IMDRF International Medical Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-18 Management Committee
21 to 25 September 2020

The eighteenth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place over web conference from 21 to 25 September 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.

On Monday, September 21st, the IMDRF/DITTA Joint Virtual Workshop "Cybersecurity: Where are we today" was held. 500 representatives from regulators, auditing organizations, healthcare providers, scientific societies and industry registered for the virtual workshop. Industry representatives and regulators shared the developments and efforts in strengthening cybersecurity for medical technologies, which was followed with a panel discussion on how to maximize collaboration and ensure cybersecurity in healthcare.

On Wednesday, September 23rd, a Virtual Open Stakeholder Forum was held. 841 representatives from industry and the research community registered for the Forum. Due to time constraints of the webinar and to enable better interaction with stakeholders, the presentation materials were made available to participants beforehand for them to go through and submit questions for panel discussion at the Forum.

The presentation materials provided regulatory updates from Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea and the USA and updates on IMDRF's eight current working groups.

The IMDRF's eight current working groups are:

a. Regulated Product Submission – Canada
b. Good Regulatory Review Practice – USA/Singapore
c. Medical Device Adverse Event Terminology – Japan
d. Personalized Medical Devices – Australia
e. Medical Device Clinical Evaluation – China
f. Medical device Cybersecurity Guide – Canada/USA
g. Principles of In Vitro Diagnostics (IVD) Medical Device Classification – Russia
h. Artificial Intelligence Medical Devices* – South Korea

Presentation materials were also provided to update on the work of:

1. WHO
2. APEC LSIF Regulatory Harmonization Steering Committee (RHSC)
3. Asian Harmonization Working Party (AHWP)

* The New Work Item Proposal on Artificial Intelligence Medical Devices was approved by the MC on 25 June 2020.

4. Pan America Health Organization (PAHO)
5. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
6. Global Medical Technology Alliance (GMTA)
7. Singapore Manufacturing Federation Medical Technology Industry Group (SMF MTIG)
8. Asia Pacific Medical Technology Association (APACMed)

The Forum comprised 3 segments where the panel addressed the questions received from participants:

1. Regulatory updates by IMDRF management committee
2. Progress of IMDRF work items
3. Stakeholders session

At the closed session of the MC meeting on September 25th, the MC discussed and made decisions regarding the documents put forward from current working groups, New Work Item Extensions proposed by MC members, IMDRF Strategic Plan 2025 as well as IMDRF SOP and other procedural matters (See Annex).

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the Final N61 document, "Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews", of the Good Regulatory Review Practices (GRRP) Working Group.

- The MC approved the Final N63 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.

- The MC approved the proposed document, "Post-Market Clinical Follow-Up Studies", of the Medical Device Clinical Evaluation Working Group for a 60-day consultation period

- The MC approved the NWIE, "Expanding the Harmonization of Adverse Event Terminology", of Adverse Event Terminology Working Group.

- The MC approved the NWIE, "Medical Device Cybersecurity Deeper Dive: Legacy Devices and Transparency of Software Components Including Use of Third-Party Software", of Cybersecurity Working Group.

- The MC approved the NWIE "Personalized Medical Devices – Considerations for validating design envelopes and personalized medical device production systems", of Personalized Medical Devices Working Group.

- The MC agreed to finalize and publish the IMDRF Strategic Plan 2021 - 2025 on the IMDRF website by end 2020.

- The MC approved the 6th Edition of IMDRF Standard Operating Procedures.

- The MC endorsed the participation of Singapore, HSA in the IMDRF NCAR Exchange Programme.