

**OUTCOME STATEMENT**  
**26<sup>th</sup> Session of the International Medical Device Regulators Forum**  
**16-20 September 2024**  
**Seattle, Washington, United States**

The 26<sup>th</sup> Session of the International Medical Device Regulators Forum (the IMDRF) was held in person in Seattle, Washington, United States from 16 to 20 September 2024. The United States chaired the session. Approximately 300 in-person attendees and over 900 virtual attendees participated in the first two days of public meetings. Approximately 100 attendees participated in person on the third day, 75 on the fourth day, and 50 on the fifth day.

**Joint IMDRF/ Industry Workshop on Developing a Medical Device Regulatory System**

The Joint IMDRF/Industry Workshop on Developing a Medical Device Regulatory System took place on 16 September 2024 as a public meeting. The agenda included four sessions on developing a medical device regulatory system with speakers and panellists from regulatory authorities, industry, the World Health Organization (WHO), and academia.

The first session featured presentations from regulatory authorities, industry, the IMDRF regional harmonization initiatives (RHIs), and the WHO. The speakers provided background on the development of a medical device regulatory system, discussed the common challenges and opportunities, and explained how IMDRF could support regulatory authorities that are developing a medical device regulatory system.

In the second session, regulatory authorities and industry described the enabling conditions for the effective regulation of medical devices and how IMDRF could enhance its support for harmonization and convergence of medical device regulatory systems.

In the third session, speakers from regulatory authorities and industry discussed the importance of reliance and recognition, basic and expanded level controls, and enforcement for premarket and postmarket activities. During the panel discussion with questions and answers, the speakers presented case examples and discussed challenges with implementing basic and expanded level controls for premarket and postmarket activities.

The final panel featured a moderated discussion with the WHO, regulatory authorities, RHIs, and industry representatives on opportunities for IMDRF to support regulatory authorities who are new to IMDRF in developing medical device regulatory systems.

**IMDRF Stakeholder Forum**

The IMDRF Stakeholder Forum took place on 17 September 2024. Representatives from the IMDRF Management Committee (MC) and Official Observers (OO) briefed attendees on regulatory updates for their jurisdictions and answered questions.

In the second session, the IMDRF Secretariat provided updates on behalf of the working group chairs on working group progress. Representatives from the Good Regulatory Review Practices

and the Clinical Evidence for IVDs Working Groups highlighted progress on their respective work items.

The third session included jurisdiction updates from the following IMDRF Affiliate Members: EDA (Egypt), CInMED (Montenegro) and SAHPRA (South Africa).

The fourth session featured the IMDRF RHIs, including:

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

Representatives from the RHIs highlighted their recent regulatory work, achievements, and commitment to align with IMDRF such as activities related to the reduction of duplication of efforts.

In the final session of the Stakeholder Forum, representatives from industry provided their perspective on what is challenging and what can be improved by the IMDRF in the new strategic plan. All presentation materials for the Joint IMDRF/Industry Workshop and the IMDRF Stakeholder Forum are available [here](#).

### **IMDRF Management Committee Open Session**

The MC Open Session was held on 18 September 2024. The open session included the MC, OOs, RHIs, Affiliate Members, and invited observers seeking Affiliate and Official Observer membership.

The IMDRF Secretariat highlighted the results of surveys undertaken by MC Members, OOs and Affiliate Members on reliance and electronic labelling. The session concluded with a moderated discussion of all attendees regarding how IMDRF can better engage with stakeholders on these topics.

The afternoon of the open session featured a discussion about the Affiliate membership with the MC and OOs. Attendees explored the future of Affiliate membership, including benefits, challenges, and recommendations for how to better support and engage these members.

### **IMDRF MC Closed Session**

The IMDRF MC Closed Session was held on 19 and 20 September 2024 with the MC and OOs. The MC discussed and took decisions regarding membership applications, publication of documents, and initiation of new work. The MC also discussed other procedural matters.

All decisions of the MC are available in the Annex.

**ANNEX**  
**DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE**

**19 and 20 September 2024**

**Seattle, Washington, United States**

In summary:

- The MC agreed to accept the applications for IMDRF Affiliate membership submitted by:
  - Botswana Medicines Regulatory Authority (BoMRA) - Botswana
  - Ministry of Health of Costa Rica (DRPIS) – Costa Rica
  - Dirección General de Medicamentos, Alimentos y Productos Sanitarios (DIGEMAPS) - Dominican Republic
  - Central Drug Standard Control Organization (CDSCO) - India
  - Drug Safety Center - Oman
  - Dirección Nacional de Vigilancia Sanitarias (DINAVISA) - Paraguay
  - Dirección General de Medicamentos, Insumos y Drogas (DIGEMID) - Peru
  - Medicines Control Authority of Zimbabwe - Zimbabwe
  
- The MC agreed to accept the application for IMDRF Official Observer membership submitted by the Saudi Food and Drug Authority (SFDA) – Saudi Arabia.
  
- The MC agreed to:
  - Approve the final document titled “Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators” (IMDRF AET WG/N85) from the Adverse Event Terminology (AET) Working Group.
  
  - Approve the draft document titled “Consideration for the selection of IMDRF Adverse Event Terminology codes and terms” for a 60-day public consultation.
  
  - Approve the revised New Work Item Proposal (NWIP) of the Artificial Intelligence/Machine Learning-enabled (AI/ML) Working Group for a document outlining a technical framework for AI lifecycle management.
  
  - Approve the NWIP of the Software as a Medical Device (SaMD) Working Group to develop a document on the essential principles and content of Predetermined Change Control Plans (PCCPs).
  
- The MC agreed to have the AET Working Group provide a webinar during the public consultation process for the “Consideration for the selection of IMDRF Adverse Event Terminology codes and terms” document to explain the document and seek feedback from stakeholders. Details will be forthcoming on the IMDRF Website.

- Based on the success of the training on Essential Principles of Safety and Performance conducted on 19 September 2024, the MC agreed to conduct another training session at the 27<sup>th</sup> Session. Training topic(s) and future sessions. To Be Determined.
- The MC agreed to collect feedback to inform the next IMDRF Strategic Plan (2026 – 2030).
- The MC supported the publication of a White Paper on the outcomes of the Joint IMDRF/Industry Workshop on developing medical device regulatory systems.
- The MC confirmed that Japan will be the IMDRF Chair and Secretariat in 2025.