



IMDRF International Medical Device
Regulators Forum

FINAL

IMDRF/MC/N1FINAL:2022 (Edition 5)

IMDRF Terms of Reference

AUTHORING GROUP

IMDRF Management Committee

19 December 2022



Preface

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document. However, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

Copyright 2022 by the International Medical Device Regulators Forum.

A handwritten signature in black ink, appearing to read 'Tracey Duffy', with a stylized flourish at the end.

Tracey Duffy, IMDRF Chair

Contents

1. Introduction	5
1.1. Mission	5
1.2. Goals	5
1.3. Objectives	5
1.4. Scope of Activities	6
2. Governance Structure	7
2.1. Organizational Structure	7
2.2. Management Committee	7
2.3. Membership	7
2.4. IMDRF Chair	7
2.5. IMDRF Secretariat	7
2.6. Official Observers	8
2.7. Invited Observers	8
2.8. Regional Harmonization Initiatives	8
2.9. Subcommittee Creation, Termination and Renewal	9
2.10. Participation on Working Groups	9
3. Work Products	10
3.1. Document Development	10
3.2. Implementation Initiatives	10
4. IMDRF Meetings	11
4.1. Conduct of IMDRF Management Committee Meetings	11
4.2. Confidentiality	11
4.3. Public IMDRF meetings	11
4.4. Decision Making	11
5. Communication	12
5.1. IMDRF Website	12
5.2. Outcome Statement	12
5.3. Logo	12

5.4. Language	12
<hr/>	
6. Funding	13
7. Review of Terms of Reference	14
Definitions	15
Appendix A	16
IMDRF Organisation	16

DRAFT

1. Introduction

This document is intended to describe the scope and nature of activity for the International Medical Device Regulators Forum (IMDRF). This document is supported by the [IMDRF Standard Operating Procedures](#) which describe the procedures followed when revising the membership of the IMDRF Management Committee, establishing Subcommittees or Working Groups, developing IMDRF Documents or managing documents previously developed under the Global Harmonization Task Force (GHTF).

1.1. Mission

The mission of the 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.

1.2. Goals

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.

1.3. Objectives

The objectives underpinning the goals of the IMDRF are to:

- Accelerate international medical device regulatory convergence¹;
- Support innovation and timely access to safe and effective medical devices globally;
- Promote open discussion and the sharing of best practices among regulatory authorities responsible for medical device regulation;
- Facilitate frequent exchange of policy and regulatory information of common interest to regulatory authorities;
- Provide opportunities to identify commonalities and develop approaches to overcome unnecessary regulatory barriers;
- Promote prospective convergence in areas of advanced and innovative technologies;
- Enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders; and

¹ "Regulatory convergence" (hereinafter "convergence") is meant to represent a voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.

- Establish develop dialogue with other relevant organizations.

1.4. Scope of Activities

The IMDRF will pursue its goals by defining, implementing and evaluating strategic priorities so that objectives are met in an efficient and effective manner.

The IMDRF will facilitate the identification, design and implementation of activities that best meet the needs of the participants with regard to convergence. The scope of activities will include:

- Working with IMDRF participants to develop a prioritized annual work plan of activities, taking into consideration the regulatory requirements and constraints that govern each regulatory authority (with respect to the sovereignty of each regulatory authority)
- Undertaking initiatives, projects and issues of common interest and concern to regulatory authorities considering, when appropriate, the input from stakeholders
- Enhancing the knowledge about regulated medical devices through information sharing
- Facilitating mechanisms for the sharing and use of relevant information and the exchange of scientific expertise
- Complementing the goals and objectives of the Global Harmonization Task Force (GHTF) by providing a structured approach to implementing, revising and maintaining GHTF documents and, if required, develop other guidance documents to achieve convergence across global medical device regulatory activities.

The IMDRF activities and initiatives (Work Products) that further convergence may fall into several categories:

1. Governance documents (created to address procedural and decision-making matters of the IMDRF).
2. Technical documents (created to address technical matters relating to the regulation of medical devices).
3. Information documents (created to provide clarification, status, and/or needed information about a particular work item where public consultation is not needed).

These documents are published on the IMDRF [website](#) for public access and broader implementation.

2. Governance Structure

2.1. IMDRF Organizational Structure

The IMDRF Organization Structure is at Appendix A.

2.2. IMDRF Management Committee

The IMDRF Management Committee (MC) makes decisions on behalf of the IMDRF; provides strategic direction; identifies and prioritizes regulatory challenges to be addressed; determines the implementation process and monitors the work plan; and authorizes resources in support of advancing IMDRF's goals and objectives.

The IMDRF MC approves the scope of the Working Groups and monitors the performance of each Working Group via quarterly reporting at IMDRF MC Closed Session Meetings.

2.3. IMDRF Membership

The IMDRF MC membership is comprised of representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, Singapore, South Korea, United States and the United Kingdom. There are two representatives per country delegation and four representatives for the European Union delegation. This allotment does not include the Chair of the IMDRF MC, who will be considered separate from the chairing country/region delegation. Each delegation shall have equal voice in decisions regarding IMDRF.

An alternate may be designated by a delegation to replace one of its members in rare instances where the member is unable to participate in a meeting. The alternate should be fully knowledgeable on IMDRF matters and have the authority to speak on behalf of the member regulatory authority.

The IMDRF MC membership will be reviewed when required. The admission of new member organizations is an IMDRF MC decision. If it is considered, over time, that the expansion to other regulatory authorities contributes to the contemporary and foreseeable public health-missioned responsibilities, membership can be expanded, with the unanimous consent of the IMDRF MC.

The IMDRF MC members can be found [here](#).

2.4. IMDRF Chair

The Chair of the IMDRF MC will lead activities of IMDRF, including conducting all the IMDRF MC meetings. The IMDRF Chair must be from a regulatory authority and will rotate annually among the members of the IMDRF MC in conjunction with the IMDRF Secretariat function.

2.5. IMDRF Secretariat

The IMDRF Secretariat is responsible for facilitating and coordinating the work of IMDRF and the IMDRF Chair by undertaking such tasks as disseminating information, coordinating IMDRF MC meetings and maintaining a repository of documents and the tools of communication such as the web. The IMDRF Secretariat corresponds to the IMDRF Chair and rotates annually.

2.6. Official Observers

The IMDRF MC may designate a limited number of Official Observers to the IMDRF MC from the World Health Organization and other regulatory authorities on the basis of perceived contribution or value to IMDRF. Official Observers do not participate in the decision-making process. Official Observers must be approved by the unanimous consent of the IMDRF MC through the process described in the IMDRF Standard Operating Procedures (SOP) and, as with IMDRF Members, need to be fully knowledgeable on IMDRF matters.

Official Observers can be found [here](#).

2.7. Invited Observers

The IMDRF MC may invite an organization or regulatory authority to attend IMDRF MC meetings on the basis of perceived contribution or value to IMDRF. Invited Observers do not participate in the decision-making process and do not have voting rights. Invited observers may only attend 'Open' portions of the IMDRF MC meetings at the invitation of the IMDRF Chair.

2.8. Affiliate Members

Regulatory Authorities who do not yet meet the criteria of Official Observer or Invited Observer, but who would like to engage with IMDRF may apply to become an Affiliate Member and participate in open IMDRF MC meetings. Affiliate Members may participate in Open Working Groups.

2.9. Regional Harmonization Initiatives

The IMDRF seeks to maintain working relationships with other international entities or regional organizations called "Regional Harmonization Initiatives (RHIs)" that have a mutual interest in medical device regulatory activities that are directly related to the common goals of fostering global convergence, leveraging resources and making available safe and effective medical devices globally.

An RHI participate in an IMDRF MC meeting by invitation of the IMDRF Chair. RHIs do not participate in the decision making process. RHIs must be approved by the unanimous consent of the IMDRF MC through the process described in IMDRF SOP.

An RHI may nominate up to two (2) regulators to attend the IMDRF MC meetings. The regulators representing the RHI may not already be a member of the IMDRF MC or Official Observer for their specific country or jurisdiction. The regulators representing the RHI must consistently represent the RHI for a period of 12 -24 months and then optimally rotate to a different regulatory authority or jurisdiction per a procedure developed by the RHI. The regulators representing the RHI must agree to keep all non-public discussions of the IMDRF MC confidential.

2.10. Subcommittee Creation, Termination and Renewal

Subcommittees (SC) are groups that are established by the IMDRF MC to draft policy documents that are created to address governance, procedural and decision making matters of the IMDRF, or other matters that are not appropriate for a Working Group. SCs may cover such issues as training, communication and document maintenance including GHTF documents. The IMDRF MC may redefine the mandate, charge new tasks, appoint/reappoint the SC Chair, create a new or terminate an existing SC.

2.11. Participation on Working Groups

A Working Group (WG) will be constituted in terms of size and representation as determined by the IMDRF MC. WGs responsible for developing technical documents, would generally involve the participation of stakeholders that have significant involvement in the development, manufacture or use of medical devices including, but not limited to, regulated industry, international entities and associations, academia, patient and consumer groups, medical professionals, and other regulatory authorities.

WGs responsible for developing technical documents that involve the exchange of sensitive or confidential information or involve the specific practices or procedures of the regulatory authorities, would be comprised exclusively of representatives from regulatory authority members. When WGs of regulatory authorities only are formed, the IMDRF MC will provide a clear and transparent justification for the limitation of membership on these WGs.

Nomination of Members, including the WG Chair, must be endorsed by the IMDRF MC. If a WG is to include stakeholders, these stakeholders should be nominated/selected based upon their expertise in the specific subject matter and their ability to actively contribute to the activities of the WG.

2.12. IMDRF Membership Status Change

IMDRF MC Members, Official Observers and Affiliate Members may have their IMDRF Membership suspended or terminated by the IMDRF MC or individual IMDRF Members may voluntarily withdrawal from the IMDRF at any time.

3. Work Products

Regulators and stakeholders may propose, in writing, projects and work items to the IMDRF MC for their consideration. These proposals can come through formal submissions to the IMDRF MC. The IMDRF MC is responsible for evaluating and deciding on all proposals and their priorities, and will instruct the development of the work plan to include the agreed upon projects. The IMDRF MC may limit the number of projects undertaken based on available resources, feasibility and member interest.

3.1. Document Development

The IMDRF undertakes initiatives and projects to address issues of common interest and concern to regulatory authorities. The key work products produced from the agreed work plan priorities consist of governance documents and technical documents.

The governance documents are consensus driven documents and are applicable to all MC members once approved by the IMDRF MC.

Technical documents relating to the regulation of medical devices will be developed to reflect the regulators' efforts to achieve convergence of regulatory practices across a specific area.

IMDRF documents can be found [here](#).

3.2. Implementation Initiatives

IMDRF MC member organizations may, in exceptional cases, decide to opt-out of or delay involvement in implementation initiatives or involvement in the development of technical documents. This could, for example, occur due to constraints presented by existing regulatory systems, decisions to delay involvement until the conclusion of a pilot or because the initiative addresses the concerns of a subset of IMDRF MC members.

4. IMDRF Meetings

The IMDRF MC will meet face-to-face biannually in March and September of each calendar year. In exceptional circumstances, the IMDRF MC may choose to hold hybrid meetings (in person and virtual attendance) should situations arise that prevent IMDRF MC members from attending the face-to-face meetings. The biannual meetings will be conducted in plenary with three successive sessions:

- a public IMDRF meeting with a structured dialogue between the IMDRF MC and stakeholders to provide input to planning strategies and suggestions for work items, exchange information with the MC, and discuss work products;
- an IMDRF MC caucus with reports from SCs and WGs (this may include closed and open sessions); and
- an IMDRF MC caucus, with adoption of the IMDRF MC meeting's report at the close.

In addition to face-to-face meetings, the IMDRF MC will have periodic web/teleconferences. There will also be periodic web/teleconferences with SCs and WGs in order to provide appropriate follow-up on work items.

4.1. Conduct of IMDRF Management Committee Meetings

IMDRF MC Meetings are generally attended by the Chair, MC members, Secretariat, Official Observers, Affiliate Members, Invited Observers and RHIs. Where a discussion item is designated 'closed', only the IMDRF Chair, MC members, Secretariat and Official Observers may attend. RHIs may attend in portions of the 'closed' session by invitation of the IMDRF Chair. Discussion items may be designated as 'closed' at the discretion of the IMDRF Chair. The IMDRF MC may invite an expert to a certain session of the IMDRF MC meeting by meeting basis.

4.2. Confidentiality

Discussions and outcomes of the closed IMDRF MC meetings as well as communications amongst IMDRF MC Members and Official Observers will be kept confidential unless the IMDRF MC Members unanimously agree to make some or all of the discussions/communications public.

4.3. Public IMDRF Meetings

In conjunction with the schedule of various IMDRF MC meetings, there will usually be a public IMDRF hybrid meeting biannually, to which all interested stakeholders are welcome. These public IMDRF meetings will provide an opportunity for broad dialogue on possible work items, planning strategies, updates from regulatory authorities or other issues.

4.4. Decision Making

All parties are committed to the goals and objectives of IMDRF and to making best efforts to reach consensus. The IMDRF MC will reach decisions by consensus and not voting. However, in exceptional cases, IMDRF MC member organizations may opt-out of decisions on implementation initiatives. The IMDRF MC will handle other exceptional instances where full consensus cannot be reached on a case-by-case basis.

5. Communication

5.1. IMDRF Website

A web hosting site for document sharing and information postings will be supported by IMDRF through a contract held by an IMDRF MC member. The member would provide the webmaster services and would work with the IMDRF Secretariat to maintain current postings to the web site or other shared location.

The IMDRF website can be found www.imdrf.org.

5.2. Outcome Statement

The IMDRF MC will issue an outcome statement of each biannual face-to-face meeting. The outcome statement will include an overview of the meeting as well as the IMDRF MC's decisions made during the meeting.

5.3. Logo

The IMDRF logo is to be used to brand activities and documents approved by the IMDRF MC.

5.4. Language

The working language of IMDRF is English. Meetings will be conducted in English and documents will be distributed in English. It is each region's responsibility to translate any documents into additional languages as needed.

6. Funding

IMDRF MC Members, Official Observers, Affiliate Members, Invited Observers, RHIs and stakeholders are responsible for their own travel to and from the meeting site and their accommodations.

DRAFT

7. Review of Terms of Reference

The Terms of Reference will be considered for review annually, at the occasion of the rotation of the IMDRF Chair, to ensure they reflect the current goals and objectives of the IMDRF.

DRAFT

Definitions

Acronym	Acronym Meaning
IMDRF	International Medical Devices Regulators Forum
SOP	Standard Operating Procedure
GHTF	Global Harmonization Task Force
Convergence	Regulatory convergence
RHIs	Regional Harmonization Initiatives

DRAFT

Appendix A

IMDRF Organization

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

