

OUTCOME STATEMENT
27th Session of the International Medical Device Regulators Forum
10-14 March 2025
Shibuya, Tokyo, JAPAN

The 27th Session of the International Medical Device Regulators Forum (the IMDRF) was chaired by Japan and held in-person in Shibuya, Tokyo, Japan from 10 to 14 March 2025. Approximately 300 in-person attendees and 350 virtual attendees participated in the first two days of public meetings. Approximately 80 attendees participated in-person on the third day, and 40 participated on the fourth and fifth days. The 27th Session was preceded by a 1-day IMDRF Training on the use of standards for Affiliate Members/Invited Observers.

IMDRF/Industry Joint Workshop on IMDRF Strategic Plan/Reliance

The IMDRF/Industry Joint Workshop took place on 10 March 2025 as a public meeting. The agenda was comprised of two parts. The first part considered topics that could be included in the IMDRF Strategic Plan 2026-2030, and the second part discussed the benefits and challenges in expanding regulatory reliance. Speakers and panellists from regulatory authorities, industry, the World Health Organization (WHO), and the IMDRF regional harmonization initiatives (RHIs) actively discussed these topics.

The first session of Part 1 was scene-setting for the Strategic Plan. The IMDRF Secretariat presented the results of a survey on potential topics for the Strategic Plan, and industry representatives provided their perspective. Panellists discussed the strengths and challenges of the IMDRF in promoting regulatory harmonization, as well as activities that could be undertaken over the next 5 years, including the enhancement of IMDRF document updates, training and capacity building in collaboration with regulators and industry, and the outcome of the recent inaugural World Medical Device Standards Congress.

In the second session of Part 1, speakers presented the status of implementation of IMDRF documents and the experience and benefits in introducing those documents in each specific country/region. Panellists also shared the specific challenges in incorporating them into their regulatory systems.

In the third session of Part 1, the focus was on training and capacity building. The Asia-Pacific Economic Cooperation (APEC) representative presented APEC's current efforts involving training and capacity building initiatives. Panellists shared their experiences, challenges and possible solutions for training, and discussed what should be prioritized for a training curriculum, and how IMDRF could contribute to provide training including exploring collaborations with other international discussion fora.

Part 2 focused on challenges in expanding reliance. Industry speakers gave an overview on the White Paper on reliance from the IMDRF 25th Session IMDRF/Industry Joint Workshop and shared jurisdictional case studies, best practices and challenges in expanding reliance.

Panellists discussed challenges in promoting reliance and how IMDRF can contribute to overcome those challenges from the perspectives of regulators and industry.

IMDRF Stakeholder Forum

The IMDRF Stakeholder Forum took place on 11 March 2025. In the first session, representatives from the IMDRF Management Committee (MC) and Official Observers (OO) briefed attendees on recent regulatory updates for their jurisdictions and answered questions.

In the second session, the IMDRF working group chairs and the IMDRF Secretariat provided updates on working group activities. The Adverse Event Terminology (AET) working group, Artificial Intelligence/Machine Learning-enabled (AI/ML) working group and Software as a Medical Device (SaMD) working group highlighted progress on their respective activities.

The third session featured the IMDRF RHIs, including:

- Africa Medical Devices Forum (AMDF)
- Asia-Pacific Economic Cooperation (APEC)
- Global Harmonization Working Party (GHWP), and
- Pan American Health Organization (PAHO) (pre-recorded).

Representatives from the IMDRF RHIs highlighted their recent regulatory achievements and harmonization efforts.

The fourth session focused on jurisdiction updates from the following IMDRF Affiliate Members:

- Public Health Institute (ISP), Chile
- Sanitary Regulation Superintendency (SRS), El Salvador
- Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe, and
- Central Drugs Standard Control Organization (CDSCO), India

In the last session of the Stakeholder Forum, the IMDRF MC welcomed the newly formed IMDRF Industry Group, which was marked by an industry panel. The purpose of the IMDRF Industry Group is to assist the IMDRF MC in international harmonization efforts. The group will provide strategic and well - informed advice and perspective to the IMDRF MC on matters relating to the advancement of medical device regulations and standardization.

All presentation materials for the IMDRF/Industry Joint Workshop and the IMDRF Stakeholder Forum are available [here](#).

IMDRF MC Open Session

The MC Open Session was held on 12 March 2025 with the MC, OOs, RHIs, Affiliate Members, the Industry Group, and Invited Observers.

In the first session, IMDRF Secretariat highlighted the reflection of the September 2024 Closed Session and January 2025 teleconference.

In the second session, discussion and presentations were on:

- Medical device nomenclature
- the WHO Global Benchmarking Tool plus Medical Devices (GBT+MD)
- Increasing use of AI in healthcare

IMDRF MC Bilateral Meetings

IMDRF MC and OOs had individual bilateral meetings with Affiliate Members, RHIs, and the IMDRF Industry Group on 12 March 2025.

The discussion included the IMDRF Strategic Plan 2026 -2030, contributions to IMDRF document development/review, and potential IMDRF/industry joint workshop topics for September 2025.

IMDRF MC Closed Session

The IMDRF MC Closed Session was held on 13 and 14 March 2025 with the MC and OOs. The MC discussed and took decisions on membership applications and publication of documents for consultation.

All MC decisions are available in the Annex.

ANNEX
DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

13 and 14 March 2025

Shibuya, Tokyo, JAPAN

In summary:

- The MC agreed to accept the applications for IMDRF Affiliate Membership submitted by:
 - Medical Device Authority (MDA) - Malaysia
 - The Center for Pharmaceutical Products Safety - Uzbekistan
 - Zanzibar Food and Drug Agency (ZFDA) - Tanzania
- The MC agreed to accept the application for IMDRF Management Committee membership submitted by Swissmedic, Swiss Agency for Therapeutic Products - Switzerland.
- The MC agreed to publish the draft document titled IMDRF/GRRP WG/N89 'Playbook for Medical Device Regulatory Reliance Programs' for a 60-day public consultation.
- The MC agreed to revisions to the IMDRF/NCAR WG/N14 FINAL:2023 (Edition 4) 'Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form'.
- The MC confirmed that Singapore will be the IMDRF Chair and Secretariat in 2026.