



IMDRF International Medical
Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-11 MANAGEMENT COMMITTEE
14 to 16 March 2017

The eleventh meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Vancouver, Canada, from 14 to 16 March 2017. The meeting was chaired by Canada. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, the Russian Federation, Singapore and the United States of America (USA). Representatives of the World Health Organization (WHO) and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC) participated as Official Observers and Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) participated as Affiliate Organizations.

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

- a. National Competent Authority Report (NCAR) - EU
- b. Software as a Medical Device (SaMD): Clinical Evaluation - USA
- c. Regulated Product Submission (RPS) - Canada
- d. Medical Device Patient Registries and discussion of New Work Item Proposal (NWIP) - USA
- e. Medical Device Adverse Event Terminology - Japan
- f. Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist and discussion of NWIP - USA
- g. Improving the quality of international medical device standards for regulatory use - EU

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

1. Official Observers
 - a. WHO
 - b. APEC LSIF RHSC
2. Affiliate Organizations

- a. AHWP
- b. PAHO
- 3. Invited Observers
 - a. Cuba
 - b. South Korea
 - c. Turkey
 - d. Malaysia
- 4. Industry
 - a. Global Medical Technology Alliance (GMTA)
 - b. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

There was a discussion on how to better involve stakeholders.

A NWIP from GMTA on a Harmonized Unique Device Identifier (UDI) Application Guide was presented to the MC during the afternoon closed session.

On the second day, an open Stakeholder Forum was held. The Forum included around 150 participants representing regulators, industry, and the research community. In the morning, participants had an opportunity to hear regulatory updates from Australia, Brazil, Canada, China, EU, Japan, Russia, Singapore, and USA and update reports on IMDRF's current work items. The morning closed with a Questions & Answers Session.

In the afternoon of day two, GMTA presented a NWIP on Harmonized Unique Device Identifier (UDI) Application Guide. This was followed by a panel discussion on cybersecurity. The panel explored the challenges, opportunities and complexity of medical device cybersecurity issues in the context of the current trends in medical technology.

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

The second day was closed with an IMDRF General Questions and Answers Session and concluding remarks by the IMDRF Chair.

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

IMDRF-12 will be held in Ottawa, Canada, on September 19-21, 2017. 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 final N42 document, “Methodological Principles in the Use of International Medical Device Registry Data”, of the Medical Device Patient Registries Working Group.
- The MC approved the final N43 document, “IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Annex A)” of the Medical Device Adverse Event Terminology Working Group.
- The MC approved the proposed N43 document “IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Annex B)” of the Medical Device Adverse Event Terminology Working Group for a two month public consultation.
- The MC approved the final N44 procedural document for the maintenance procedure for IMDRF AE terminologies of the Medical Device Adverse Event Terminology Working Group.
- The MC agreed to post the final N45 document “Data Exchange Guidelines – Common Data Elements for Medical Device Identification” of the Regulated Products Submission Working Group on the IMDRF website as an information document.
- The MC approved the final N40 document, “Competence, Training, and Conduct Requirements for Regulatory Reviewers” of the Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist Working Group.
- The MC approved the NWIP: Review and Update of GHTF Essential Principles of Safety and Performance of Medical Devices (GHTF/SG1/N68:2012).
- The MC approved the NWIP: A Tool to Assess Usability of Registries to Support Regulatory Decision Making.
- The MC agreed to consider the GMTA NWIP at the September IMDRF MC meeting following submission of a draft Harmonized Unique Device Identifier (UDI) Application Guide by GMTA.

- The MC agreed to develop more detailed criteria and procedures for new IMDRF membership.

Vancouver, Canada
16 March 2017