IMDRF

International Medical Device Regulators Forum

# Outcome Statement
# of the IMDRF Management Committee

## 28 February to 1 March 2012

The inaugural meeting of the International Medical Device Regulators Forum (IMDRF) was held in Singapore from 28 February to 1 March 2012 and was a great success. IMDRF made several positive steps forward in developing the new Forum, as well as plans for transitioning several key items from the Global Harmonization Task Force (GHTF) by the end of 2012.

On the first day of the Forum the regulators from Australia, Brazil, Canada, Europe, Japan, and the United States of America met to agree on the Terms of Reference for IMDRF and to discuss proposals for new work items. Regulators from China and the Russian Federation also attended as observers, along with representatives of the World Health Organization.

The Management Committee agreed on a Terms of Reference document, which is now available at www.imdrf.org. In accordance with the Terms of Reference, the document will be reviewed annually. The Management Committee agreed that the next task is to develop more detailed operating procedures to cover issues such as membership criteria for the Management Committee and Working Groups, as well as procedures for document handling. IMDRF will develop a pathway, in advance of the September 2012 IMDRF meeting, for other regulators to become new members or observers for future meetings.

The Management Committee also agreed to develop a formal strategy for the management and maintenance of GHTF documents.

Regarding proposals for work items, the following topics were submitted prior to the meeting and discussed:

a. A review of the NCAR system
b. Roadmap for implementation of a UDI system
c. Standardized submission requirements for pre-market assessment of medical devices
d. Medical Device Single Audit Program (MDSAP)
e. Non-clinical and clinical evaluation regarding nanomaterials
f. International Standards recognized by IMDRF Management Committee members
g. Guidance on how to determine risk/benefit analysis
h. Regulated Product Submission.

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The second day of the Forum was an open day attended by approximately 100 stakeholders representing a range of sectors. Constructive comments on the new work item proposals were provided, as well as more general governance issues such as ensuring transparency and a mechanism for management and maintenance of GHTF guidance documents.

On the final day of the meeting, after further discussion of the proposals and taking into account comments received in the Open Session, the Management Committee agreed to progress five work items. A summary of these work items is attached. Further information will be made available on the website, as it becomes available. It is expected that Working Groups to progress the work items will be formed in the near future.

The Management Committee considered a request by industry for observer status on the Management Committee. In response, and given the unique position of industry, the Management Committee agreed that representative stakeholder delegations would be invited to attend nominated sessions of future meetings to provide an update on key issues. Stakeholders wishing to provide updates at future meetings should submit a proposal via email to the IMDRF Secretariat (imdrf.secretariat@tga.gov.au).

The Management Committee recognizes the important work of the Asian Harmonization Working Party (AHWP) and will extend an invitation for AHWP to be presented at future IMDRF Management Committee meetings.

The Management Committee was provided with an update on the work of the Regulatory Harmonization Steering Committee (RHSC) of the APEC Life Sciences Innovation Forum. It was agreed that, given the common goal of regulatory convergence, close links between IMDRF and the RHSC are important and an invitation to the RHSC to become an IMDRF Affiliate Organization will be extended.

The next meeting of IMDRF will take place in Sydney, Australia on 25 to 27 September 2012. The Open Stakeholder Session will be held on 26 September.

*Singapore*
*March 2012*

Attachment

**Initial IMDRF work items for progression**

| ***Work Item*** | ***Work Group Membership*** | ***Coordinator*** |
|---|---|---|
| **A review of the NCAR system**<br>The NCAR Exchange Program facilitates the exchange of relevant post market safety information on medical devices with global distribution. The aim is to trigger rapid adoption of field safety corrective actions in all concerned geographies to avoid death or serious deterioration of health, when relevant.<br>This work will review the current arrangements and advise on opportunities for improvement and possible expansion of the system to also include select pre-market decisions and other post-market actions. | *Regulator membership* | *Isabelle Demade, Europe* |
| **Roadmap for implementation of UDI system**<br>This item seeks to define the path to implementing a globally harmonized approach to a uniform device identification system, and builds on the earlier work of GHTF. | *Regulator and stakeholder membership* | *Laurent Selles, Europe* |
| **Medical Device Single Audit Program (MDSAP)**<br>The Work Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program. This action will complement the current ISO13485 revision process under which IMDRF seeks modifications to achieve a harmonized standard amongst its members. | *Regulator membership* | *Kim Trautman, US* |
| **Recognized standards**<br>The task is to create a list of International Standards used for medical device regulatory purposes that are recognized by IMDRF Management Committee members. | *No Work Group required for initial information gathering phase* | *Matthias Neumann, Europe* |
| **Regulated Product Submission**<br>This work will take advantage of a project underway internationally that will result in a messaging standard that supports the electronic transmission of regulatory submissions. This work will define a common 'Table of Contents' for medical device regulatory submissions as a first step in defining a common data set. | *Regulator only and regulator and stakeholder membership* | *Mike Ward, Canada* |