IMDRF UPDATES

Entrusted by Dr. YUAN Lin
2018 IMDRF Chair, CHINA
Speaker :Wang Xiaoxue
2018 IMDRF Secritariat
Oct. 25th, 2018, Malaysia

MANAGEMENT COMMITTEE MEMBERS

- Australia
- Brazil
- Canada
- China
- The European Union
- Japan
- The Russian Federation
- Singapore
- South Korea
- the United States

OFFICIAL OBSERVER

- **WHO**
  (World Health Organization)

REGIONAL HARMONIZATION INITIATIVES

- **APEC**

  (APEC LSIF Regulatory Harmonization Steering Committee)
- **AHWP**

  (Asian Harmonization Working Party)
- **PAHO**

  (Pan American Health Organization)

COOPERATIONS WITH AHWP

Attending IMDRF Open Forums as RHIs Representatives

- Mr.Ali M.Al-dalaan was invited to make presentation on AHWP Updates,in March ,Shanghai .
- Mr.Zamane Abd Rahman, was invited to make presentation on AHWP Updates,in September Beijing.

MEETINGS TO-DATE

- Chair and secretariat rotate on annual basis,beginning with Australia(2012),EU(2013),US(2014),Japan(2015),Brazil(2016),Canada(2017),China(2018)

- Australia hosts IMDRF website.

- Two 3 day meetings per year,each of which features a public session that serves to update and hear from stakeholders.

13TH IMDRF MC MEETING

March,2018 IMDRF Management Committee Shanghai Meeting

14TH IMDRF MC MEETING

September,2018 IMDRF Committee Beijing Meeting

UPDATES

The IMDRF's Seven Current Working Groups

- Regulated Product Submission (RPS) - Canada
- Medical Device Adverse Event Terminology - Japan
- Good Regulatory Review Practices - USA
- Standards - USA
- Personalized Medical Devices-Australia
- Unique Device Identification - EU
- Medical device clinical evaluation-China

UPDATES

- **Regulated Product Submission (RPS) - Canada**

  RPS

  Table of Contents(ToC)

  Implementation

UPDATES

- **Medical Device Adverse Event Terminology - Japan**

  regulatory purpose

  N43 and annexes

UPDATES

- **Good Regulatory Review Practices – USA**

  N47

  Essential Principles of Safety and Performance

UPDATES

- **Standards – USA**

  N51

UPDATES

- **Personalized Medical Devices-Australia**

  N49

  definitions for personalized Medical Devices

UPDATES

- **Unique Device Identification – EU**

  Three documents for public consultation

UPDATES

- **Medical device clinical evaluation-China**

  New work item approved by the 13th IMDRF MC Meeting in Shanghai.

UPDATES

Three Newly Approved Work Items

- *Regulatory Pathways* **-Australia**
- *Cybersecurity*-**USA and Canada**
- *Premarket Review Organizations- Recognition Requirements and Processes*-**USA and Singapore**

UPDATES

In 2018

- 4 final technique documents were approved.
  (N46、N47、N49 、N51)
- 2 new working group were established.
  (clinical evaluation WG and cybersecurity WG)
- 1 working group is closed.
  (Patient Registry WG)

NEXT

- New Work Item Proposal (NWIP) **adoption process** is under discussing 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.

- The MC agreed to provide **additional clarity** regarding the **criteria** to become an **Official Observer** and a **Management Committee member** of the IMDRF.

- IMDRF-15 is going to be held in Moscow, the Russian Federation, from March 19th to 21st, 2019.

- The 2018 secretariat will undertake the following routine work by the end of 2018.

- **You can find more information and documents of IMDRF on its website http://www.imdrf.org/**

Thank You!