IMDRF International Medical Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-17 Management Committee
18 March 2020

The seventeenth closed session meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place over web conference on 18 March 2020. The meeting was chaired by Singapore. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, Russia, Singapore, South Korea and the United States of America (USA). Representatives of the World Health Organization (WHO) participated as Official Observer.

In the MC meeting, the MC discussed and made decisions regarding the documents submitted by current working groups, New Work Item Proposals and New Work Item Extensions proposed by MC members.

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the Final N59 document, "Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews", of the Good Regulatory Review Practices (GRRP) Working Group.

- The MC approved the proposed document, "Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews", of the Good Regulatory Review Practices (GRRP) Working Group for a 60-day consultation period.

- The MC approved the Final N43 document, "IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes", of the Adverse Event Terminology Working Group.

- The MC approved the Final N44 document, "Maintenance of IMDRF AE Terminologies", of the Adverse Event Terminology Working Group.

- The MC approved the Memorandum of Understanding (MOU) between IMDRF and ICH.

- The MC accepted the Final document, "IMDRF Standards Liaison Program Framework", of the Standards Working Group as an internal SOP for interactions between IMDRF and the Standard Development Organizations and decided to close the Standards Working Group at this time.

- The MC agreed that a one page overview of the Liaison Program be published on the IMDRF website.

- The MC approved the Final N58 document, "Personalized Medical Devices – Regulatory Pathways", of the Personalized Medical Devices Working Group.

- The MC approved the Final N60 document, "Principles and Practices for Medical Device Cybersecurity", of the Medical Device Cybersecurity Working Group.

- The MC approved the proposed document, "Principles of In Vitro Diagnostic (IVD) Medical Devices Classification" of the IVD Working Group for a 60-day consultation period. The MC decided not to include the SaMD IVD classification in the document.

- The MC supported the participation of Singapore in the IMDRF NCAR Exchange Program.