



IMDRF International Medical
Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-7 MANAGEMENT COMMITTEE
24 to 26 March 2015

The seventh meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Tokyo (Japan), from 24 to 26 March 2015. The meeting was chaired by Japan. 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 an Official Observer and Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) as an Affiliate Organization also participated.

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

1. Medical Device Single Audit Program (MDSAP)
2. National Competent Authority Report (NCAR)
3. Regulated Product Submission (RPS)
4. Software as a Medical Device (SaMD)
5. Medical Device Patient Registries
6. Use of ISO14155: 2011

A Revised New Work Item Proposal (NWIPs) and one NWIP were also presented to the MC:

1. Development of common terminology and code related to adverse events of medical devices – Japan MC Delegation
2. List of International Standards recognized by IMDRF Management Committee Members, Phase II- GMTA

The MC invited MedDRA to make presentation on the proposed collaboration between IMDRF and MedDRA.

The MC also discussed IMDRF strategic plan to identify its direction for the coming years to better coordinate its activities and allocate its limited resources. The MC will finalize the plan in Kyoto meeting in September 2015.

In the afternoon, an open session was held that included MC members, Official Observers, and Invited Observers. Brief statements were provided by the WHO and the APEC as an Official Observer, as well as the following Invited Observers:

- a. AHWP
- b. PAHO
- c. Global Medical Technology Alliance (GMTA)
- d. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

On the second day, an open Stakeholder Forum was held. The Forum included more than 150 participants representing regulators, industry, healthcare professionals, and the research community members. Participants had an opportunity to hear updates on the regulatory situation in the eight jurisdictions of the MC members. In addition, update reports were provided on IMDRF's current work items, presentations were made on New Work Item Proposals (NWIPs), and stakeholders had an opportunity to share their views and ideas on the work of IMDRF.

In the afternoon on day two, stakeholders held three sessions focused on MDSAP, SaMD and activities of AHWP, APEC, PAHO, WHO, DITTA and GMTA.

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

The MC also discussed collaboration between IMDRF and IEC.

IMDRF-8 will be held in Kyoto, Japan, 15-17 September 2015. Details on the Stakeholder Forum will be communicated on the IMDRF website, including a theme for possible presentations by stakeholders on that occasion.

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the proposed N8 and N24 documents, “Medical Device Single Audit Program (MDSAP): Guidance on Regulatory Authority Assessment Methods of Auditing Organization’s Processes” and “Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports” of the MDSAP Working Group for two-month public consultation.
- The MC approved the final N14 document, “Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form” and requested the working group to work on implementing material and a detailed pilot plan.
- The MC approved the proposed N23 document, “Software as a Medical Device: Application of Quality Management Systems,” of the SaMD working group for two-month public consultation.
- The MC agreed to post the final document N26 IMDRF Table of Contents (ToC) pilot plan on the IMDRF website as Information Document. The MC approved proposed N27, N28 document, “Assembly and Technical Guide for IMDRF Table of Contents (ToC) Submissions (ToC-based submissions),” Standard ToC Folder Structure,” of the RPS working group for two-month public consultation.
- The MC agreed to post the final document N25 outlining use of ISO 14155: 2011, “Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice,” in each of the IMDRF MC jurisdictions on the IMDRF website as Information Document.
- The MC approved the revised New Work Item Proposal, “Development of common terminology and code related to adverse event of medical device.” The scope of the Working Group will be reconsidered at the end of Phase I. The MC agreed the formation of a regulators-only Working Group on Adverse Event Terminology and Coding while the MC explores coordination with ISO TC210 WG3 to further refine the scope of work for the Working Group to be open to Stakeholders.
- With regard to the New Work Item Proposal, “List of core horizontal standards to be recognized by IMDRF Management Committee: Phase II” (presented by GMTA), the MC agreed to draft Information Documents on international standards listed below in each of the respective IMDRF MC jurisdictions. These documents will be finalized at the MC meeting in Kyoto in September 2015. In preparation for the meeting in Kyoto, the MC will explore additional actions to take related to standards.
 - ISO 14971:2007, “ Medical devices_- Application of risk management to medical devices,”

- IEC 62304:2006, "Medical device software_- Software life cycle processes,"
- IEC 60601-1: "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,"
- ISO10993, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process," and
- ISO11137-1: 2006, "Sterilization of health care products_- Radiation_- Part_1: Requirements for development, validation and routine control of a sterilization process for medical devices."

Tokyo, Japan
26 March, 2015