IMDRF International Medical Device Regulators Forum

Updates of International Medical Devices Regulators Forum (IMDRF) activities

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Management Committee (1/3)

The current members are:

- Australia
- Brazil
- Canada
- China
- European Union
- Japan
- Russia
- United States of America

Management Committee (2/3)

Official Observers:

- World Health Organization (WHO)
- APEC Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (RHSC)

Affiliate Organizations as Invited Observers:

- Asian Harmonization Working Party (AHWP)
- Pan American Health Organization (PAHO)

Management Committee (3/3)

The roles of IMDRF Chair and Secretariat rotate annually:

2012 – Australia, TGA

2013 – European Union, European Commission

2014 – USA, Food and Drug Administration

2015 – Japan, MHLW/PMDA

2016 – Brazil, ANVISA

IMDRF Work Items (1/2)

1. Medical Device Single Audit Program (MDSAP) *(completed)*
2. National Competent Authority Report (NCAR) Exchange Programme
3. Regulated Product Submission (RPS)
4. Software as a Medical Device (SaMD)

IMDRF Work Items (2/2)

5. Patient Registries
6. Adverse Event Terminology and Coding
7. New Work Item – Competence and Training Requirements for Pre-market Reviewers and Product Specialist

Final Documents issued in 2015 (1/4)

- Technical Documents
  - Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form (N14, NCAR)
  - Software as a Medical Device (SaMD): Application of Quality Management System (N23, SaMD)
  - Medical Device Regulatory Audit Reports (N24, MDSAP)
  - Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations (N8, MDSAP)

Final Documents issued in 2015 (2/4)

- Information Documents
  - Statements regarding use of standard

    ISO 14155:2011, ISO 14971:2007, IEC 62304:2006, IEC 60601-1, ISO10993-1: 2009, ISO11137-1: 2006

  - Clarification of the Term “Legal Entity” for MDSAP Recognition Purposes (N29, MDSAP)

Final Documents issued in 2015 (3/4)

- Information Documents
  - Medical Devices: Post-Market Surveillance -IMDRF National Competent Authority Report (NCAR) Pilot Plan (N30, NCAR)
  - Medical Devices: Post Market Surveillance: National Competent Authority Report (NCAR) Pilot Plan; Implementing Material (N31, NCAR)
  - Strategic Assessment of Electronic Submission Messaging Formats (N32, RPS)

Final Documents issued in 2015 (4/4)

- IMDRF Strategic Plan 2020 (issued on 2 October 2015)
  a. Strategic Priorities from 2016 to 2020
     1. *Enhance Post-Market Surveillance*
     2. *Improve the Effectiveness and Efficiency of Pre-Market Review*

  b. Relationships with Stakeholders

     IMDRF will continue to encourage collaboration and outreach with Affiliate Organizations

Summary of on-going activities (1/3)

- **NCAR:** Full implementation of the Exchange Programme, involving IMDRF MC members, is expected to start in April 2016, following completion of a pilot which is ongoing until March 2016. First evaluation of the Programme implementation will be conducted in March 2017.

- **RPS:** 1) ToC pilot with actual multi-jurisdictional pre-market application has been started and will be continued at least until September 2016. 2) A document for Common Data Elements is under discussion for finalization with comments from the public consultation taken into account.

Summary of on-going activities (2/3)

- **SaMD:** Recruiting of members for discussion of the new topic “Clinical Evaluation” approved in September 2015 based on a public survey has been started.

- **Patient Registries:** N33 document is under public consultation.

Summary of on-going activities (3/3)

- **AE Terminology and Coding:** A new document is under development while the WG closely communicates with ISO TC 210.

- **Competence and Training Requirements for Pre-market Reviewers and Product Specialist:** The new WG activity has been approved in September 2015.

Thank you

Acknowledgment of the very hard work performed and the outstanding results by IMDRF Working Group representatives.

References

IMDRF ORIGINS

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

Origins

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), and to accelerate international medical device regulatory harmonization and convergence.

Management Committee

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

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 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

IMDRF Objectives

- 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

IMDRF Objectives

- Enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders
- Establish develop dialogue with other relevant organizations.

IMDRF Work Items

- Specific tasks to be completed in a 18-24 month period with public consultation
- Avoid work items that involved legislative changes, as they are not typically solely within the control of the respective regulator and cannot typically be accomplished within 18 – 24 months.

IMDRF Work Items

Implementation initiatives:

- All jurisdiction are expected to implement the outputs of agreed upon Final IMDRF work items.
- 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.