



IMDRF International Medical
Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-9 MANAGEMENT COMMITTEE
8 to 10 March 2016

The ninth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Brasília (Brazil), from 8 to 10 March 2016. The meeting was chaired by Brazil. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, and the United States of America. Representatives of the World Health Organization (WHO) and Asia-Pacific Economic Cooperation (APEC) as Official Observers and Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) as Affiliate Organizations also participated.

On the first day, the MC discussed the progress achieved on the current work items:

1. Medical Device Single Audit Program (MDSAP)
2. National Competent Authority Report (NCAR)
3. Software as a Medical Device (SaMD): Clinical Evaluation
4. Regulated Product Submission (RPS)
5. Medical Device Patient Registries
6. Medical Device Adverse Event Terminology
7. Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist

A New Work Item Proposal (NWIP) and a New Work Item Extension Proposal (NWIEP) were presented to the MC:

1. NWIP: Improving the quality of international medical device standards for regulatory use – from EU (This NWIP incorporates DITTA’s previous proposal “Guideline - Medical Device standards for regulatory purpose”)
2. NWIEP: Development of common terminology and code related to adverse event of medical device: Evaluation terms – from IMDRF AE WG (PMDA/MHLW)

In the afternoon, there was an open session including MC members, Official Observers, Affiliate Organizations and Invited Observers. Brief statements were provided by:

1. Official Observer
 - a. WHO
 - b. APEC LSIF Regulatory Harmonization Steering Committee
2. Affiliate Organizations
 - a. Asian Harmonization Working Party (AHWP)

- b. Pan American Health Organization (PAHO)
3. Industry
- a. GMTA
 - b. DITTA
 - c. ABIMO / ABIMED

Brief statements were also provided by Invited Observers:

1. MERCOSUR
2. Argentina
3. Colombia
4. Cuba
5. Mexico

On the second day, an open Stakeholder Forum was held. The Forum included around 220 participants representing regulators, industry, healthcare professionals, and the research community members. Participants had in the morning an opportunity to hear updates on the regulatory situation in the eight jurisdictions of the MC members and update reports on IMDRF's current work items. The morning was closed with a Questions & Answers Session.

In the afternoon of day two, presentations were made on New Work Item Proposal (NWIP). Stakeholders and participants had an opportunity to hear updates about the work of:

1. DITTA
2. GMTA
3. APEC
4. WHO
5. AHWP
6. PAHO

Sessions also included presentations on:

1. MDSAP Pilot
2. IMDRF ToC Pilot
3. MERCOSUR
4. Regulatory convergence on Medical Devices – An international trade approach – Brazilian Trade Investment Promotion Agency – APEX

The second day was closed with an IMDRF General Questions and Answers Session and concluding remarks by the IMDRF Chair. Issues raised throughout the day included:

- Expanded participation in the ToC and MDSAP pilots
- The regulation of software including mobile apps, as medical devices
- Continued support for the MDSAP pilot
- Strategic plan – engagement and interest
- Maintaining balance between pre and post market requirements while enabling innovation

On the third day of the meeting, the MC discussed feedback from the public Stakeholder Forum, and made decisions regarding current and proposed Work Items (*see Annex*).

IMDRF-10 will be held in Brazil, (city to be determined), 13-15 September 2016. Details on the venue and on the Stakeholder Forum will be communicated on the IMDRF website.

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the Edition 2 of FINAL IMDRF/MDSAP WG/N3 (2016), *“Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”*, of the MDSAP working group.
- The MC approved the Final N19 Document, *“Common Data Element for Medical Device Identification”* of the RPS working group.
- The MC approved the New Work Item Proposal, *“Improving the quality of international medical device standards for regulatory use”*. This will be an open working group chaired by the EU. The EU chair will seek participation by IMDRF members, industry, and SDOs.
- The MC approved the New Work Item Extension Proposal to Medical Device Adverse Event Terminology: *“Development of common terminology and code related to adverse event of medical device: Evaluation terms”*.

Brasília DF, Brazil
10 March 2016