



**IMDRF** International Medical  
Device Regulators Forum

## Final Document

**Title:** IMDRF Terms of Reference  
**Authoring Group:** IMDRF Management Committee  
**Date:** 17 December 2014

A handwritten signature in black ink, appearing to read 'J. Shuren', with a long horizontal flourish extending to the right.

Jeff Shuren, IMDRF Chair

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 © 2014 by the International Medical Device Regulators Forum.

# International Medical Device Regulators Forum

## Terms of Reference

### I. Introduction

#### A. Mission

The mission 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.

#### B. Goals

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.

#### C. Objectives

The objectives underpinning the goals of IMDRF are to:

- Accelerate international medical device regulatory convergence
- 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
- Establish develop dialogue with other relevant organizations.

<sup>1</sup> "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.

## **D. Scope of Activities**

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

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.

IMDRF activities and initiatives (work products) that further convergence may fall into three 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); and,
3. information documents (created to provide clarification, status, and/or needed information about a particular work item where public consultation is not needed).

## **II. Governance Structure**

### **A. Organization Structure**

See Appendix A

### **B. Management Committee**

The 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.

## **Membership**

MC membership is comprised of representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation and the United States. There are two representatives per country delegation and four representatives for the European Union delegation. This allotment does not include the Chair of the 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.

MC membership will be reviewed when required. The admission of new member organizations is a 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 MC.

## **Chair**

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

## **Secretariat**

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

## **Official Observers**

The Management Committee may designate a limited number of Official Observers to the MC from the World Health Organization, other regulatory authorities, or Affiliate Organizations (as outlined below) 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 MC and, as with Members, need to be fully knowledgeable on IMDRF matters.

## **Invited Observers**

The MC may invite a person or organization to attend a MC meeting on the basis of perceived contribution or value to IMDRF. Invited Observers do not participate in the decision making process, and attend meetings or portions of the MC meetings at the invitation of the Chair.

## **Affiliate Organizations**

IMDRF seeks to maintain working relationships with other international entities, regional organizations, or "Affiliate Organizations" 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 Affiliate Organization may be invited to attend a MC meeting as an Official Observer or an Invited Observer.

An Affiliate Organization that wishes to become an Official Observer must meet the follow criteria and must be approved by the unanimous consent of the MC:

- A regulators only portion of the Affiliate Organization will be the IMDRF Official Observer with a maximum of two representatives attending IMDRF MC meetings and teleconference;
- The regulators representing the Affiliate Organization may not already be a member of IMDRF Management Committee for their specific country or jurisdiction;
- The regulators representing the Affiliate Organization must be from a regulatory authority that has had appropriate medical device legislation/regulations in place for a minimum of three years;
- The regulators representing the Affiliate Organization must agree to keep all non-public discussions of the IMDRF MC confidential;
- The regulators representing the Affiliate Organization should have several years' experience in international and/or regional harmonization initiatives;
- The regulators representing the Affiliate Organization must consistently represent the Affiliate Organization for a period of 12 -24 months and then optimally rotate to a different regulatory authority or jurisdiction per a procedure developed by the Affiliate Organization; and,
- The regulators representing the Affiliate Organization will provide a written report of each IMDRF Management Committee meeting to their Affiliate Organization, will make a brief presentation at each MC meeting updating the IMDRF MC on activities within their Affiliate Organization, and be responsible for collecting and collating comments on any IMDRF documents out for consultation or other issues where their Affiliate Organization opinion is requested by the MC.

### **Subcommittees Creation/Termination/Renewal**

Subcommittees (SC) are groups that are established by the 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 MC may redefine the mandate, charge new tasks, appoint/reappoint the SC Chair, create a new or terminate an existing SC.

### **Participation on Working Groups**

A Working Group (WG) will be constituted in terms of size and representation as determined by the 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 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 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.

### **III. Work Products**

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

#### **Document Development**

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 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.

#### **Implementation Initiatives**

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 MC members.

### **IV. Meetings**

IMDRF will initially meet face-to-face biannually dependent on the Chair/Secretariat, who is responsible for hosting the meetings. The biannual meetings will be conducted in plenary with three successive sessions:

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

In addition to face-to-face meetings the 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.

## **Conduct of MC Meetings**

MC Meetings are generally attended by the Chair, MC members, Secretariat, Official Observers and Invited Observers. Where a discussion item is designated 'closed', only the Chair, MC members, Secretariat and Official Observers may attend. Discussion items may be designated as 'closed' at the discretion of the Chair.

## **Confidentiality**

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

## **Public IMDRF meetings**

In conjunction with the MC's bi-annual face-to-face meetings, there will usually be a public IMDRF meeting, to which all interested stakeholders are welcome. This public meeting will provide an opportunity for open discussions on possible work items, planning strategies or other issues.

## **Decision Making**

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

## **V. Communication**

### **Website**

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

### **Annual Report**

The MC will issue a public annual report of activities and accomplishments of IMDRF.

### **Logo**

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

### **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.

## **VI. Funding**

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

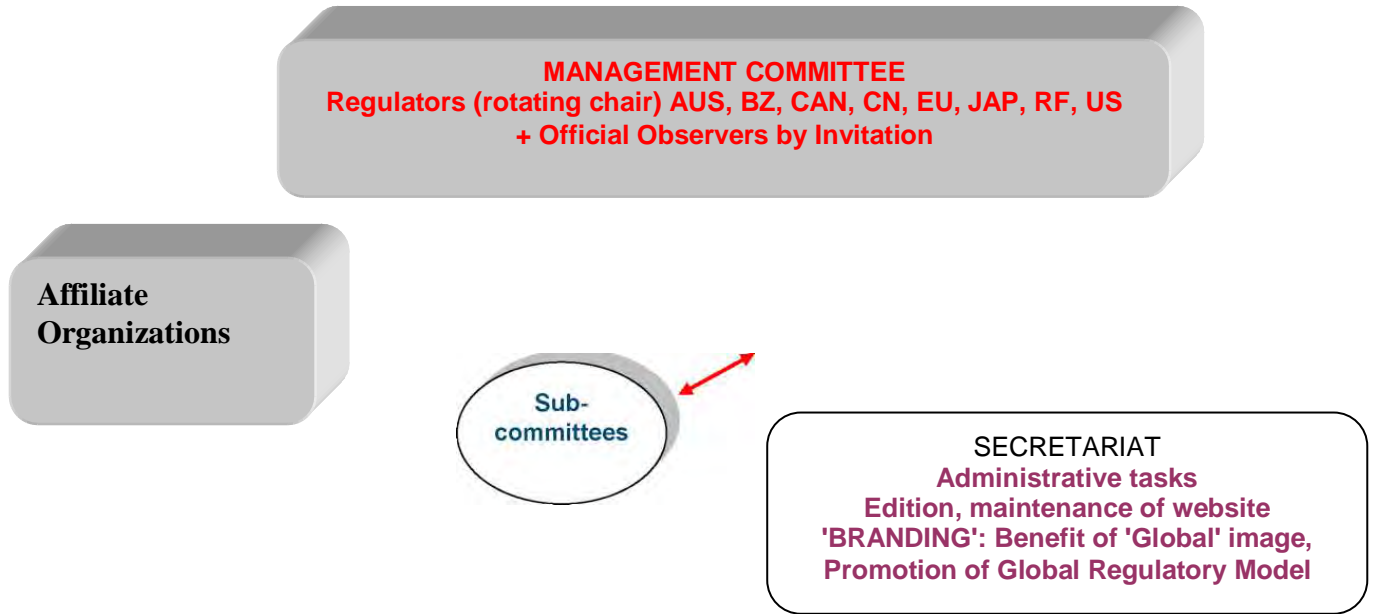
## **VII. Review of Terms of Reference**

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



Appendix A - IMDRF Organization

**INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM**



**MANAGEMENT LEVEL** *Decision Making, strategic direction, work plan monitoring*



**OPERATIONAL LEVEL** *Technical document development*