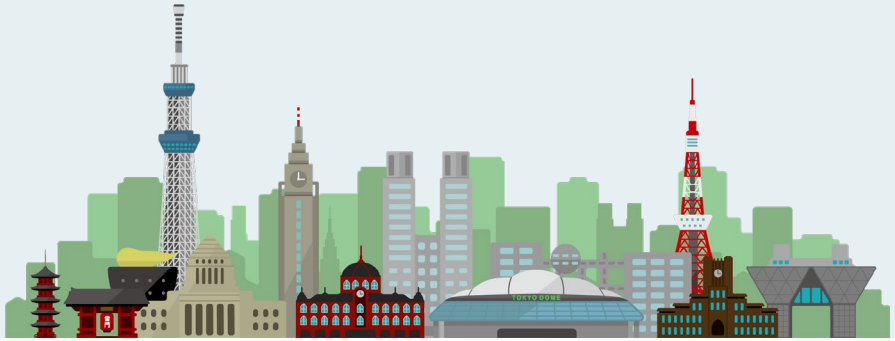
IMDRF International Medical Device Regulators Forum



IMDRF-Industry Joint Workshop

IMDRF 27th Sessions in Tokyo, 2025
March 10, United Nations University

IMDRF International Medical Device Regulators Forum

Structure of today's workshop

Topic I: IMDRF Strategic Plan 2026-2030

Session1:
Scene Setting

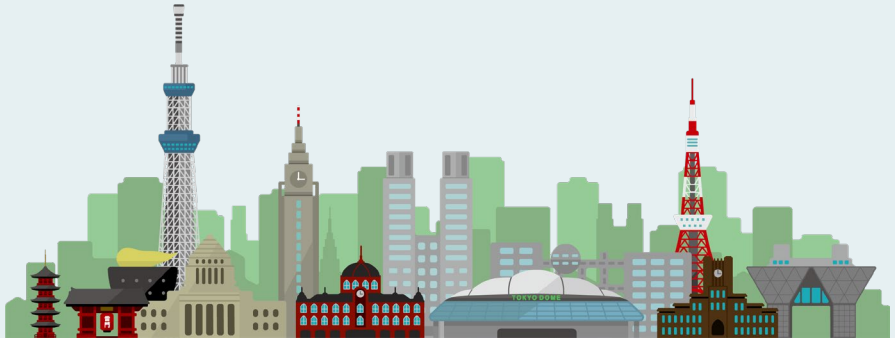
Session2:
Progress and Challenges in Implementation of IMDRF Guidance Document

Session3:
Education models for Training and Capacity Building at Current IMDRF initiatives, RHI experience

Topic II: Challenges in expanding Reliance

Based on the discussion at IMDRF 25th Session

IMDRF International Medical Device Regulators Forum



IMDRF Strategic Plan 2026 – 2030
Overview of survey result

Madoka Murakami, Ph.D.

IMDRF 2025 Secretariat
Deputy Review Director
Office of SaMD, PMDA, Japan

IMDRF-Industry Joint Workshop
Topic I: IMDRF Strategic Plan 2026-2030
Session1 Scene Setting

Background:

The IMDRF Strategic Plan is published every 5 years aligned with the IMDRF mission, goals, objectives, and scope of activities on IMDRF Terms of Reference. **2025 is** the final year of the current IMDRF Strategic Plan 2020-2025, and **the year of formulation and publication of the next IMDRF Strategic Plan 2026-2030**. At the IMDRF 26th Session, the MC agreed to conduct a survey among stakeholders to obtain the necessary input to consider IMDRF's vision and priority initiatives in preparation for the creation of the next Strategic Plan.

The aim of this survey is to collect the following items to be included in the next Strategic Plan.

- ✓ **Key Objective and priority area candidates**
- ✓ **Multiple perspectives on IMDRF activities**
- ✓ **Key words, phrases, expressions, and terms that make up the text**

Survey to IMDRF Members and Stakeholders

To whom?

IMDRF MC members, Official Observers, RHIs, Affiliate Members, Industry (GMTA, DITTA)

About what?

Strengths and challenges of IMDRF
Possible priority topics
Implementation and use of IMDRF guidance document

When?

November 8, 2024 to January 8, 2025

Respondents

IMDRF MC Members

- Australia – TGA
- Brazil - ANVISA
- Canada - Health Canada
- European Union - European Commission
- Japan - MHLW/PMDA
- Singapore - HSA
- South Korea - MFDS
- United Kingdom - MHRA
- United States of America – FDA

IMDRF Official Observers

- Argentina - ANMAT
- Switzerland - Swissmedic
- Saudi Arabia – SFDA
- WHO

IMDRF Affiliate Members

- Botswana
- Chile
- Chinese Taipei
- Costa Rica
- Cuba
- Dominican Republic
- Egypt
- El Salvador
- India
- Kenya
- Mexico
- Montenegro
- Nigeria
- Oman
- Paraguay
- Tanzania

IMDRF RHI

- GHWP

Industry

- DITTA
- GMTA

Overview of survey questions

Category	Questions about:	MC, OO	Affiliate	RHI	Industry
1. Current status of IMDRF	Strengths, benefits	x	x	x	x
	Challenges, difficulties	x	x	x	x
2. Topics for IMDRF activity/guidance document	Innovative Topics	x	x	x	x
	Foundational topics	x	x	x	x
3. Implementation and use of IMDRF guidance document	Support for introduction to regulatory system		x		
	Promoting the implementation			x	
	Expectation to IMDRF document				x

IMDRF International Medical Device Regulators Forum

1. Current status of IMDRF: **Strength, benefits**

MC member, Official Observers

Guidance Document

out of 13 responses

- Development of guidance documents on innovative topics by developed regulated countries
- Developing and maintaining fundamental guidance documents that serve as the basis for global medical device regulation
- Activities in collaboration with international standards organizations
- Cooperation with the global medical device industry
- Sharing experience in regulatory implementation of international medical device guidance documents and standards
- Bringing together international stakeholders in face-to-face meetings

Engagement with stakeholders

Other comments;

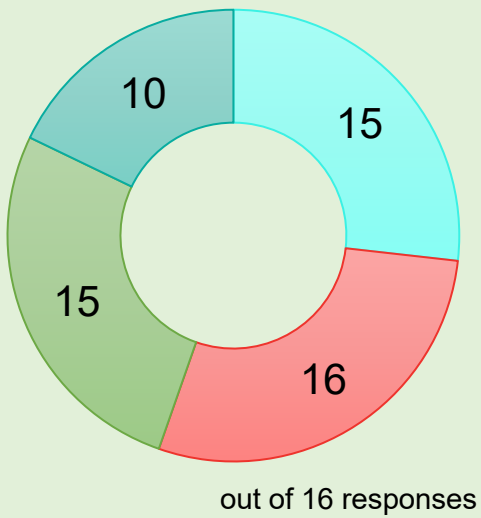
- ✓ World-lead organization in medical device regulation
- ✓ Setting foundation of medical device regulation
- ✓ Sharing expertise, capability, knowledge and ideas
- ✓ Promoting regulatory convergence
- ✓ Transparency of the process
- ✓ Robust discussions among experts

etc.

IMDRF International Medical Device Regulators Forum

1. Current status of IMDRF: **Strength, benefits**

Affiliate Members



out of 16 responses

- Participation in IMDRF WG activities
- **Stay up to date with the latest activities related to medical device regulations**
- Communication with experienced MC members from various countries
- Collection of best practices

RHI

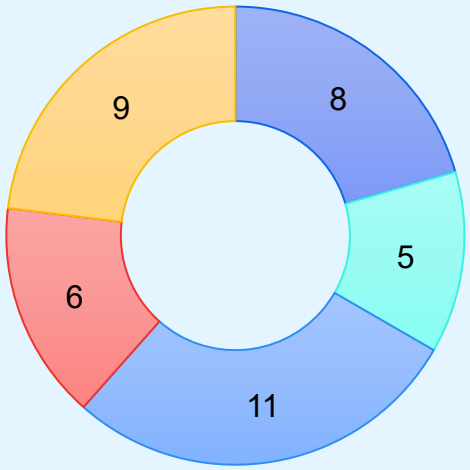
- ☒ Participation in IMDRF WG activities
- ☒ Stay up to date with the latest activities related to medical device regulations
- ☒ Other (Please propose specific approach)

Other comment:

- ✓ To enable dialogues towards common goals on medical device regulatory convergence, harmonization and reliance.

1. Current status of IMDRF: **Challenges, difficulties**

MC member, Official Observers



out of 13 responses

- Clarification of the position of activities and guidance documents in the regulatory model
- Frequency of updates to published guidance documents
- Mechanism to disseminate the contents and correct interpretation of published guidance documents
- Engagement with regions with few IMDRF members
- Engagement with academia, healthcare professionals and patients

Other comments;

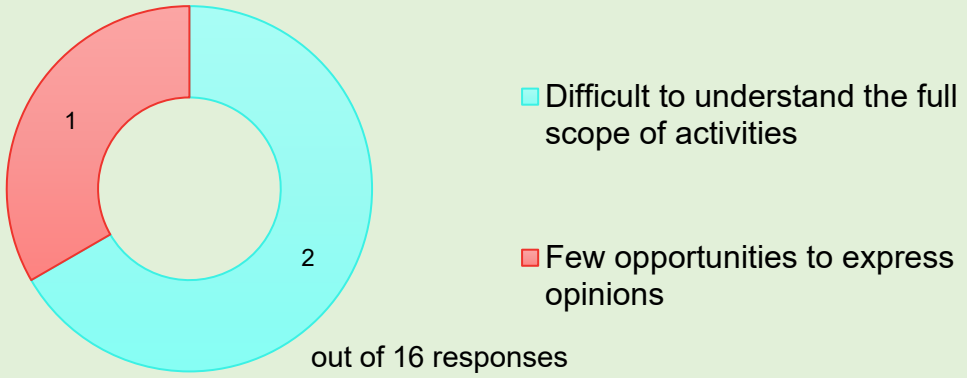
- ✓ Different priorities within IMDRF members
- ✓ Keeping up with emerging technologies
- ✓ Different maturity of regulatory system or expertise
- ✓ Limited resource for providing training
- ✓ Relationships with Regional Harmonization Initiatives
- ✓ Maintenance of GHTF documents

etc.

IMDRF International Medical Device Regulators Forum

1. Current status of IMDRF: **Challenges, difficulties**

Affiliate Members



out of 16 responses

Other comments;
- ✓ Language
- ✓ Logistical issue
- ✓ Participation in WGs or curtain types of activity
- ✓ Participation in IMDRRF decision making
- ✓ Levels of maturity

etc.

RHI

- ☐ Difficult to see the coordination with own organization's activities
- ☐ Few opportunities to express opinions
- ☒ Other (Please propose specific approach)

Other comments:
- ✓ Faster communication
- ✓ Transparency on topic selection and work phase

IMDRF International Medical Device Regulators Forum

2. Topics for IMDRF activity/guidance document

MC member, Official Observers

Innovative topics:

- ✓ Reliance
- ✓ Cybersecurity
- ✓ Generative AI-enabled medical device
- ✓ Clinical evaluation of innovative technologies
- ✓ Remanufacturing of medical device
- ✓ In-silico clinical trials
- ✓ Personalized medicines and companion diagnostics
- ✓ Orphan medical devices
- ✓ UDI 2.0
- ✓ Supply resilience for critical/essential devices
- ✓ Framework for global heath emergency

etc.

Foundational topics:

- ✓ Essential Principles
- ✓ Medical Device Classification
- ✓ QMS (including SaMD)
- ✓ Clinical evidence for Medical Device
- ✓ Clinical evidence for IVD
- ✓ Post-market Surveillance
- ✓ AE Terminology
- ✓ UDI
- ✓ GHTF document

etc.

IMDRF International Medical Device Regulators Forum

2. Topics for IMDRF activity/guidance document

Affiliate Members

Innovative topics:

- ✓ AI/ML-enabled medical device
- ✓ Digital health
- ✓ Cybersecurity
- ✓ Modeling and simulation
- ✓ RWE
- ✓ Regulatory process for innovative medical devices
- ✓ Innovative technology such as 3D printing
- ✓ Combination product
- ✓ Reprocessed/refurbished medical device
- ✓ Informatics tools for post-market surveillance

etc.

RHI

Innovative topics:

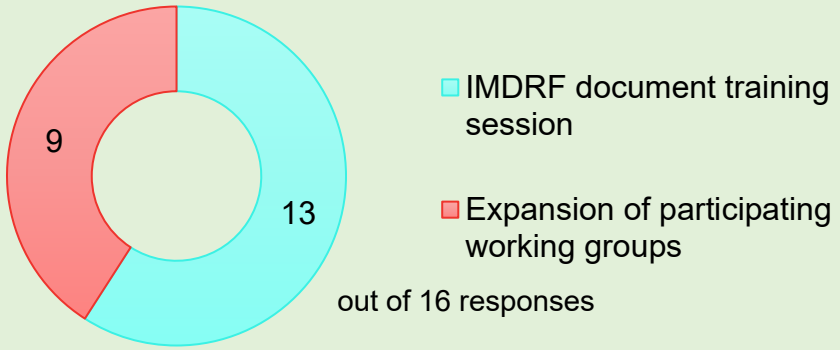
- ✓ Joint review mechanism for combination products
- ✓ Regulatory convergence in emerging markets
- ✓ Cybersecurity, data privacy, and interoperability
- ✓ Change management
- ✓ e-Labeling and e-IFU
- ✓ Innovative evidence (i.e. real world evidence, in silico modeling, synthetic samples)
- ✓ IVD clinical pathways
- ✓ CDx clinical evidence harmonization

etc.

Foundational topics from Affiliate Members and RHIs are pretty much the same as those MC members identify

3. Implementation of IMDRF guidance document

Affiliate Members



out of 16 responses

Other comments;
- ✓ Experience and information sharing
- ✓ Informatic tools for PMS
- ✓ Partnership with IMDRF and RAs
- ✓ Mentorship program

etc.

RHI

- ☒ IMDRF document training session
- ☒ Expansion of participating working groups
- ☒ Other (Please propose specific approach)

Other comments;
- ✓ Including participation of regulatory authorities from different maturity levels in the development process.
- ✓ Creating online FAQ session for common questions/feedbacks

etc.

Next Step

- Discussion within IMDRF MC members based on the result of survey and workshop Communication with IMDRF Stakeholders
- Drafting by IMDRF Secretariat and MC members
- Publication in the last quarter of this year

Thank you very much for your contribution to the survey!

IMDRF International Medical Device Regulators Forum

Thank you

ありがとうございます