



IMDRF International Medical
Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-8 MANAGEMENT COMMITTEE
15 to 17 September 2015

The eighth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Kyoto (Japan), from 15 to 17 September 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 current 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. Medical Device Adverse Event Terminology
7. Use of Standards

Two New Work Item Proposals (NWIPs) were also presented to the MC:

1. Software as a Medical Device (SaMD): Clinical Evaluation
2. Good Regulatory Review Practice – Competence and Training Requirement for Pre-market Reviewers and Product Specialist

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

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 invited Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA) based on their request to make a presentation on standards.

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. DITTA

On the second day, an open Stakeholder Forum was held. The Forum included more than 150 participants representing regulators, industry, healthcare professionals, and members of the research community. 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, the MC held QA session based on questions submitted by stakeholders prior to the meeting and also held session on the IMDRF Strategic Plan. Sessions focused on NCAR, RPS and on the activities of AHWP, APEC, PAHO, WHO, DITTA and GMTA were held.

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

The MC also discussed collaboration between IMDRF and ISO/IEC.

IMDRF-9 will be held in Brasilia, Brazil, 8-10 March 2016. 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 final N8 and N24 documents, “Medical Device Single Audit Program (MDSAP): Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations” and “Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports” of the MDSAP Working Group. The MC also agreed to post the final N29 document, “Clarification of the Term “Legal Entity” for MDSAP Recognition Purposes” on the IMDRF website as Information Document.
- The MC agreed to post the final N30 document, “Medical Devices: Post-Market Surveillance -IMDRF National Competent Authority Report (NCAR) Pilot Plan” and the final N31 document “Medical Devices: Post Market Surveillance: National Competent Authority Report (NCAR) Pilot Plan; Implementing Material” of the NCAR working group on the IMDRF website as Information Document.
- The MC approved the final N23 document, “Software as a Medical Device (SaMD): Application of Quality Management System” of the SaMD working group.
- The MC agreed to post the final N32 document “Strategic Assessment of Electronic Submission Messaging Formats” of the RPS working group on the IMDRF website as Information Document. The MC also agreed to open a web page dedicated to ToC Pilot for communication with stakeholders on the IMDRF website.
- The MC agreed to post the proposed N33 document of the Registry working group for two-month public consultation together with an indication of issues on which opinions are sought.
- The MC agreed to post the final document N34, N35, N36, N37, N38 outlining use of standards listed below on the IMDRF website as Information Document.
 - 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”,
 - ISO10993-1: 2009 “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”.

- The MC approved the New Work Item Proposal, “Software as a Medical Device (SaMD): Clinical Evaluation.”
- The MC approved the New Work Item Proposal, “Good Regulatory Review Practice – Competence and Training Requirements for Pre-market Reviewers and Product Specialist.”
- The MC approved the final N39 document “IMDRF Strategic Plan 2020.”

Kyoto, Japan
17 September, 2015