International Medical Device Regulators Forum (IMDRF)

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What is IMDRF?

- The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, as a forum to discuss future directions in medical device regulatory harmonization. It 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). The Forum will accelerate international medical device regulatory harmonization and convergence.

Goal

- 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.

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.

“Regulatory convergence”

- “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.

IMDRF Management Committee

- The IMDRF Management Committee, composed of regulatory officials, will provide guidance on strategies, policies, directions, membership and activities of the Forum. Furthermore, the Management Committee will oversee Ad Hoc Working Groups which may draw upon expertise from various stakeholder groups such as industry, academia, healthcare professionals, consumer and patient groups.

IMDRF Management Committee

- The inaugural IMDRF Chair and secretariat is Australia.
  - **Chair:**
    Dr Larry Kelly
    Group Coordinator
    Monitoring and Compliance Group
    Therapeutic Goods Administration
    Australia
    Email: imdrf.chair@tga.gov.au

  - **Secretariat:**
    Email: imdrf.secretariat@tga.gov.au

IMDRF Management Committee

- The role IMDRF Chair and secretariat will rotate annually.

- The next IMDRF Chair and secretariat will be the European Union.

Current Composition of IMDRF

- Management Committee Members:
  - Australia
  - Brazil
  - Canada
  - Europe
  - Japan
  - US

Current Composition of IMDRF

- Observers:
  - China
  - Russian Federation
  - World Health Organization

Current Composition of IMDRF

- Invited Affiliate Organizations:
  - Asian Harmonization Working Party (AHWP)
  - Asian-Pacific Economic Cooperation (APEC)

Inaugural IMDRF Meeting

- Was held in Singapore from 28 February to 1 March 2012 and was a great success.

- IMDRF made several positive steps forward in developing the new Forum, as well as plans for transitioning several key items from the Global Harmonization Task Force by the end of 2012.

Inaugural IMDRF Meeting

- On the first day the Management Committee agreed on a Terms of Reference document, which is now available at:

  www.imdrf.org

Inaugural IMDRF Meeting

- In accordance with the Terms of Reference, the document will be reviewed annually.

- The Management Committee agreed that the next task is to develop more detailed operating procedures to cover issues such as membership criteria for the Management Committee and Working Groups, as well as procedures for document handling.

Inaugural IMDRF Meeting

- IMDRF will offer a pathway for other regulators to become new members or observers for future meetings.

Inaugural IMDRF Meeting

- The second day of the Forum was an open day attended by approximately 100 stakeholders representing a range of sectors. Constructive comments on the new work item proposals were provided, as well as more general issues such as ensuring transparency and a mechanism for management and maintenance of GHTF guidance documents.

Inaugural IMDRF Meeting

- The final day of the meeting, after further discussion of the proposals and taking into account comments received, the Management Committee agreed to progress five Working Group items.

IMDRF Work Items

A Review of the NCAR system

- The NCAR Exchange Program facilitates the exchange of relevant post market safety information on medical devices with global distribution. The aim is to trigger rapid adoption of field safety corrective actions in all concerned geographies to avoid death or serious deterioration of health, when relevant.

IMDRF Work Items

A Review of the NCAR system

- This work will review the current arrangements and advise on opportunities for improvement and possible expansion of the system to also include select pre-market decisions and other post-market actions.
- *Regulator membership*
- *Coordinator: Isabelle Demade, Europe*

IMDRF Work Items

Roadmap for implementation of UDI system

- This item seeks to define the path to implementing a globally harmonized approach to a uniform device identification system, and builds on the earlier work of GHTF.
- *Regulator and stakeholder membership*
- *Coordinator: Laurent Selles, Europe*

IMDRF Work Items

Medical Device Single Audit Program (MDSAP)

- The Work Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.

IMDRF Work Items

Medical Device Single Audit Program (MDSAP)

- This action will complement the current ISO13485 revision process under which IMDRF seeks modifications to achieve a harmonized standard amongst its members.
- *Regulator membership*
- *Coordinator: Kim Trautman, US*

IMDRF Work Items

Recognized standards

- The task is to create a list of International Standards used for medical device regulatory purposes that are recognized by IMDRF Management Committee members.
- *No Work Group required for initial information gathering phase*
- *Coordinator: Matthias Neumann, Europe*

IMDRF Work Items

Regulated Product Submission

- This work will take advantage of a project underway internationally that will result in a messaging standard that supports the electronic transmission of regulatory submissions. This work will define a common 'Table of Contents' for medical device regulatory submissions as a first step in defining a common data set.

IMDRF Work Items

Regulated Product Submission

- *Regulator only and regulator and stakeholder membership*
- *Coordinator: Mike Ward, Canada*

Opportunity for Involvement

- Different opportunity for organization such as AHWP, APEC, PAHO, etc.

- Other stakeholders such as regulated industry, academia, research groups, patient registry organizations, etc.

Next Meeting of IMDRF

Sydney, Australia on 25 to 27 September 2012

The Open Stakeholder Session will be held on 26 September.

Future

- Look forward to some exciting areas of progress for regulatory convergence

- Benefit patient health, patient access, and provide a more global view both on short term goals and longer term goals by IMDRF regulators