International Harmonization and the International Medical Device Regulators Forum (IMDRF)

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International harmonization means patients have better access to safe, effective, high-quality, and innovative medical devices.

- The medical device sector has become increasingly globalized and complex.
- Each economy may develop and implement its own regulatory requirements and its own path to market products, especially as emerging technologies are considered.
- This means regulatory authorities must administer, and industry must navigate adherence to, numerous and sometimes redundant regulatory requirements.
- Reducing these inefficiencies through harmonization, convergence, and reliance on the work of others promotes a more effective regulatory model for medical devices.
- Ultimately, a more efficient and effective model means patients globally have better access to safe, effective, innovative, and high-quality medical devices.

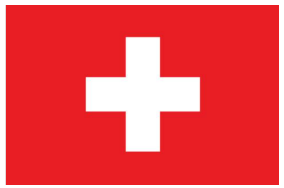
IMDRF Background

- Launched in February 2012
- Successor to the Global Harmonization Task Force (GHTF)
- Chair and secretariat rotate on annual basis, beginning with Australia (2012), EU (2013), US (2014), Japan (2015), Brazil (2016), Canada (2017), China (2018), Russia (2019), Singapore (2020), S. Korea (2021), Australia (2021)
  - Europe is the current IMDRF Chair, US will chair in 2024
- Decisions are made by consensus, not voting
- 2 in person meetings per year (March and September)
  - Includes public stakeholder session which provides updates from MC members, IMDRF working groups, RHIs, industry associations, etc.
- 2 teleconferences per year (January and June)
- Working groups develop internationally harmonized documents on premarket and postmarket topics.

Affiliate Members

Official Observers

World Health Organization



Regional Harmonization Initiatives

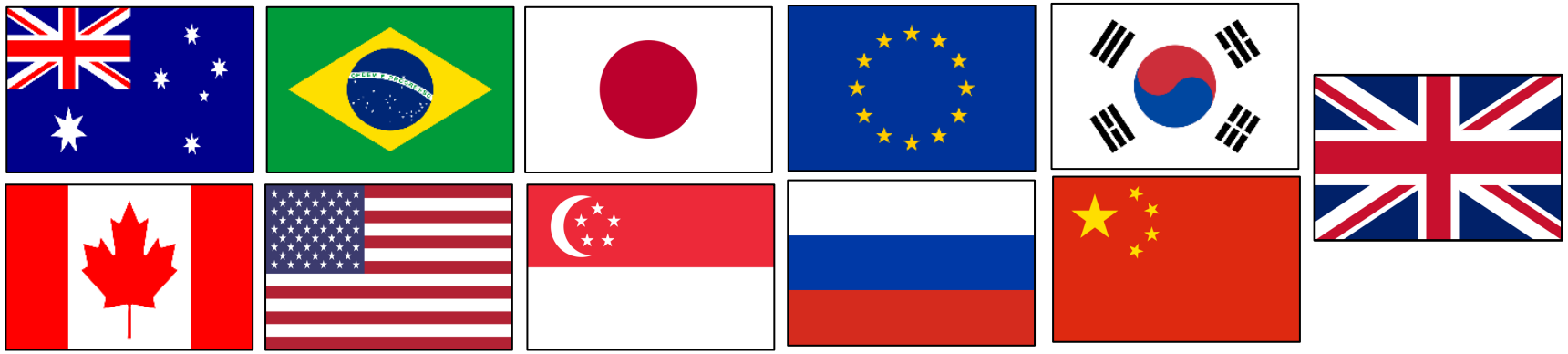
APEC
Asia-Pacific Economic Cooperation

African Medical Devices Forum

Pan American Health Organization

GHWP
Global Harmonization Working Party
Towards Medical Device Harmonization

Management Committee (MC) Members



FDA

IMDRF
International Medical Device Regulators Forum

www.imdrf.org

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Current Working Groups

FDA

Good Regulatory Review Practices
- Chairs: US and Singapore

Regulated Product Submission
- Chairs: US and Canada

Cybersecurity
- Chairs: US and Canada

Software as a Medical Device
- Chair: US and Canada

Adverse Event Terminology
- Chairs: US and Germany

Artificial Intelligence
- Chair: US and UK

Personalized Medical Devices
- Chair: Australia

Quality Management Systems
- Chair: US and Europe

Some working groups include industry representatives
Harmonized documents are created by each WG within 12-18 months

IMDRF
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Closed Working Groups

FDA

- Medical Device Single Audit Program (MDSAP)
- Standards
- Unique Device Identification (UDI)
- National Competent Authority Report (NCAR)
- Patient Registries
- Clinical Evaluation
- Principles of In Vitro Diagnostic Medical Device Classification

IMDRF Membership and Engagement Benefits

- Gain perspective from regulators around the world that have varied regulatory systems in place
  - Reliance models versus fully implemented TPLC regulatory systems and everything in between
- Resource conservation
  - Saves time, money, manpower, and facilitates bringing high quality products to market when IMDRF principles are followed
- Proposed documents
  - Proposed documents put out by WGs are available on the IMDRF website
  - Gives anyone the ability to see the direction and thought process of the active WGs
- Participation in Open Sessions
  - A RA, global industry association, or stakeholder association can request to attend IMDRF Open Sessions as an Invited Observer

How to Participate in IMDRF

- Comment on proposed documents:
  - http://www.imdrf.org/consultations/consultations.asp
  - Posted shortly after meetings (January, March, June, September)
- Participate in IMDRF Working Groups when possible
- Participate through Regional Harmonization Initiatives
- Apply for Affiliate Membership
- Attend IMDRF Meetings
  - Face to face meetings always in March and September
    - Usually 3rd week of each of the months
  - Next meeting:
    - Berlin, Germany September 25-26, 2023

Implementation of IMDRF Documents

- IMDRF and GHTF documents should be adopted with no revisions when possible.
- Participation and engagement in IMDRF is key to ensure that requirements in documents do not conflict with jurisdictional requirements:
  - Participate in working groups
  - Attend meetings
  - Comment on draft documents
  - Apply for membership

Membership Categories

- Member
- Official Observer
- Affiliate Member
- Regional Harmonization Initiative

IMDRF Standard Operating Procedures | International Medical Device Regulators Forum

IMDRF Membership Application Form | International Medical Device Regulators Forum

IMDRF Membership
Affiliate Member

- Must be a Regulatory Authority
- Have a recognized commitment to the objectives of IMDRF demonstrated by implementation or a plan for implementation of IMDRF documents
- Commit to provide annual updates on the implementation of IMDRF documents at Management Committee meetings

IMDRF Membership
Official Observer

- Must be a Regulatory Authority
- Operate a mature or maturing system for medical device regulation which should include:
  - Established laws and regulations for medical devices building substantially on GHTF and IMDRF foundations and principles
  - Proper competencies for effective implementation and enforcement of the established laws and regulation
  - A system for conformity assessment of devices building on GHTF and IMDRF guidance documents, and sufficient resources and regulatory expertise to perform its duties

IMDRF Membership
Official Observer (cont.)

- Contribute to scientific or regulatory innovation in the field of medical devices as demonstrated by development of guidance(s) in emerging technical and regulatory issues
- Have the capacity to contribute resources and expertise to the objectives of IMDRF by participation in public IMDRF meetings for the last 2 consecutive years, participation in at least two Working Groups the last 2 consecutive years as observers, and providing input to document consultations
- Have a recognized commitment to the objectives of IMDRF demonstrated by implementation of IMDRF documents

IMDRF Membership Member

- Must be a Regulatory Authority
- Have been a regional influence
- Participate in all IMDRF MC meetings (including teleconferences) for the last 2 consecutive years
- Participate in a majority of Working Groups as an Official Observer for the last 2 consecutive years, providing active contribution
- Have been an Official Observer for at least the last 2 consecutive years prior to the application for membership
- Have sufficient capacity to chair the MC and provide the Secretariat for a year, including hosting 2 face to face meetings and 2 scheduled teleconferences

From a U.S. perspective, we use and recommend IMDRF technical documents.

As one example, the document “Principles of Conformity Assessment for Medical Devices” (GHTF/SG1/N78:2012) provides an overview of the elements of a medical device regulatory framework.

There are 5 conformity assessment elements included in the document “Principles of Conformity Assessment for Medical Devices” (GHTF/SG1/N78:2012).

- Quality management system (QMS)
- System for post-marketing surveillance
- Technical documentation
- Declaration of conformity
- Registration of manufacturers and their medical devices by the Regulatory Authority

Reliance is a key strategy for regulatory authorities, especially considering resource constraints and opportunities to encourage innovation and improve patient access through international harmonization.

Thank You/Questions?