the Global Harmonisation Task Force and its purpo

Global Harmonization Task Force

- Rationale
- Members
- Vision
- Activities

IMDRF International Medical Device Regulators Forum

17.3.3 Describe the Global Harmonisation Task Force and its purpose

Unit C 17.3 Global Medical Equipment Regulations

Module 279-17-C Regulations, Standards and Ethics

International Harmonization of Regulations: rationale

Medical devices are used worldwide. With the rapid growth in the global market for medical devices, there is a need to harmonize national standards in order to **minimize regulatory barriers, facilitate trade** and **improve access to new technologies**.

Harmonization also reduces the **cost of implementing regulations** for governments and local industry.

International Harmonization of Regulations

the **Global Harmonization Task Force**, founded in 1993, was a **voluntary** international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The purpose of the GHTF was to encourage a **convergence in standards and regulatory practices** related to the **safety**, **performance** and **quality** of medical devices.

The primary way in which the GHTF achieves its goals is through the production of **a series of guidance documents** that together describe **a global regulatory model for medical devices**. These documents can then be adopted/ implemented by member national regulatory authorities or others.

Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

The organisation GHTF no longer exists (since end-2012), and has been replaced by the IMDRF

International Harmonization of Regulations: IMDRF

The International Medical Device Regulators Forum (IMDRF) was set up in 2011 as a **forum** to discuss future directions in medical device regulatory harmonization.

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 to **accelerate international medical device regulatory harmonization and convergence.**

IMDRF International Medical Device Regulators Forum

see: http://www.imdrf.org/

IMDRF Members

The current members are:

Australia	Therapeutic Goods Administration
Brazil	National Health Surveillance Agency (ANVISA)
Canada	Health Canada
China	China Food and Drug Administration
European Union	European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Japan	Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare
Russia	Russian Ministry of Health
USA	US Food and Drug Administration

The World Health Organization (WHO) and the APEC LSIF Regulatory Harmonization Steering Committee are **Official Observers**.

The Asian Harmonization Working Party (AHWP) and the Pan American Health Organization (PAHO) are **IMDRF Affiliate Organizations**.

IMDRF: current work

IMDRF is currently progressing the following work items:

Work item	Working Group Membership	Coordinator
Adverse Event Terminology	Regulator membership	Hiroshi Ishikawa, Japan
Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers	Regulator membership	Melissa Torres, USA
Patient Registries	Regulator and stakeholder membership	Danica Marinac-Dabic, USA
Software as a Medical Device	Regulator and stakeholder membership	Bakul Patel, USA
A review of the NCAR system	Regulator membership	Jean-Francois Roche, Europe
Medical Device Single Audit Program (MDSAP)	Regulator membership	Kimberly Trautman, USA
Regulated Product Submission	Regulator only and regulator and stakeholder membership	Nancy Shadeed, Canada

this list is here only to see what sort of things the IMDRF is doing….

IMDRF: want to join?

IMDRF welcomes input and participation by medical device sector stakeholders. Participation takes places via a number of channels including:

- Participation in open member working groups
- Attendance and participation in the regular IMDRF open stakeholder forums
- Attendance as invited participants at IMDRF Management Committee meetings

The aim of IMDRF is to accelerate international medical device regulatory harmonization and convergence. For this to be achieved, close collaboration between regulators and stakeholders is essential, and in particular between regulators and the regulated industry.

Interested parties can signal their preliminary interest in attending the next open session in 2016 by contacting the IMDRF Secretariat at imdrf.secretariat@anvisa.gov.br.

- Add your name to the IMDRF stakeholder mailing list
- Make a suggestion for a work item
- Advise us of any GHTF or IMDRF Guidance documents that need updating
- View the invitation to the next Open Stakeholder Forum

END

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see https://www.thet.org/