



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization



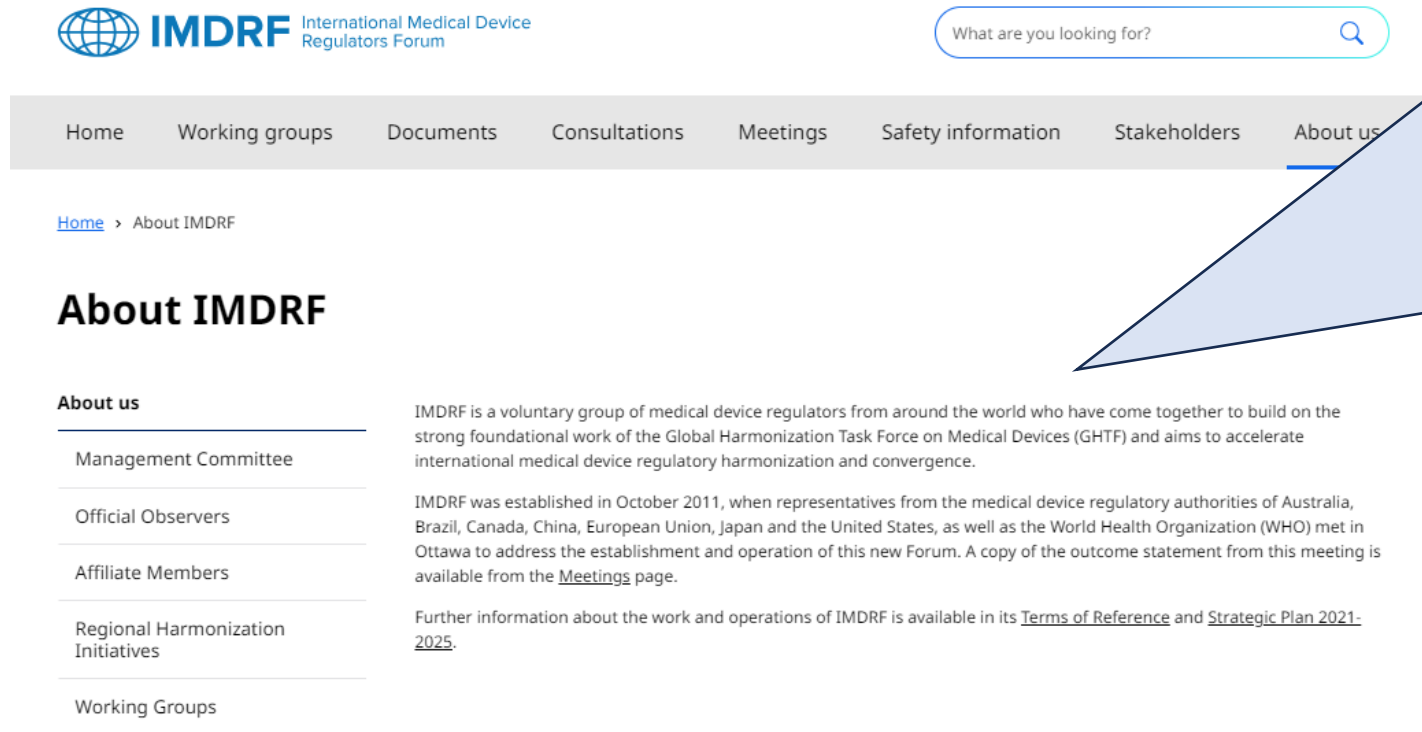
IMDRF International Medical Device
Regulators Forum

Overview, Framework, Strategic Plan

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IMDRF: Background & Overview



The screenshot shows the 'About IMDRF' page on the IMDRF website. At the top left is the IMDRF logo (a globe) and the text 'IMDRF International Medical Device Regulators Forum'. To the right is a search bar with the placeholder text 'What are you looking for?'. Below the search bar is a navigation menu with links: Home, Working groups, Documents, Consultations, Meetings, Safety information, Stakeholders, and About us. The 'About us' link is highlighted. Below the navigation menu is a breadcrumb trail: 'Home > About IMDRF'. The main heading is 'About IMDRF'. On the left side, there is a sidebar with a heading 'About us' and a list of links: Management Committee, Official Observers, Affiliate Members, Regional Harmonization Initiatives, and Working Groups. The main content area contains two paragraphs of text. The first paragraph states: 'IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.' The second paragraph states: 'IMDRF was established in October 2011, when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as the World Health Organization (WHO) met in Ottawa to address the establishment and operation of this new Forum. A copy of the outcome statement from this meeting is available from the [Meetings](#) page.' Below the second paragraph, it says: 'Further information about the work and operations of IMDRF is available in its [Terms of Reference](#) and [Strategic Plan 2021-2025](#).'

“IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.”
www.imdrf.org

- United to pursue regulatory convergence for medical devices.
- Started in 2011
- Rooted in work laid by Global Harmonization Task Force (GHTF) on medical devices

IMDRF Organizational Structure

 **IMDRF** International Medical Device Regulators Forum

Final Document

IMDRF/MC/N2FINAL:2024 (Edition 12)

IMDRF Standard Operating Procedures

AUTHORING GROUP
IMDRF Management Committee

24 June 2024



- **Management Committee:** Health Authorities from various regions overseeing the Forum’s strategies, policies and directions.
- **Official Observers:** Contributes to oversight activities, including participation in closed sessions of the management committee.
- **Affiliates**
 - **Affiliate Members:** Regulatory Authorities who join and engage in IMDRF activities, opening doors to convergence activities and IMDRF working groups
 - **Regional Harmonization Initiatives:** play an important role supporting additional collaboration between regulators and the exchange of knowledge and information to promote convergence.
- **Technical Working Groups:** groups are established by the IMDRF MC to undertake defined work tasks (e.g. development of technical documents, training material), as identified in the work plan.

Current IMDRF Technical Working Groups

Working groups

[RSS feed](#) 



Adverse Event Terminology

Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.



Artificial Intelligence/Machine Learning-enabled

Seeking to harmonize internationally, principles to help promote the development of safe and effective AI/ML enabled medical devices



Clinical Evidence for In Vitro Diagnostic Medical Devices

A working group on Clinical evidence for in vitro diagnostic (IVD) medical devices



Good Regulatory Review Practices

Develop good review practices for pre-market reviews and evaluations.



Personalized Medical Devices (PMD)

Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.



Quality Management Systems

Ensure alignment of IMDRF QMS and risk management documents with current international standards



Regulated Product Submission

Harmonize the format and content of regulatory submissions.



Software as a Medical Device

Promote consistency in regulatory assessment for Software as a Medical Device to reach patients more efficiently.

www.imdrf.org/working-groups

IMDRF Documents, Meeting Materials, Consultations



Documents

IMDRF documents support regulatory harmonization and convergence of IMDRF.

Please note that Working Group Chairs and Members requiring access to the **current** IMDRF documentation templates should email requests to the Secretariat at IMDRF2024@fda.hhs.gov


 **Technical documents**
Final documents produced by a working group

 **GHTF final documents**
Final documents created by the Global Harmonization Task force (GHTF) that are still current.

 **Procedural documents**
Operational planning and guidance

 **Information documents**
Reference material for IMDRF members

 **Meeting outcome statements**
Official meeting summaries including MC decisions

 **GHTF archives**
Historical information and archived documents produced by the Global Harmonization Task Force (GHTF)

Management committee meetings

Filter by year

- 2024
- 2023
- 2022
- 2021
- 2020
- 2019
- 2018
- 2017

Seattle, Washington USA (hosted by USA)

Meeting no: 26 Date: 16 September 2024 - 20 September 2024 Location: Seattle, Washington, USA

Washington DC, USA (hosted by USA)

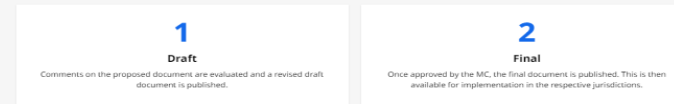
Meeting no: 25 Date: 11 March 2024 - 15 March 2024 Location: Washington DC

Berlin, Germany (hosted by European Commission on behalf of the EU)

Meeting no: 24 Date: 25 September 2023 - 29 September 2023 Location: Berlin

Consultations

How it works



Current consultations

Considerations for the Selection of IMDRF Adverse Event Terminology

The objective of this document is to provide further guidance on the correct application and consistent use of the terminology. The document provides guidance for all stakeholders:

- providing general coding principles on reporting incidents using IMDRF codes;

Started: 10 October 2024

Closing: 8 January 2025

[View details](#)

Closed consultations

[View closed consultations archive](#)

European Commission on behalf of the EU)

March 2023 Location: Brussels

ralia)

- 16 September 2022 Location: Australia

ralia)

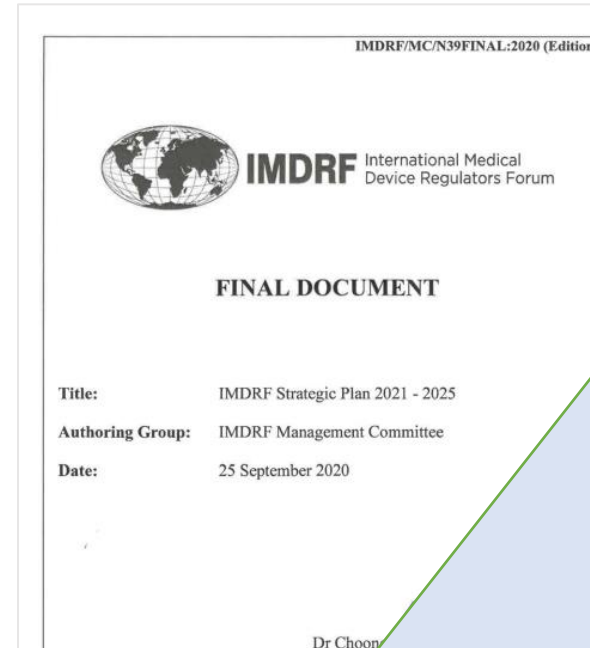
tion: Australia

Republic of Korea)

16 September 2021 Location: Republic of Korea

Republic of Korea)

IMDRF Strategic Plan 2021-2025



Over the next five years IMDRF will continue to build on its achievements from the 2020 Strategic Plan, with an emphasis on the two key objectives below:

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 life cycle processes

IMDRF Key Objectives 2021-2025

Over the next five years IMDRF will continue to build on its achievements from the 2020 Strategic Plan, with an emphasis on the two key objectives below:

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 life cycle processes

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

Treatment delayed could be treatment denied especially for critically ill patients. Therefore, in addition to ensuring the quality, safety and effectiveness of medical devices, regulators should also be facilitators ensuring patients have timely access to essential medical devices. Fostering a transparent, well-defined regulatory process to demonstrate safety and effectiveness could significantly speed up the total time taken for safe and priority medical device innovations to reach patients. IMDRF will continue to proactively identify useful innovative areas and set up working groups to develop clear guidance to support prospective regulatory convergence in these areas.

IMDRF will continue to work collaboratively within the MC and also with various external stakeholders³ and partners to share information and knowledge on an on-going basis. This includes working with standards setting bodies to play an active role in ensuring that international standards continue to be effective tools in conforming to essential principles for safety and performance for medical devices.

³ medical devices industries, other regulators, international organizations, standards development organizations, patient and professional associations, and academia, in IMDRF working groups, as appropriate.

IMDRF also seeks to promote further development of useful and relevant international standards for innovative technologies in medical devices to enhance their safety and effectiveness.

In addition, IMDRF has also embarked on a challenging journey towards achieving a single pre-market review process for medical devices. We are currently developing the building blocks and working towards all MC members receiving the same set of information in the pre-market submissions.

IMDRF Key Priorities 2021-2025

IMDRF Key Priorities 2021-2025

To improve accessibility to safe medical devices, key areas of opportunity arise in achieving greater global convergence of pre- and post-market requirements and regulatory reviews.

Priority areas

To deliver our key objectives, IMDRF will prioritise work on:

1. Pre-market
2. Post-market
3. Relationships with stakeholders

The priority areas are interdependent. Success will require concerted action across all these areas.

Plan of Action

In this section we describe each of our priority areas and the initiatives that will support their achievement. The initiatives provide an ambitious but achievable program of work. However, they are not intended as a prescriptive roadmap and are not an exhaustive list of everything we will do. We know that constant change is part of our environment and we will be ready to adapt and respond to new opportunities and challenges that emerge over the next five years.

Measures of success

For our Strategic Plan to be successful the outcomes must also be measurable.

The IMDRF MC will monitor and report on the progress of its work and implementation of IMDRF outputs.



Priority 1: Pre-Market

Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices.

The innovation landscape is rapidly evolving and this calls for more tailored and fit for purpose regulatory requirements. Promoting harmonized pre-market review requirements will improve transparency and predictability to stakeholders enabling timely access to safe and effective medical devices for patients.

For each topic, the following steps will occur to deliver IMDRF outputs:

- ✓ Consultation undertaken with stakeholders
- ✓ Drafting of a proposal for MC consideration
- ✓ MC agreement and publishing of IMDRF outputs
- ✓ Implementation considerations and adoption by IMDRF members

PRIORITY AREA: Pre-market

Topic: Personalized Medical Devices

A tailored regulatory approach that takes into consideration the unique characteristics and risks of each of these types of devices, which is significantly different from other standard mass-produced medical devices has been proposed.

Topic: Software as a Medical Device

Develop international definitions, risk category framework, and quality management system.

Topic: Regulated Product Submissions

'Early-stage' development of Regulatory Product Submissions including, ToC for non-IVD market authorization and IVD market authorization.

Topic: Medical Device Evidence Evaluation

Improve Quantity and Quality of Clinical Data.

Topic: Good Regulatory Review Practice

Develop Good Review Practices for pre-market reviews/evaluations.

Topic: Artificial Intelligence Medical Devices (AIMDs)

Develop a harmonised approach to the management of artificial intelligence (AI) medical devices.

Priority 2: Post-Market

Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients.

Post-market regulatory controls complement pre-market requirements for medical devices. While pre-market requirements can address known and foreseeable risks, an effective post-market surveillance is necessary to manage evolving and new risks effectively. In pursuing the strategic priorities, IMDRF would seek to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

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PRIORITY AREA: Post-Market

Topic: Cyber Security

A life cycle approach to effectively manage cybersecurity risks in medical devices. Striking the right balance between pre-market and post-market requirements.

Topic: Adverse Event Terminology

Harmonize adverse event terminology to expand terminology and systems being used to code information relating to medical device adverse events.

Topic: Unique Device Identifiers

Development of non-binding rules for creating, using, and maintaining unique device identifiers and related activities.

Priority 3: Relationships with Stakeholders

IMDRF values transparency and inclusiveness. IMDRF will continue to promote close communication about IMDRF activities and outputs with stakeholders, such as:

- medical devices industries,
- other regulators,
- international organizations,
- standards development organizations,
- patient and professional associations, and
- academia, in IMDRF working groups, as appropriate.

IMDRF will continue to encourage collaboration and outreach with Regional Harmonisation Initiatives and other interested regulatory authorities. IMDRF will seek opportunities to develop stronger relationships with organizations that help advance our mission, such as standards development organizations. IMDRF will work towards promoting regulatory convergence by developing consistent training programs to facilitate harmonised regulatory approaches and consistent implementation among various jurisdictions. In addition, IMDRF will consider new membership requests based on the established IMDRF ToR and Standard Operating Procedures.

Summary, Observations, & Future

- Recent focus on reliance across regulatory systems globally (meeting topics; reliance playbook, affiliate membership trainings, etc.)
- Encourage greater partnerships and learnings amongst regulators
- Importance of training; limit misinformation and misunderstanding
- Focus on partnerships for patients across all stakeholders
- Next IMDRF Strategic Plan in 2025

More information on IMDRF's website: www.imdrf.org and can sign up to be notified of updates through IMDRF [RSS Feeds](#).