Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

IMDRF Updates

28th GHWP Annual Meeting/TC Meeting
9th - 12th Dec, 2024
Kuala Lumpur, Malaysia

Miho Sato, PhD

Principal Coordinator

Office of International Programs

Pharmaceuticals and Medical Devices Agency

Introduction and Governance

Mission

IMDRF International Medical Device Regulators Forum

To strategically **accelerate** international medical device **regulatory convergence** to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

Learn more about IMDRF through this short video: https://www.youtube.com/watch?v=WioWqRO2Xsw

Goals

IMDRF International Medical Device Regulators Forum

The IMDRF is established to address the common public health regulatory challenges to convergence due to the **globalization of medical device production** and **the emergence of new technologies**. IMDRF provides the structure where the strategic decisions and operational mandates are made by public health-missioned medical device regulators, based on **appropriate, equitable and transparent input from stakeholders.**

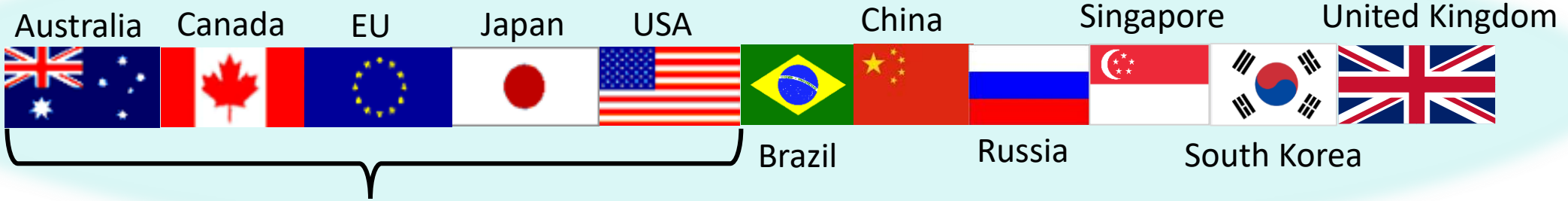
Learn more about IMDRF through this short video: https://www.youtube.com/watch?v=WioWqRO2Xsw

IMDRF (International Medical Device Regulators Forum)

GHTF → Replaced (2012) → IMDRF International Medical Device Regulators Forum

(As of October, 2024)

Management Committee members



Official Observers

World Health Organization

Argentina, Saudi Arabia, Switzerland

Regional Harmonization Initiatives

Asia-Pacific Economic Cooperation (APEC)

Pan American Health Organization

Global Harmonization Working Party (GHWP) Towards Medical Device Harmonization

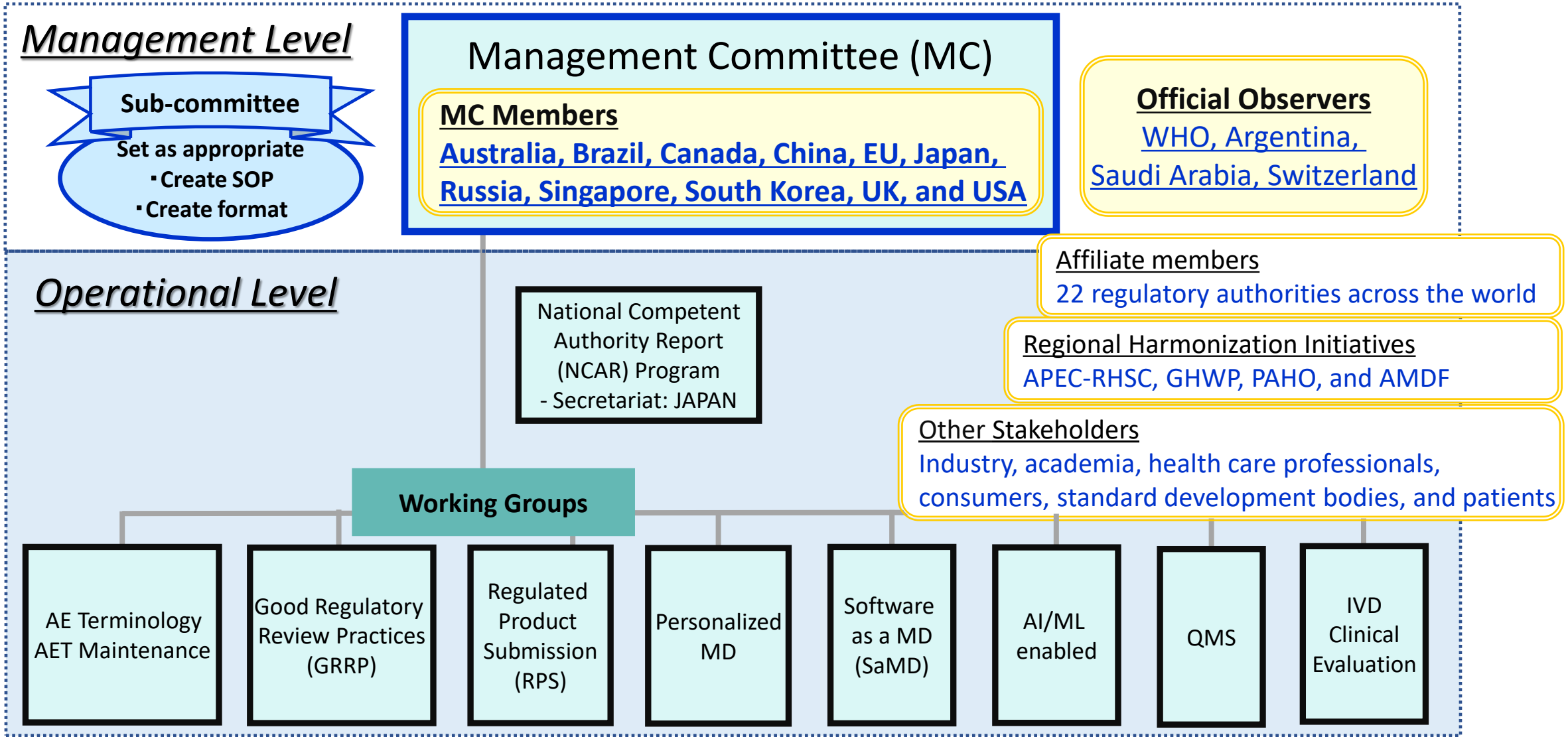
African Medical Devices Forum (AMDF)

Affiliate members

Botswana, Chile, Chinese Taipei, Costa Rica, Cuba, Dominican Republic, Egypt, El Salvador, Ethiopia, India, Israel, Jordan, Kenya, Mexico, Montenegro, Nigeria, Oman, Paraguay, Peru, South Africa, Tanzania, Zimbabwe (total 22 RAs)

Structure of IMDRF

(As of October, 2024)



Affiliate members (Eligibility criteria)

- being a **regulatory authority**;

- having
  - a **recognized commitment** to the objectives of IMDRF demonstrated by implementation of IMDRF documents

  or
  - a **detailed plan for implementation** of IMDRF documents as part of their regulatory framework;

and

- commit to **providing annual updates on the implementation** of IMDRF documents at IMDRF MC Open Sessions.

Engagement : Other stakeholders

IMDRF **welcomes input/participation by medical device sector stakeholders**.

Participation takes places via a number of channels including:

- Participation in **open member working groups**
- Attendance and participation in the **regular IMDRF open stakeholder forums**
- Attendance **as invited participants** at IMDRF Management Committee meetings

https://www.imdrf.org/stakeholders

Activities for Affiliate members & stakeholders

- Training Development

https://www.imdrf.org/imdrf-trainings

- Publish the implementation report

https://www.imdrf.org/documents/imdrf-document-implementation-report-0

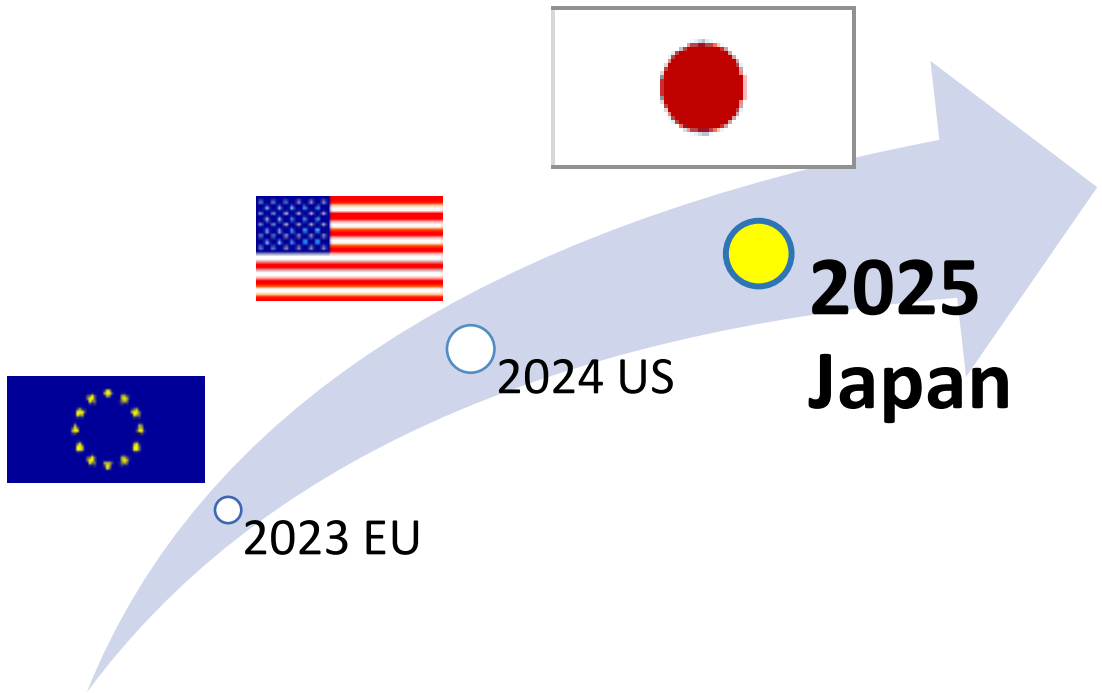
IMDRF Technical Documents *(published from Feb 2022 to present)*

- *IMDRF/AET WG/N85 - Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators*
- *IMDRF/PMD WG/N74 - Personalized Medical Devices – Production Verification and Validation*
- *IMDRF/CYBER WG/N73 - Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity*
- *IMDRF/GRRP WG/N71 - Medical Device Regulatory Review Report: Guidance Regarding Information to be Included*
- *IMDRF/CYBER WG/N70 - Principles and Practices for the Cybersecurity of Legacy Medical Devices*
- *IMDRF/RPS WG/N9 - Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)*
- *IMDRF/RPS WG/N13 - In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC)*
- *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/AE WG/N43 - Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*
- *IMDRF/PMD WG/N58 - Personalized Medical Devices – Regulatory Pathways*
- *IMDRF/NCAR WG/N14 - Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form.*
- *IMDRF/AIMD WG/N67 - Machine Learning-enabled Medical Devices: Key Terms and Definitions*

https://www.imdrf.org/documents/library?f%5B0%5D=type%3Atechnical_document

IMDRF 2025

The 2025 IMDRF Chair/Secretariat



IMDRF International Medical Device Regulators Forum

The roles of IMDRF Chair and Secretariat

- Leading activities of IMDRF
  including conducting all the IMDRF MC meetings
- Disseminating information
- Coordinating IMDRF MC meetings
- Maintaining a repository of documents & the tools of communication
- **Leading to create Strategic Plan 2026-2030**

IMDRF Strategic Plan (2021-2025)

Mission of IMDRF

The mission1 of the International Medical Device Regulators Forum (IMDRF) is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

IMDRF Key Objectives 2021-2025

1. *Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance*

2. *Strengthening post-market surveillance for medical devices and implement regulatory lifecycle processes*

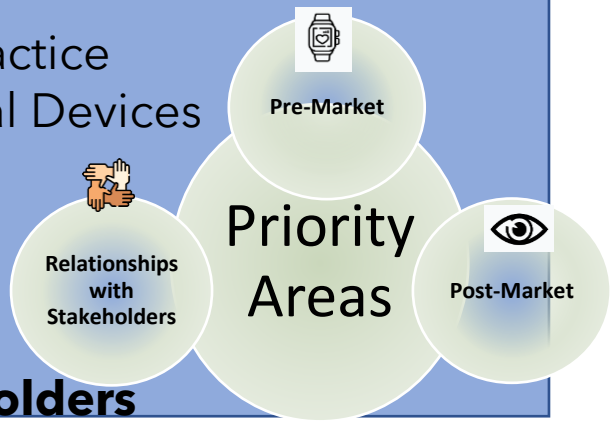
Priority 1: Pre-Market

Topic: Personalized Medical Devices
Topic: Software as a Medical Device
Topic: Regulated Product Submissions
Topic: Medical Device Evidence Evaluation (Clinical Evaluation)
Topic: Good Regulatory Review Practice
Topic: Artificial Intelligence Medical Devices

Priority 2: Post Market

Topic: Cyber Security
Topic: Adverse Event Terminology
Topic: Unique Device Identifiers

Priority 3: Relationships with Stakeholders



https://www.imdrf.org/documents/imdrf-strategic-plan-2021-2025

IMDRF Strategic Plan (2026-2030)

- As the IMDRF 2025 Chair & Secretariat, **Japan will draft and released the IMDRF Strategic Plan (2026-2030) by the end of 2025**.

- **A survey is currently being conducted** to gather input from IMDRF members (including affiliate members and RHI) and stakeholders (including the industry associations)

Thank you
for your response!

Thank you for your attention!

IMDRF 2025 Secretariat
IMDRF2025@pmda.go.jp

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MHLW Website
https://www.mhlw.go.jp/english/

PMDA Website
https://www.pmda.go.jp/english/index.html