



**IMDRF** International Medical  
Device Regulators Forum

**Outcome Statement  
of the IMDRF Management Committee**

**25 to 27 September 2012**

The second meeting of the International Medical Device Regulators Forum (IMDRF) was held in Sydney from 25 to 27 September 2012. The Management Committee (MC) meeting was attended by regulators from Australia, Brazil, Canada, Europe, Japan and the United States of America. Regulators from China as well as representatives from the World Health Organization (WHO) and the Chair of the Asian Harmonization Working Party (AHWP) also attended. A representative from Singapore's Health Sciences Authority and New Zealand's Medsafe joined the meeting as Invited Observers.

This was an important meeting to further progress IMDRF's priority work items. On the first day of the Forum the MC met to discuss progress relating to:

- a. Review of the NCAR system;
- b. Roadmap for Implementation of UDI system;
- c. Medical Device Single Audit Program;
- d. Recognized standards; and
- e. Regulated Product Submission

The MC also held a special session with representatives from the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA) to discuss key issues, including industry engagement with regulators and industry expectation of IMDRF processes, as well as key issues for the medical device/technology sector over the next 5–10 years. Other discussion items included trends in medical device/technology innovation and global manufacturing, proposed changes in global regulation as well as issues regarding supply-chain integrity.

The MC agreed on an IMDRF website prototype, which is currently in development.

The second day of the Forum was an open day attended by over 80 stakeholders representing a range of sectors. The Forum was provided with member/jurisdictional updates. In addition, update reports were provided on IMDRF's priority work items and stakeholders had an opportunity to share their views and ideas on key issues.

On the final day of the meeting, matters arising from the Open Stakeholder Forum were discussed by the MC. The MC also considered issues relating to IMDRF's Operating Procedures.

***IMDRF work items***

Progress on all work items has been strong. In summary:

- The NCAR Working Group will produce a critical review of its effectiveness, with a report to the MC at its March 2013 meeting.
- Three main components of the UDI work are on track to be completed as proposed draft documents by March 2013, with the final two components as proposed draft documents by November 2013.
- A draft document relating the Medical Device Single Audit program will be released for consultation by late October. Additional documents relating to this work item are being prepared as proposed drafts for the March 2013 meeting of IMDRF.
- Draft documents from the Regulated Product Submission working group will be available for the March 2013 meeting. The working group dealing with the Table of Contents will be expanded to include non-regulatory membership and will have draft documents available for the March 2013 meeting.
- An initial survey of the uptake of international standards by the MC members was presented. The next phase will involve an analysis of the data and report of that analysis for the March 2013 IMDRF meeting.

A copy of the work item update reports with further detail is available at [www.imdrf.org](http://www.imdrf.org).

The Management Committee also discussed possible future IMDRF work items, including

- a. The development of an IMDRF training strategy
- b. Developing international harmonized software regulatory environment
- c. The Medical Device Single Audit Program - the inclusion of competency documents, special audits and code of conduct
- d. Issues with the safety of medical devices used in apheresis procedures for blood donations, and
- e. Harmonized guidance for risk-benefit determination.

It was agreed that: the outline of a preliminary training strategy will be developed; further information will be sought on particular software issues; harmonized guidance for risk-benefit determination will be considered at the next meeting; competency documents, special audits and code of conduct are to be included within the scope of the Medical Device Single Audit Program work task. IMDRF MC members will report back in November on their experiences with medical devices used in apheresis procedures.

Stakeholders wishing to provide updates at future meetings will be able to submit a proposal to the Secretariat via the IMDRF website (the Secretariat can also be contacted by email [imdrf.secretariat@tga.gov.au](mailto:imdrf.secretariat@tga.gov.au)).

The next meeting of IMDRF will take place in France on 19 to 21 March 2013. Details of the Stakeholder Session will be advised on the IMDRF website as soon as they become available.

*Sydney*  
*27 September 2012*