



IMDRF

International Medical
Device Regulators Forum

IMDRF Status Update

Dec 1, 2021

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Ministry of Food and Drug Safety, Korea



IMDRF

International Medical
Device Regulators Forum

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IMDRF Management Committee Meetings in 2021

	March	September
Date	16 th – 25 th March	9 th – 16 th September
	IMDRF-DITTA Joint Workshop Open Session of MC Meeting Open Stakeholder Forum Closed Session of MC Meeting	
Participants	➤ Management Committee Australia, Brazil, Canada, China, EU, Japan, Russia, Singapore, South Korea, USA	
	➤ Official Observers WHO, UK	➤ Official Observers WHO, UK, Argentina



IMDRF International Medical Device Regulators Forum

IMDRF-DITTA Joint Workshop

March



IMDRF / DITTA
Joint Virtual Workshop

WHAT TO LEARN FROM
COVID-19?

TAKING PLACE DURING THE 19th MEETING OF IMDRF

REGISTER HERE!

WORKSHOP PROGRAMME
&
SPEAKERS OVERVIEW

TUESDAY 16 MARCH 2021
12:00 to 14:30 CET / 20:00 to 22:30 KST (Korea Standard Time) / 7:00 to 09:30 EST

September



IMDRF / DITTA
Joint Virtual Workshop

UDI GLOBAL HARMONIZATION

TAKING PLACE DURING THE 20th MEETING OF IMDRF

REGISTER HERE!

WORKSHOP PROGRAMME
&
SPEAKERS OVERVIEW

THURSDAY 9 SEPTEMBER 2021
12:00 to 14:30 CET / 20:00 to 22:30 KST (Korea Standard Time) / 7:00 to 9:30 US EST



Stakeholder Forum – Special Session : COVID-19 (September, 2021)



World Health Organization

[Update on the WHO EUL for IVDs]

- WHO experience with EUL reviews
- Challenges : product dossier, QMS



Global Medical Technology Alliance
Innovating for a Healthier World

[Recommendation]

- Promote rapid review and approval mechanisms
- Ensure adequate training and communication for regulators
- Leverage regulatory agility beyond pandemic



Ministry of Food and Drug Safety

[Update on MFDS's Lessons]

- Regulatory Support(review & QMS) for Market authorization of IVDs and Medical equipment
- Establishment of the Act on medical products to respond to crisis on public health
- Improvement of Information Sharing (e.g. IMDRF)



Brief Statement on COVID-19

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International Medical Device Regulators Forum

Created in February 2011, the International Medical Device Regulators Forum (IMDRF) is a forum of voluntary medical device regulators from around the world who have come together to build on the strong foundational work of the [Global Harmonization Task Force on Medical Devices \(GHTF\)](#), and to accelerate international medical device regulatory harmonization and convergence.

For further information, please refer to IMDRF's [Strategic Plan 2021-2025 - PDF \(496kb\)](#)

The International Medical Device Regulators Forum (IMDRF) acknowledges the significant impact that COVID-19 continues to have on all countries and citizens. The use of essential medical devices such as ventilators, oxygen concentrators, syringes and test kits have contributed to the efforts of pandemic responses around the world, as have other products regulated in some countries such as surgical face masks.

The IMDRF held a Joint Workshop on COVID-19 in March 2021, where members shared their experiences and challenges during the pandemic. Some of these included emergency use or other systems to expedite access and supply of essential medical devices, flexible and pragmatic approaches to regulatory processes such as remote inspections, and publishing information about approval pathways and availability of critical medical devices.

A link to each member country's website is below, where you can find out more detailed information.

Noticeboard

- Strategic Plan
- Artificial Intelligence Medical Devices (AIMDs) Working Group
- Closed session management committee meeting outcome statement

Stakeholder views

- Mailing list
- Item suggestions
- Document suggestions



Decisions by the IMDRF MC

Working Groups

- **AIMD : Public consultation on proposed document**
- **MDSAP : Revision of N4, N6 and N11 document**
- **MDCE & IVD : Working Groups Closed**
- **NWIP : Revision and Update of the GHTE clinical evidence documents for IVD**

IMDRF Secretariat

IMDRF Secretariat 2022

- **Australia will be the IMDRF Secretariat in 2022**
 - A team is being assembled to support the Chair next year



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Thank you