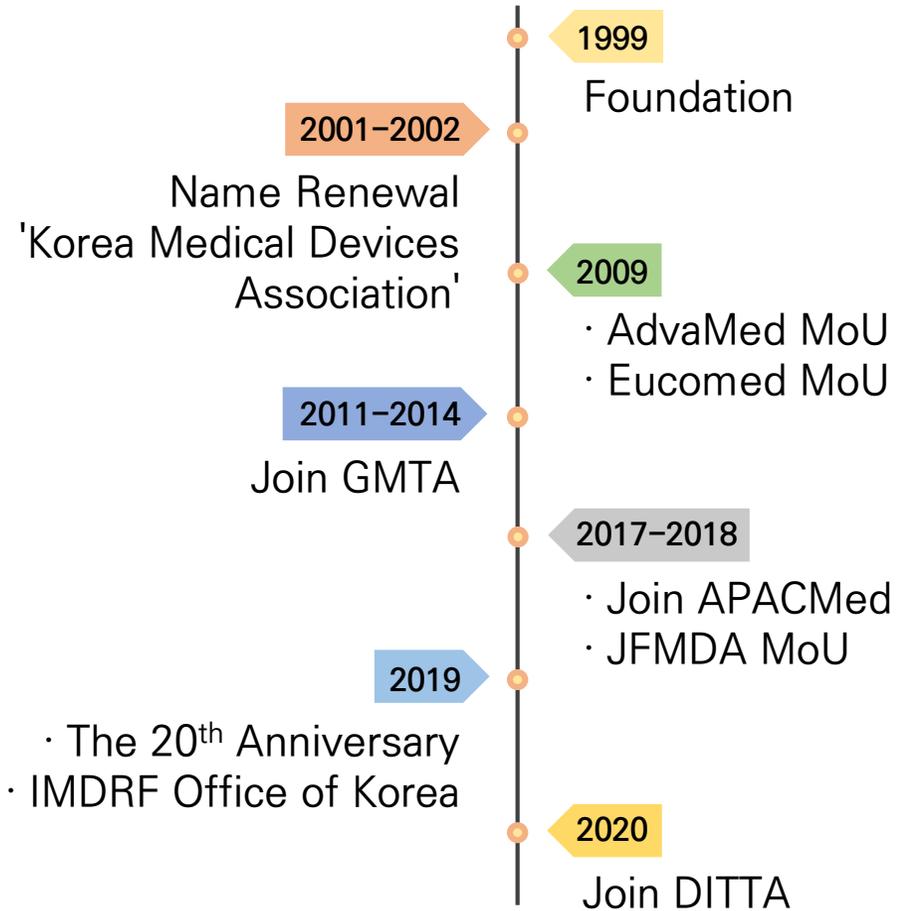
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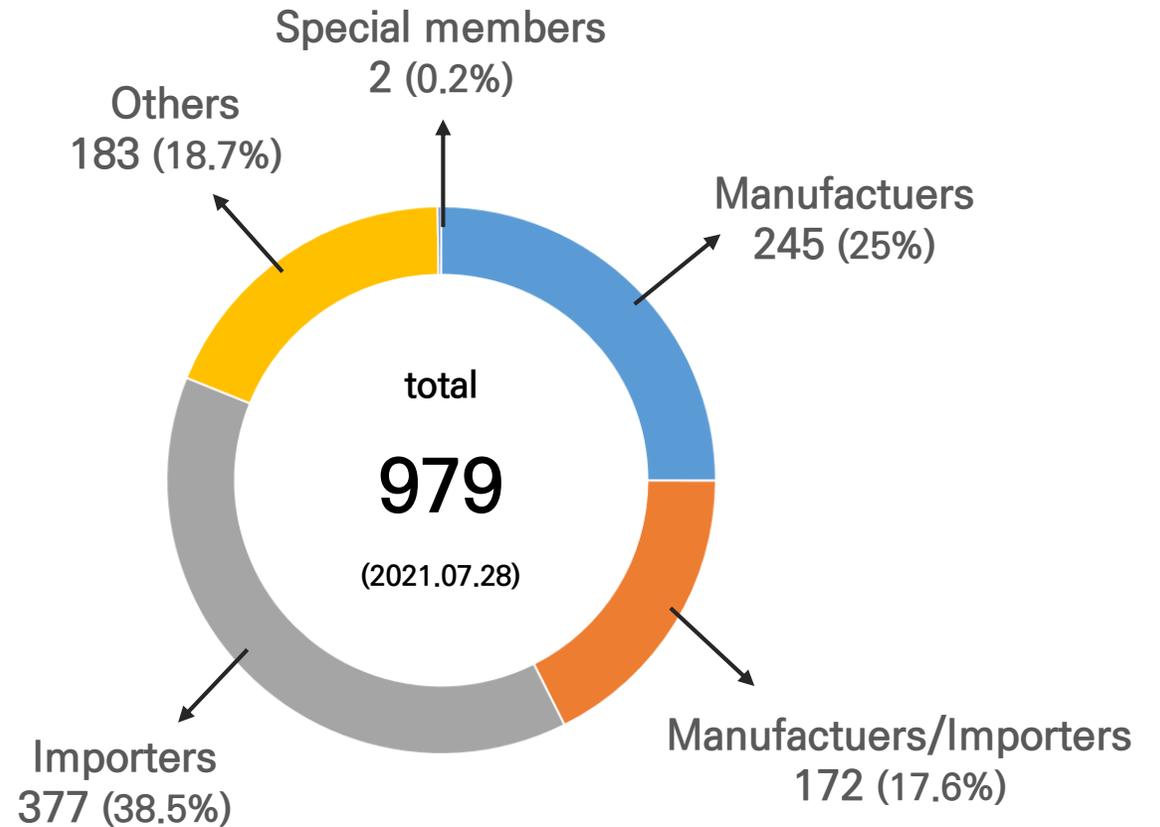


1.1 Overview of KMDIA

History



Members

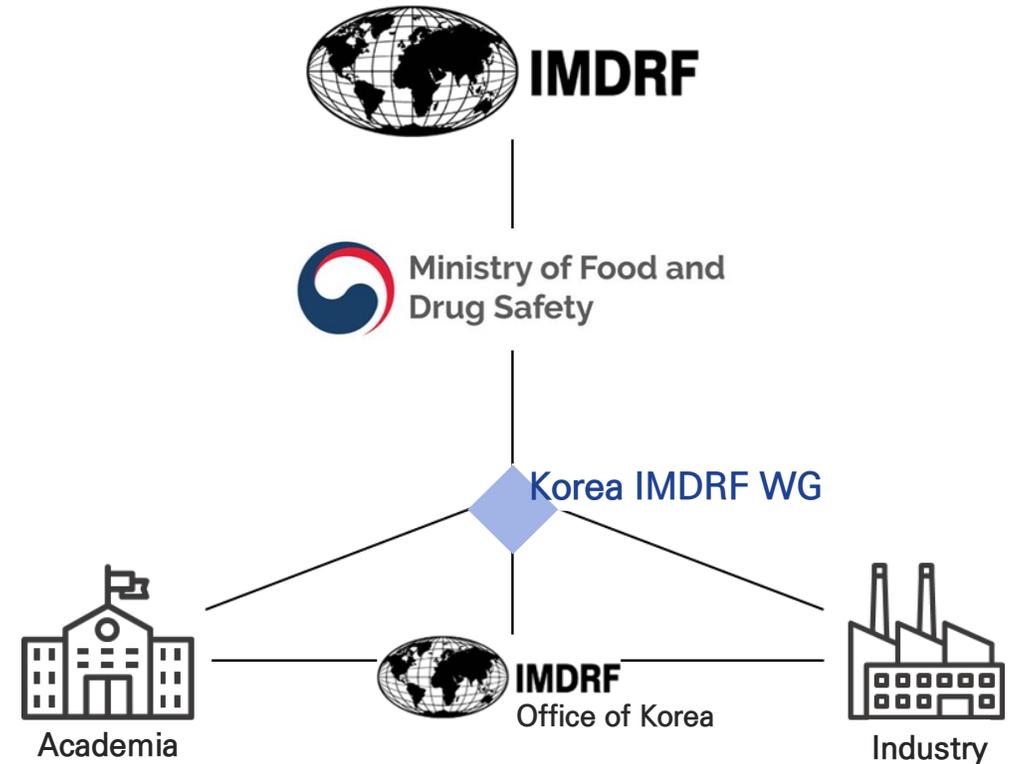


1.2 IMDRF Office of Korea



- ✓ **Date of Foundation** : May in 2019
- ✓ **Roles:**
 - To assist MFDS with IMDRF related work
 - To bridge between the regulatory authority and Korea IMDRF Working Groups
 - To bridge between Korean industry and global industry

How it works:



2.1 Korea IMDRF Working Groups

Overview

- Organized by MFDS
- 12 WGs + 1 Advisory Group

* Industry, Association&Organization, Academia, Regulatory Authority

IMDRF WG	Korea IMDRF WG
RPS (국제 공통허가 심사서류)	RPS
PMD (개인 맞춤형 의료기기)	PMD
IVDD (체외진단 의료기기 지침)	IVDD
GRRP (우수심사기준)	GRRP
Standards (기준규격)	Standard
SaMD (의료용 소프트웨어)	SaMD
AIMD (인공지능 의료기기)	AIMD

IMDRF WG	Korea IMDRF WG
AET (부작용 용어)	AET & NCAR
NCAR (규제당국 간 부작용 보고체계)	
MDSAP (품질시스템 단일심사 프로그램)	MDSAP
CS (의료기기 사이버보안)	CS
MDCE (환자등록정보)	PR & CE
PR (임상평가)	
UDI (의료기기 고유식별 코드)	UDI

2.2

Korea IMDRF Working Groups

Roles and Activities

1. To assist MFDS with IMDRF related work
 - Suggesting agenda or opinion (IMDRF Guidelines)
 - Involving the preparation of IMDRF-DITTA Joint Workshop
 - Reviewing translated version of IMDRF guidelines

2. To share and exchange the industry's view on IMDRF related work
 - General Meeting (2/a year) : MFDS, Korea IMDRF WGs, KMDIA

3. To expand global network

| Thank you