Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

1927-2017 FICCI @90

# AHWP TC Report Highlights

**Ali Al dalaan, MBA-IT,PRA,QMS-LA**
Executive Director, Radiological Health
AHWP Technical committee Chair

**22nd Asian Harmonization Working Party Annual Meeting**
**4-8 December, 2017 New Delhi**

# TC Team

| TC Office Bearers | Positions |
|---|---|
| **Chair**<br>**Co-Chair**<br>**Co-Chair**<br>**Secretary** | Mr Ali M Al-Dalaan<br>Dr Jeong-Rim Lee<br>Mr Alfred Kwek<br>Mr Jack Wong<br>Ms Carol Yan<br>Ms Chadaporn Tanakasemsub (Miang) |
| **Work Groups** | **Positions** |
| **WG1: Pre-market** | Chair - Mr. Essam Mohammed Al Mohandis<br>Co-Chair – Ms. Kate Hyeong Joo Kim |
| **WG2: Pre-market - IVDD** | Chair - Mr. Wen-Wei TSAI<br>Co-Chair – Ir. Albert POON |
| **WG3: Pre-market - Software as a Medical Device** | Chair - Dr. Rama SETHURAMAN<br>Co-Chair - Mr Tony Yip |
| **WG4: Post-market** | Chair - Ms. Jennifer MAK<br>Co-Chair – Ms Kitty Mao |
| **WG5: Clinical Evidence for performance & safety** | Chair - Ms. Yuwadee PATANAWONG<br>Co-Chair - Ms. Sumati Randeo |
| **WG6: Quality Management Systems: Audit & assessment** | Chair - Mr. Abdullah AL RASHEED<br>Co-Chair - Ms. Shirley SUM |
| **WG7: Quality Management Systems: Operation & implementation** | Chair - Ms. Aidahwaty M.Olaybal<br>Co-Chair - Mr. Ee Bin Liew |
| **WG8: Standards** | Chair - Ms. Maria Cecilia MATIENZO<br>Co-Chair – Mr Tony Low |
| **STC (UDI & Nomenclature)** | Chair - Ms. LI Jun<br>Co-Chair – Ms Carol Yan |

# TC Co-operation with International Organizations

# AHWP TC Collaboration Works

## IMDRF

- Participation in IMDRF meetings
- Participation of IMDRF in AHWP meeting in Cebu in Nov, 2016.
- Participation of AHWP in different IMDRF WGs :
  - ✓ RPS
  - ✓ MDSAP
  - ✓ Adverse Event Terminology
  - ✓ Personalized Medical Devices
  - ✓ UDI


## DITTA

- AHWP-DITTA Joint Workshops in 2016 & 2017

## APACMed

- Participation of APACMed as a "NEW" liaison member in 2016
- Participation of AHWP in 2016 Asia Pacific Medtech Forum in Singapore in 2016 & 2017

## APEC

- Participation of AHWP in various APEC activities :
  - ✓ APEC Harmonization Center (AHC)
  - ✓ APEC Medical Device Vigilance Roadmap
  - ✓ NWI on Medical Device

## WHO

- AHWP-WHO joint meeting for IVD PQ program in Cebu in Nov, 2016
- Participation of AHWP in WHO Technical consultation on G6PD IVDs in Geneva in Sept, 2016

## IEC

- AHWP WG members participate in IEC TC activities :
  - ✓ IEC/TC62

## ISO

- AHWP WG members participate in various ISO TC activities :
  - ✓ ISO/TC212
  - ✓ ISO/TC210
  - ✓ ISO/TC194

# TC Co-operation with International Organizations (1)

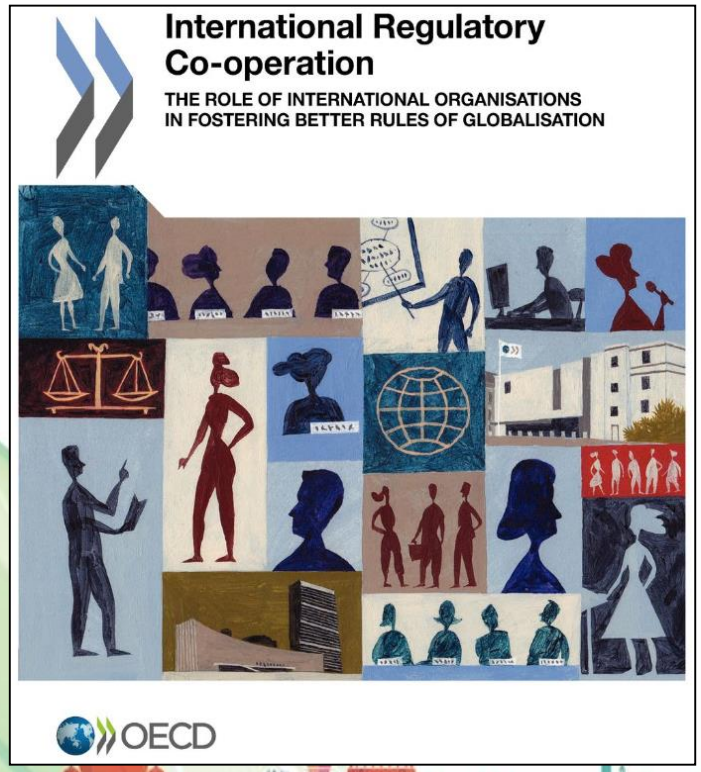
- ISO TC 210 Nov 15-20, 2015 review ISO 13485-2016 FD and handbook Seattle, USA. AHWP TC participated.
- 9th IMDRF Meeting, March 7 – 11, 2016 Brasilia, Brazil. TC Co-Chair presented AHWP TC activities.
- Asia Pacific Health Care Summit 2016, April 7-8, 2016, Singapore. TC Chair was a speaker.
- WHO Inter-Country Meeting on Designing & Implementing Regulatory Program For MD, April 11-14, 2016. Hosted by SFDA. Riyadh, Saudi Arabia. Joanna Koh presented AHWP TC (Playbook).
- OECD Meeting of International Organizations, April 11-15, 2016, Paris, France. TC Co-Chair presented AHWP & TC activities.
- APEC RHSC Workshop of Medical Device Vigilance, Sept 5, 2016, Seoul, Korea. WG4 Chair presented AHWP TC.

# TC Co-operation with International Organizations (2)

- 10th IMDRF Meeting, Sept 13 – 15, 2016, Florianopolis, Brazil. TC Co-Chair presented AHWP TC activities.
- 11th IMDRF Meeting, March 13-16, 2017, Vancouver, Canada. TC Co-Chair presented AHWP TC activities.
- APEC RHSC Workshop of Medical Device Vigilance, Sept 11-12, 2017, Seoul, Korea. Representative of WG4 presented AHWP TC.
- RAPS Regulatory Convergence, Sept 17-20, 2016, San Jose, USA. TC Chair speaks in this event.
- 12th IMDFR Meeting, September 19-21, 2017, Ottawa, Canada. TC Co-Chair presented AHWP TC activities.

# TC Co-operation with International Organizations (3)

- ✓ OECD Publication - The Role of International Organizations in Fostering Better Rules of Globalization, Nov 2, 2016. Collaboration on drafting OECD report.
- ✓ Collaboration on drafting OECD Report - International Regulatory Co-operation & International Organizations - The case of AHWP in 2017




**International Regulatory Co-operation and International Organizations**

**The Case of AHWP**

# TC Meeting and Activities

- International Workshop on Regulatory Harmonization of Medical Devices, Feb 2016, Korea. AHWP Capacity Building Program was presented.
- AHWP TC Leaders Meeting & Regulators Forum, April 27-29, 2016, Seoul, Korea.
- The 2nd International Medical Device Communication Forum, June 2016, Seoul, Korea.
- AHWP TC Leaders Meeting, March 2-3, 2017, HK.
- International Medical Device Conference, August 7-9, 2017, Penang, Malaysia.

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# AHWP TC Achievements

## 2014 - 2017

# AHWP TC Meetings

## 2015

**20th AHWP Annual Meeting**

Nov 2-6th in Bangkok, Thailand

- 241 participants from 28 countries
- 11 main themes and 6 panel discussions with 36 speakers
- 2 new member economies

**TC Leaders Meeting**

Mar 19-20th in Singapore

## 2016


**21st AHWP Annual Meeting**

Nov 21-25th in Cebu, Philippines

- 300 participants from 40 countries
- 12 main themes and 5 panel discussions with 66 speakers
- 4 new member economies
- 1 new liaison

**TC Leaders Meeting**

April 27-29th in Seoul, Korea

## 2017

**TC Leaders Meeting**

March 2-3rd in Hong Kong, China

- TC progress for 2017 AHWP work items between AHWP leaders, advisors and WG members

**22nd AHWP Annual Meeting**

Dec 4-8th in Delhi, India

# TC Leaders Meeting on Mar 2-3, 2017, Hong Kong

# AHWP TC Leaders Meeting & Regulators Forum, on April 27-29, 2016, Seoul, Korea

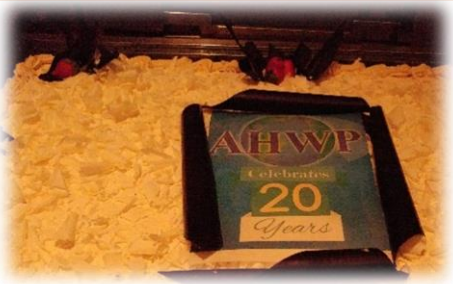
# AHWP Annual Meeting

- Held on Nov 21st to 25th, 2016 in Cebu, Philippines
- About 300 Participants from 40 different countries
- 9 other international organizations' representatives
- 66 speakers
- 12 main themes & 5 panel discussion sessions
- 4 new member economies
- 1 new industry liaison

# Enhancement of Global Partnership

- AHWP Playbook Training
- AHWP TC Workshop
- 20th AHWP TC Meeting
- 21st AHWP Annual Meeting

Cebu, Philippines, 2016



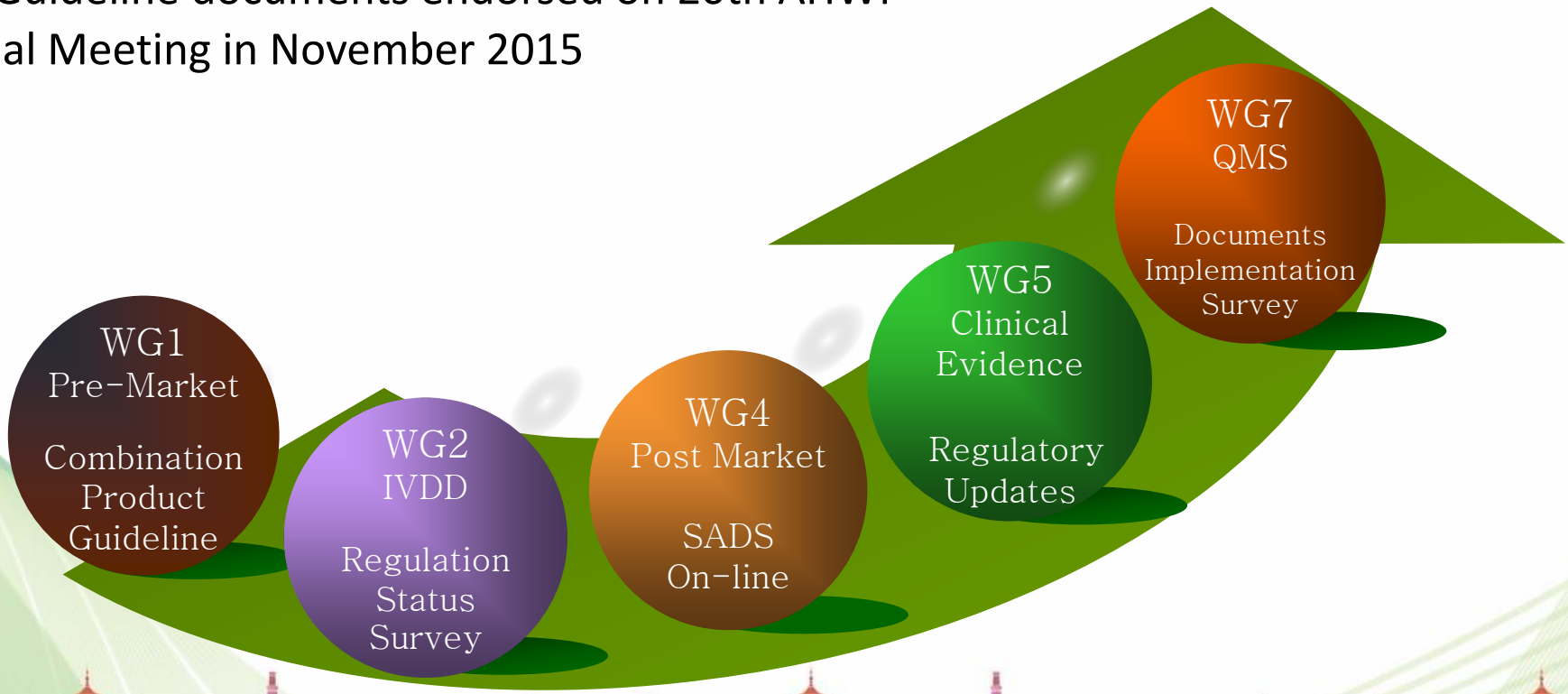



- Delegates from Asia Pacific, Middle East, Africa, South America, USA, Canada, Europe Regions
- International Organizations including IMDRF, WHO, APEC, ASEAN, DITTA, APACMED, GMTA, GMDN, IEC, ISO, Academic, etc.

# Development and Implementation of AHWP Guidelines

## AHWP WG achievements:

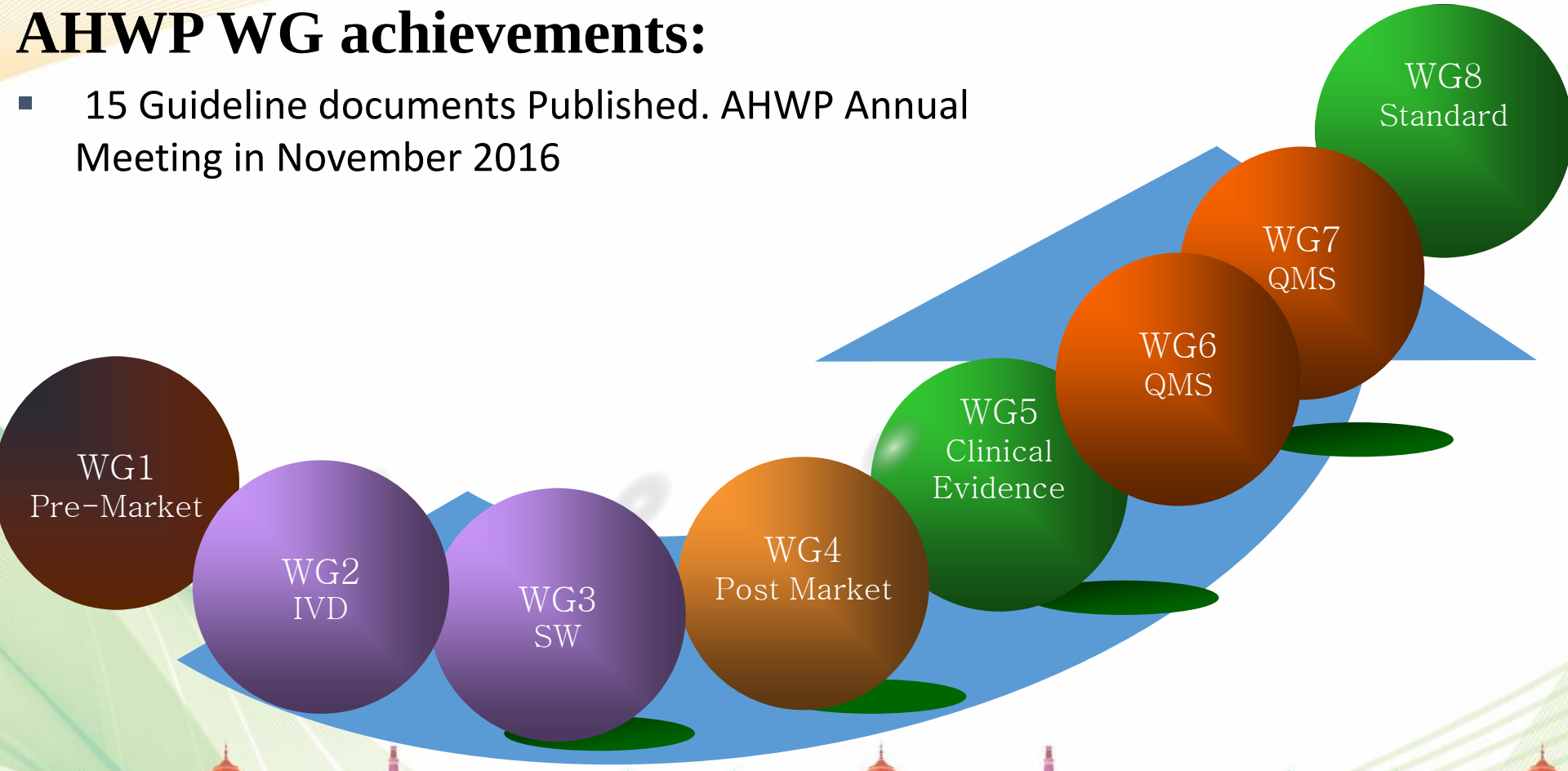
- 11 Guideline documents endorsed on 20th AHWP Annual Meeting in November 2015



# Development and Implementation of AHWP Guidelines

## AHWP WG achievements:

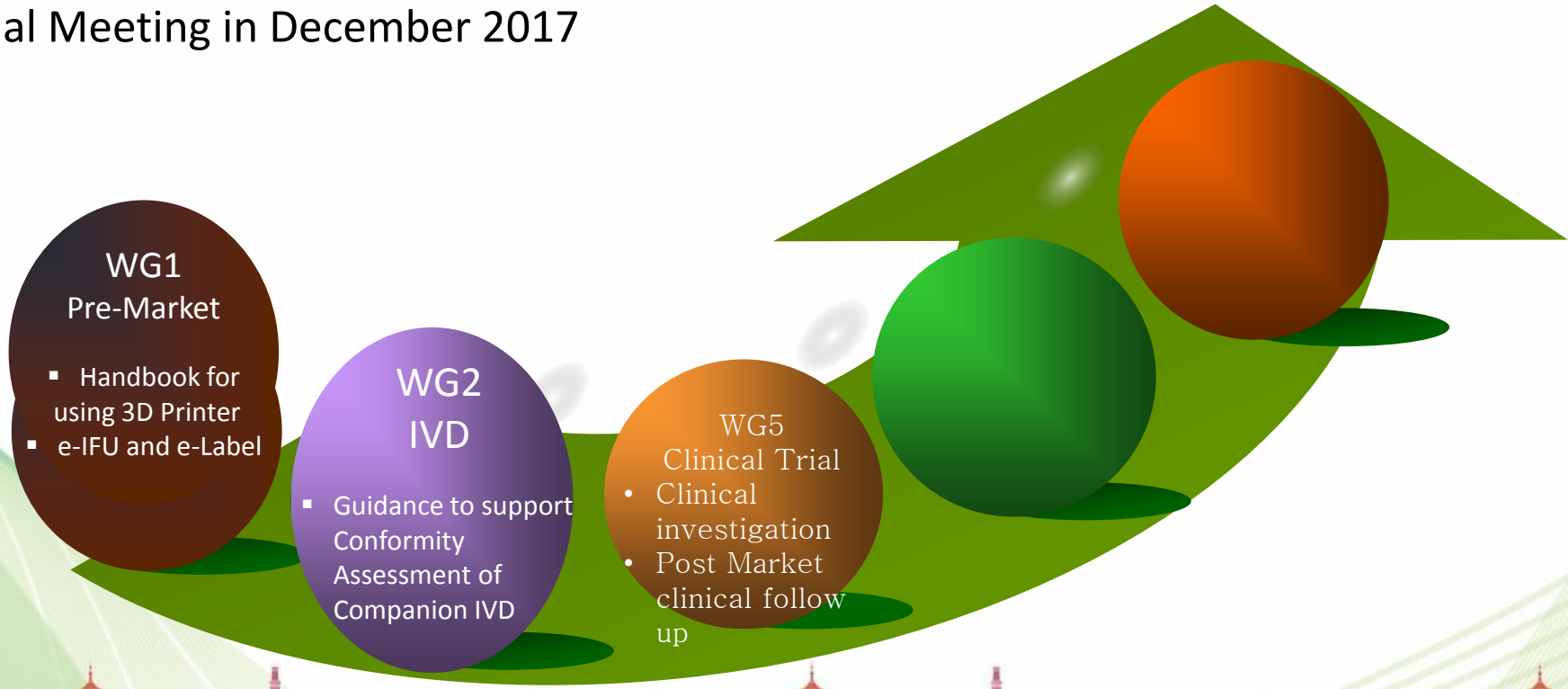
- 15 Guideline documents Published. AHWP Annual Meeting in November 2016



# Development and Implementation of AHWP Guidelines

## AHWP WG achievements:

- 3 Guideline documents endorsed on 22th AHWP Annual Meeting in December 2017



# Work Groups Achievements 2014 -2017

## WG 1

- Guidance on regulatory practices for Combination products
- Guidance for minor change reporting
- Handbook for Approval of Patient-matched Medical Devices Using 3D Printers (Target endorsement Dec 2017)
- Regulation and treatment of e-IFU and e-Label of Medical Devices - Review of International Practice (Target endorsement Dec 2017)

# Work Groups Achievements 2014 -2017

## WG2

- Guidance Document for Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’
- Guidance Document for Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Devices
- Guidance Document for Classification of IVDs
- Guidance Document for In Vitro Companion Diagnostic Devices
- Label and Instructions for Use for IVD Medical Devices
- Guidance Document for Conformity Assessment for IVDs (to be endorsed 2017)

# Work Groups Achievements 2014 -2017

## WG3

- Guidance document on Qualification of Medical Device Software
- Guidance document on Risk Categorisation of SaMD
- White paper on Pre-market Submission requirements for SaMD(working draft ready for public consultation)
- White paper on  Cyber Security for SaMD(in progress)

# Work Groups Achievements 2014 -2017

## WG4

- Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting .
- Develop guidelines on Adverse Events (AE) reporting for PCI devices
- Review and update the existing WG4 guidance documents on SADS
- Survey report on post-market control of medical devices (2017)
- Analyze global and local adverse event report practices of medical devices (2017)
- Update the post-market resource center, the hyperlinks submitted to the Secretariat for sharing at the AHWP website (2017)

# Work Groups Achievements 2014 -2017

## WG5

- Global Clinical Regulatory updates & collaboration with International standards bodies like ISO 14155 with regards to developing new guidance documents.
- ISO 14155 TC Gap Analysis with ICH GCP and ISO 13485:2016
- Updates on APAC  New Regulations
- Updates on IMDRF WG on software clinical evaluation

# Work Groups Achievements 2014 -2017

Cont. **WG5**

- WG5 meeting took place in June 2017 in Sydney. The following updates were shared and accomplished.
  - Updates on IMDRF WG, India MDR, EU MDR IVDR,
  - Regulatory Environment in Australia: TGA Device Regulations & Planned MMDR Reforms, Introduction to the New TGA Clinical Evidence Guideline and national clinical landscape in Australia
- Guidance document to be endorsed:
  - Guidance document on General Principles of Clinical Investigation Audit & Inspection
  - Guidance document on Post Market Clinical Follow-Up Studies

# Work Groups Achievements 2014 -2017

| WG6 | Work Item | Deliverables | Timeline | Status |
|---|---|---|---|---|
| 1 | Reviewing IMDRF proposed documents N8R2 and N24R2 | Guidance document | Q2, 2015 | Done |
| 2 | Finalizing Importer & Distributor Guidance doc. | Guidance document | Q3, 2015 | Done |
| 3 | Conducting training session during annual meeting on I/D adopted guidance documents | Workshop | Q4, 2015 | Done |
| 3 | Aligning WG6 documents with WG7 documents | | Q1, 2016 | Done |
| 4 | Reviewing IMDRF final document N11 &N22 | Guidance document | Q1, 2016 | Done |
| 5 | Reviewing IMDRF final document N3 &N4 | Guidance document | Q3,2016 | Done |
| 6 | Reviewing IMDRF final document N5 &N6 | Guidance document | Q1, 2017 | On hold |
| 7 | Submit the IMDRF documents for comments as draft proposed documents for AHWP ME | Draft documents | Q2, 2017 | On hold |
| 8 | Final documents to be submitted for comments | Final documents | Q3, 2017 | On hold |
| 9 | Endorsement on the adopted documents during annual meeting | Final adopted document | Q4, 2017 | On hold |
| 10 | Conduct training session on MDSAP document | Training | Q1,2017 | Done |
| 11 | Conducting training session during annual meeting on IMDRF MDSAP guidance documents | Workshop | Q4, 2017 | All arrangement been done |
| 12 | AHWP/WG6/NXPDRX <DRAFT> Guidance on Understanding the Roles of IMDRF documents concerning auditing | Guidance document | Sept 2017-April 2018 | DRAFT for review |

# Work Groups Achievements 2014 -2017

## WG7

- Participated ISO13485 handbook, (25 Sept), reference AHWP guidance document in bibliography. **Definitive guide for ISO13485 worldwide**
- Revised IAF MD9 (21 June), reference AHWP guidance document in bibliography, and included provision of **up to 50% reduction in auditor man-days** if the entity is an importer/distributor during ISO13485 certification.
- Involved in ISO14971 drafting committee, ISO24971 drafting committee, DGuide 63 drafting committee, and PMS processes ISO TR20416 drafting committee – **to release all standards and TR by 2019.**
- **Attended every ISO TC210 plenary** as AHWP representative for 3 consecutive years.

# Work Groups Achievements 2014 -2017

## WG8

- Create List of Recognised Standards used in AHWP member economies

# Work Groups Achievements 2014 -2017

## STG

- Continue interaction and exchange progress with international platforms for UDI and nomenclature status
- Exchange progress and knowledge during CIMDR in Aug. in China
  - US implementation and experience
  - EU MDR requirements
  - Industry practice and lesson learned
  - Update China progress
  - Share the status of AHWP countries
- Visited US FDA in 2017 to get more understanding of US UDI practice
- EU roundtable to understand EU requirements on UDI
- Shared the IMDRF guidance documentation with WG members and extended the possibility of adopting IMDRF document in 2018
- Alignment to adopt and transform IMDRF document into AHWP guideline

# AHWP Capacity Building Program

## CBP Overview

- Kick-off Nov 6th, 2015 in Bangkok, Thailand
- CB workshop Nov 21-22nd, 2016 in Cebu, Philippines
- APACMed sponsorship USD 30k

## In Country Trainings

### Indonesia

- July 28-29th, 2016
- 50 Indonesia regulators
- 20 experts from industry
- Topics: AHWP's essential principles of safety and performance and Clinical studies

### Malaysia

- August 10th, 2017
- 200 international regulators, experts and industry
- Topics: software, information technology, post-market considerations

### Vietnam

- August 25-26th, 2016
- 50 Vietnam regulators and experts from industry
- Topics: classification of medical devices & IVDs, pre-market approval, post-market surveillance

### Kazakhstan

- October 23-24th, 2017
- 25 regulators and experts from testing lab
- Topics: CSDT for premarket registration submission, Risks classification, Good distribution practice; QMS audit of manufacturing sites

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Latest news: www.ahwp.info
Email inquiry: secretariat@ahwp.info

# Thank you