



OUTCOME STATEMENT

25th Session of the International Medical Device Regulators Forum

11-15 March 2024

Washington, District of Columbia, United States

The 25th Session of the International Medical Device Regulators Forum (the IMDRF) was held in person in Washington, District of Columbia, United States from 11 to 15 March 2024. The United States chaired the session. Approximately 400 in-person attendees and 800 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. Presentations are available [here](#).

Joint IMDRF/ Industry Workshop on Reliance

The Joint IMDRF/Industry Workshop on Reliance took place on 11 March 2024 as a public meeting. The agenda included four sessions on reliance with speakers and panellists from regulatory authorities, industry, global health organizations, and academia.

The first session featured presentations from regulatory authorities, industry, and the World Health Organization (WHO). The speakers defined what reliance is, described how reliance is used globally, articulated the role of standards in supporting reliance, and explained why reliance is important.

In the second session, regulatory authorities and the Pan American Health Organization (PAHO) described specific premarket reliance models and industry representatives highlighted their experiences using these models. During the panel discussion with questions and answers, the speakers emphasized that models of reliance save resources, encourage innovation, bring devices to the market faster, and ensure patient access.

In the third session, speakers from regulatory authorities and industry presented case studies on reliance during post-market surveillance and monitoring.

The final panel featured a moderated discussion with regulators and industry representatives on opportunities to implement reliance more globally. The panellists opined on potential activities for the IMDRF to undertake to support reliance.

IMDRF Open Stakeholder Forum

The IMDRF Open Stakeholder Forum took place on 12 March 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 Software as a Medical Device (SaMD) and the Regulated Product Submission Working Groups highlighted progress on their respective work items.

The third session welcomed ISP (Chile), TFDA (Chinese Taipei), CECMED (Cuba), and MTIIR (Israel) as new IMDRF Affiliate members in a moderated discussion of updates from their jurisdictions and challenges faced.

The fourth session featured the IMDRF Regional Harmonization Initiatives (RHIs), including:

- the African 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 and harmonization efforts, as well as priorities related to the IMDRF.

In the final session of the Stakeholder Forum, representatives from industry provided their perspective on what is new, what is challenging, and what can be improved by the IMDRF. 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 13 March 2024. The open session included the MC, OOs, RHIs, Affiliate Members, applicants seeking Affiliate membership, and invited observers from CDSCO (India) and SFDA (Saudi Arabia).

The first session featured presentations from representatives on their training experience, including recommendations and challenges. Presenters included:

- World Health Organization (WHO)
- Medical Device Regulatory Convergence Project (MDRC)
- Trinity College Dublin
- Technical College Lubeck
- Stanford University

- Global Medical Technology Alliance (GMTA)
- Global Diagnostic Imaging, Healthcare, IT, and Radiation Therapy Trade Association (DITTA)

The IMDRF Secretariat also highlighted the results of the IMDRF training survey undertaken by Affiliate Members, Affiliate applicants, and industry on training to IMDRF technical documents. The session concluded with a moderated discussion of the panelists and all attendees regarding how the IMDRF can support training on technical documents.

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 14 and 15 March 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 future training on IMDRF documents and other procedural matters.

All decisions of the MC are available in the Annex.

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

14 and 15 March 2024

Washington, District of Columbia, United States

In summary:

- The MC agreed to accept the applications for IMDRF Affiliate membership submitted by:
 - Dirección Nacional de Medicamentos (DNM) - El Salvador
 - Ethiopian Food and Drug Administration (EFDA) - Ethiopia
 - Jordan Food and Drug Administration (JFDA) - Jordan
 - PPB - Kenya
 - Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) - Mexico
 - National Agency for Food and Drug Administration and Control (NAFDAC) - Nigeria
 - Tanzania Medicines and Medical Device Authority (TMDA) - Tanzania

- The MC agreed to:
 - Approve and post as final the eight Good Regulatory Review Practices (GRRP) documents which were revised to have consistent terminology, including:
 - IMDRF/GRRP WG/N40 - Competence, Training, and Conduct Requirements for Regulatory Reviewers
 - IMDRF/GRRP WG/N47 - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
 - IMDRF/GRRP WG/N52 - Principles of Labelling for Medical Devices and IVD Medical Devices
 - IMDRF/GRRP WG/N59 - Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
 - IMDRF/GRRP WG/N61 - Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
 - IMDRF/GRRP WG/N63 - Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
 - IMDRF/GRRP WG/N66 - Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews
 - IMDRF/GRRP WG/N71 - Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

- Approve the proposal from the Personalized Medical Devices Working Group to develop training and guidance materials for stakeholders.
- Approve the New Work Item Proposal (NWIP) of the Artificial Intelligence/Machine Learning-enabled (AI/ML) Working Group for a document on AI lifecycle management.
- Approve the NWIP to update and streamline Global Harmonization Task Force (GHTF) documents on clinical evidence for In Vitro Diagnostics.
- Based on stakeholder feedback, the MC agreed to develop training for IMDRF/GRRP WG/N47 - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices and that this training will include practical examples.
- The MC supported the publication of a White Paper on the outcomes of the Joint IMDRF/Industry Workshop on Reliance.