



OUTCOME STATEMENT

of the IMDRF-14 MANAGEMENT COMMITTEE

18 to 20 September 2018

The fourteenth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Beijing, China, from 18 to 20 September 2018. The meeting was chaired by China. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, the Russian Federation, Singapore, South Korea and the United States of America (USA). Representatives of the World Health Organization (WHO) as Official Observer, and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC), the Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) as Regional Harmonization Initiatives, also participated.

On the first day, an Open Stakeholder Forum was held according to the IMDRF-13 MC decision in March 2018 of changing the meeting format. The Open Stakeholder Forum included more than 300 participants representing regulators, industry, and the research community, etc. In the morning, update presentations and reports on the regulatory situation in the ten jurisdictions of the MC members and IMDRF's seven current working groups were provided. Participants had opportunities to share their views and ideas with presenters in Question & Answer sessions.

The IMDRF's seven current working groups are:

- a. Regulated Product Submission (RPS) - Canada
- b. Medical Device Adverse Event Terminology - Japan
- c. Good Regulatory Review Practices - USA
- d. Standards - USA
- e. Personalized Medical Devices-Australia
- f. Unique Device Identification - EU
- g. Medical device clinical evaluation-China

In the afternoon of day one, there was a panel discussion on Robotic Medical Devices. The panel explored the challenges, opportunities and the complexity of Robotic Medical Device issues in the context of the current trends in medical technology.

After the panel discussion, stakeholders and participants had an opportunity to hear updates about the work of Industry, Official Observer, Regional Harmonization Initiatives, and Invited Observers:

--Industry

1. China Association for Medical Devices Industry (CAMDI)
2. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
3. Global Medical Technology Alliance (GMTA)

--Official Observer

4. WHO

--Regional Harmonization Initiatives

5. APEC LSIF RHSC
6. AHWP
7. PAHO

--Invited Observers

8. Hong Kong SAR, PRC
9. Mexico (COFEPRIS)

The first day was closed with a Question and Answer session and concluding remarks by China National Medical Products Administration (NMPA).

On the second day, the MC firstly held an open session with DITTA and GMTA. The MC received feedback with respect to the progression of each IMDRF work item. DITTA and GMTA also presented their visions on future work that may be considered by the IMDRF MC as well. The Chair of ISO TC210 WG1 presented an update on ISO 13485. After that, the MC heard a presentation from Mexico COFEPRIS. .

In the MC meeting's following sessions, the MC discussed the matters arising from the Open Stakeholder Forum and the session with industry. The MC also discussed and made decisions regarding the documents put forward from current working groups, the New Work Item Proposals and New Work Item Extensions proposed by MC members and/or industry, as well as some procedural issues (see Annex).

IMDRF-15 is proposed to be held in Moscow, the Russian Federation, from March 19th to 21st, 2019. 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 Final N47 document, “Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices” of the Good Regulatory Review Practices Working Group.
- The MC approved Final N51 document, “Optimizing Standards for Regulatory Use” of the Standards Working Group.
- The MC approved Final N49 document, “Definitions for Personalized Medical Devices” of the Personalized Medical Devices Working Group.
- The MC approved the New Work Item Extension “Personalized Medical Devices - Regulatory Pathways” of the Personalized Medical Devices Working Group led by Australia
- The MC approved the New Work Item Proposal “Medical Device Cybersecurity”, and agreed to establish a new Working Group to undertake this Item (both USA and Canada to lead).
- The MC approved the New Work Item Proposal “Medical Device Premarket Review Organization Recognition Requirements and Processes” of the Good Regulatory Review Practices Working Group (both USA and Singapore to lead).
- The MC discussed the proposed changes to the New Work Item Proposal (NWIP) adoption process and the SOP will be revised accordingly.
- In the interest of transparency, the MC agreed to develop a document indicating the implementation of IMDRF documents by member jurisdictions, which will be made publicly available.
- The MC agreed to provide additional clarity regarding the criteria to become an Official Observer and a Management Committee member of the IMDRF.
- The MC agreed the IMDRF will provide a position statement to ISO on the proposed revision of ISO 13485.

Beijing, China

20 September 2018