The International Medical Device Regulators Forum (IMDRF)External Link Disclaimer is a group of medical device regulators from around the world that have voluntarily come together to harmonize the regulatory requirements for medical products that vary from country to country.

The current IMDRF members represent medical device regulatory authorities in:

- Australia - Therapeutic Goods AdministrationExternal Link Disclaimer
- Brazil - Brazilian Health Regulatory Agency (ANVISA)External Link Disclaimer
- Canada - Health CanadaExternal Link Disclaimer
- China - National Medical Products AdministrationExternal Link Disclaimer
- European Union - European Commission - Directorate-General for Health and Food SafetyExternal Link Disclaimer
- Japan - Pharmaceuticals and Medical Devices AgencyExternal Link Disclaimer and the Ministry of Health, Labour and WelfareExternal Link Disclaimer
- Singapore - Health Sciences AuthorityExternal Link Disclaimer
- South Korea - Ministry of Food and Drug SafetyExternal Link Disclaimer
- United Kingdom - Medicines and Healthcare products Regulatory AgencyExternal Link Disclaimer
- United States - U.S. Food and Drug Administration

The World Health Organization (WHO), Argentina, Saudi Arabia, and Switzerland are Official Observers. The Asia Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum's (LSIF) Regulatory Harmonization Steering Committee, the Global Harmonization Working Party (GHWP), the Pan American Health Organization (PAHO), and the African Medical Devices Forum (AMDF) are Regional Harmonization Initiatives with IMDRF. IMDRF Affiliate Members include medical device regulatory authorities from Botswana, Chile, Chinese Taipei, Costa Rica, Cuba, Dominican Republic, Egypt, El Salvador, Ethiopia, India, Israel, Jordan, Kenya, Mexico, Montenegro, Nigeria, Oman, Paraguay, Peru, South Africa, Tanzania, and Zimbabwe.

As the U.S. member, the FDA actively participates in the IMDRF management committee as well as on IMDRF working groupsExternal Link Disclaimer including:

- Adverse Event Terminology,
- Artificial Intelligence/Machine Learning-Enabled,
- Good Regulatory Review Practices,
- Personalized Medical Devices,
- Quality Management Systems (QMS),
- Regulated Product Submission, and
- Software as a Medical Device (SaMD).

IMDRF develops internationally agreed-upon documents related to a wide variety of topics affecting medical devices. Draft IMDRF documents are available for public review and comment for a period of 60-90 days. IMDRF Management Committee members, observers, affiliate members, regional harmonization initiatives and affiliate organizations will often solicit feedback from their stakeholders on these draft documents. In some cases—such as when the IMDRF document conveys guidance—the FDA may also solicit feedback on the draft IMDRF documents by publishing a notice of availability of the guidance for public comment in the *Federal Register*.

When finalized, IMDRF members adopt these documents where appropriate, and in some cases adapt them to meet the regulatory requirements of their jurisdictions. Because IMDRF documents vary in nature, from standard operating procedures (SOPs) and terminology to policy documents, FDA adoption of these documents will differ depending on the type of document. For example, the FDA may adopt an IMDRF document that describes policies as an FDA guidance document, when the document meets the definition of an FDA guidance document (per 21 CFR 10.115). Since the policies and concepts within IMDRF documents are often broad, FDA may also issue additional guidance documents or update existing guidance documents to include information regarding the adoption and implementation of the policies and concepts in IMDRF documents within the FDA's regulatory framework.

For other non-guidance IMDRF documents, such as SOPs or terminology, the FDA may adopt these documents by incorporating them into existing medical device regulatory practices. The FDA committed to assess the extent of CDRH implementation of IMDRF documents and report this information publicly as part of the Medical Device User Fee Amendments of 2022 (MDUFA V). The FDA will work collaboratively with industry and other members of the medical device ecosystem to implement these harmonized documents and help assure that safe and effective medical devices are available to patients in the U.S. and globally.

Global Harmonization Task Force (GHTF)

The **Global Harmonization Task Force (GHTF)** was "a voluntary group of representatives from national medical device regulatory authorities (such as the U.S. Food and Drug Administration (FDA)) and the members of the medical device industry" whose goal was the standardization of medical device regulation across the world. The representatives from its five founding members (the European Union, the United States, Canada, Japan and Australia) were divided into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework. Founded in 1992, the GHTF was created in "an effort to respond to the growing need for international harmonization in the regulation of medical devices."

The GHTF disbanded late in 2012. Its mission has been taken over by the International Medical Device Regulators Forum (IMDRF), a successor organization composed of officials from regulatory agencies— not industry — around the world. The GHTF website is no longer operational.

Mission statement

As quoted from the GHTF site now (IMDRF), "The purpose of the GHTF is to encourage the convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation

and facilitating international trade, and the primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. These documents, which are developed by four different GHTF Study Groups, can then be adopted/implemented by member national regulatory authorities.

The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF Founding Members."

Stated succinctly, the organization aims to standardize medical device regulations around the world by exchange of information.

Membership

Founding members

The founding members consist of regulatory authorities or industry members from the EU, the United States, Japan, Australia and Canada because of their well established and high standards in medical device regulations. Members also participate in the steering committee, which can recommend the inclusion of other participants in Study Groups to be a part of all GHTF activities.

Participating members

Participating members consist of representatives from regulatory agencies or medical device trade associations not a part of the founding members. Participating members are to facilitate the adoption of as much of the GHTF's policies in their region/agency as possible within legal parameters. Participating members can also take part in Study Groups as well as other expert working groups.

Liaison bodies

Liaison bodies are public health organizations, international standard-setting bodies or other groups who can contribute to or benefit from participation in GHTF. Liaison Bodies are encouraged to promote GHTF guidelines to their members and incorporate them into their work. Liaison bodies are permitted to nominate observers for GHTF Study Groups and other expert working groups.

Observers

Observers must be nominated by members and approved by the Study Group Chair. The level of participation that an Observer is granted is also decided by the Study Group Chair.

Operating structure

Steering committee

The purpose of the Steering Committee is to provide policy and direction for the GHTF. It is responsible for the assignment and oversight of new work items, adopt and monitor GHTF guidance documents and the authorization and promotion of GHTF training events.

The Steering Committee members consist of up to 8 members from each of the Founding Members' regions. Of the 8 members, up to 4 may be from the regulatory sectors and up to 4

from the industry sectors. The Chain and Vice Chair members of the controlling region are not to be included in this number.

Study groups

There are five study groups in the GHTF, each with a different focus. The size of each Study Group is to be determined by the Study Group Chair. Recommended members include one participant from each region with founding member status as well as appropriate numbers from regulatory agencies and industry technical experts.

Study Group 1

Study Group 1 is concerned with the current medical device regulatory systems. From examining the current field, the group isolates the principles suitable for harmonization as well as those that pose a threat to harmonization. The Group also deals with the standardization of pre-market submissions and product labelling.

Examples of documents put out by Study Group 1 include Principles of Medical Devices Classification, and Labelling for Medical Devices.

Study Group 2

Study Group 2 is concerned with medical device vigilance such as medical device reporting and post market surveillance. The Group is designed to harmonize the data collection and reporting systems of the industry. Examples of documents put out by Study Group 2 include Medical Devices Post Market Surveillance: Content of Field Safety Notices, Manufacturer's Trend Reporting of Adverse Events and National Competent Authority Report Exchange Criteria including reference to the use of the GMDN.

Study Group 3

Study Group 3 is concerned with examining and harmonizing current quality systems requirements. Examples of documents put out by Study Group 3 include Implementation of Risk Management Principles and Activities Within a Quality Management System and Quality Management Systems - Process Validation Guidance.

Study Group 4

Study Group 4 is concerned with examining current quality systems auditing practices and the harmonization of the auditing process. Examples of documents put out by Study Group 4 include Training Requirements for Auditors and Guidelines for Regulatory Auditing of Quality Management.

Study Group 5

Study Group 5 is concerned with the convergence of clinical practices. This includes the harmonization of clinical terms, reports and evaluations. Study Group 5 has yet to produce any final documents, but areas of proposed topics include Clinical Evaluation and Clinical Evidence.

Study Group Chair

The Study Group Chair member is appointed for a three-year term by the Steering Committee. Upon completion of the term, the Chair is re-evaluated by the Steering Committee based on the needs of the Study Group. The support of a Vice Chair member usually consists of a member from the industry in a different region from the Chair.

Global Medical Device Nomenclature (GMDN)

Global Medical Device Nomenclature (GMDN) is a system of internationally agreed generic descriptors used to identify all medical device products. This nomenclature is a naming system for products which include those used for the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

The Global Medical Device Nomenclature (GMDN) is the leading global standard for the naming, classification and categorisation of medical devices. Anyone can register for free as a member on the GMDN website to access and use any GMDN Term.

The GMDN provides Healthcare Professionals, Regulators, Manufacturers and others with a common language to communicate and share information.

GMDN enables safer and more effective patient care, fosters innovation and collaboration in the medical device industry, and supports global harmonisation of regulatory requirements.

The GMDN is designed to be flexible and adaptable to accommodate new and emerging technologies, and it is continually updated to reflect changes in the medical device landscape. The system is used by Regulators in nearly 70 countries worldwide and has members in around 140 countries across the globe. It has become a critical component of the global regulatory infrastructure for medical devices.

The full GMDN is available for free to Regulators, Healthcare Providers and Academic Researchers.

Governance

The GMDN meets the need to identify medical devices at the global level, as identified in the Global Harmonization Task Force (GHTF) that have since disbanded (2012) and replaced by the IMDRF

GMDN is managed by the GMDN Agency, a non-profit organization and Registered Charity, which reports to its Board of Trustees, that represent medical device regulators and industry.

To maintain independence, the GMDN also receives scrutiny from two independent advice bodies – the Technical Advisory Group, and the Authorities Strategic Advisory Group.

Technical Advisory Group

The Technical Advisory Group (TAG) meet regularly and provide advice to the Board of Trustees on matters of relevance to the satisfactory maintenance of the GMDN, including:

- Ways to ensure that the GMDN meets International requirements of regulatory bodies, industry and other stakeholders as the primary working nomenclature.
- New and emerging international needs for nomenclatures.

- Means of ensuring that developing technologies are monitored and incorporated as appropriate.

Authorities Strategic Advisory Group

The Authorities Strategic Advisory Group (ASAG) represents medical device Regulators that use the GMDN. The ASAG's key role is to provide advice and feedback to Trustees and the GMDN Agency, including:

- Having appropriate review structures in place to ensure that relevant stakeholders, including from different regions, can provide feedback and be consulted about the GMDN supporting their needs.
- The promotion of the GMDN to encourage broader adoption and global harmonisation of the GMDN as a detailed nomenclature that underpins an efficient and effective regulatory model of safety and performance for medical devices.
- Enhancing medical device safety by use of the GMDN that facilitates and promotes data exchange and analysis.

As a regulated charity, all ASAG members and observers are volunteers and not funded for activity linked with GMDN Agency governance. The ASAG committee meet regularly, and the Trustees are invited as observers.

The committee is currently made up of representatives from the UK's Medicines and Healthcare products Regulatory Agency (MHRA), the Brazilian Health Regulatory Agency (ANVISA), the United States Food and Drug Administration (FDA), Australia's Therapeutic Goods Administration (TGA) and Health Canada.