24th Asian Harmonization Working Party (AHWP) Annual Meeting

Tran Quan
AHWP Vice-Chair (Industry)
Vice President, Regulatory/Government Affairs/Quality Assurance
Asia Pacific, Align Technology
Purpose of Medical Device Regulations

Why Regulate Medical Devices?

• Protect and promote public health
• Block or remove unsafe and ineffective products from market
• Deter counterfeiting
• Control promotional practices
Our Journey to Regulatory Harmonization

- 1992: GHTF
- 1996: LSIF
- 2002: Global model Regulatory Framework
- 2004: APEC
- 2009: RHSC
- 2012: AMDC
- 2015: AMDD for 10 member states
- 2017: 30 member economies Regulator-Industry
- 2019: Implemented globally

>50 Guidance documents

FUTURE

Big Data
• AHWP Annual Meeting (200+ Participants)
  - Participation of global organizations (IMDRF, WHO, APEC, OECD, etc)
  - Joint workshop plans with liaisons
  - Strategy for Improvement of Regulatory Capacity, Enforcement and Co-operation
23rd AHWP TC Meeting
April 09-10, 2019, Riyadh Saudi Arabia

- AHWP Technical Committee
  Short-term & long-term Plans update
  - Guideline topics and development plans by each WGs
  - Development of Competency Framework White Paper by AHWP Capacity Building
  - In-country training plans

#SFDA is hosting the opening of the 2019 AHWP TC leader meeting. His excellency, prof. @aljadhey: "#SFDA emphasizes the importance of global and scientific approach in promoting public health from any hazardous resulting from medical devices". #Saudi_FDA #SuLinda_News
Goal 1
To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

Goal 2
To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

Goal 3
To promote capacity building in member economies and to foster strategic membership expansion.

Goal 4
To work in collaboration with related international organizations such as International Medical Device Regulators Forum (IMDRF), WHO, ISO, IEC.
AHWP Membership

AHWP Member Countries or Regions: 30 (23 Years)
Asia, Middle East, Africa, S. America

- Brunei Darussalam
- Cambodia
- Chile
- Chinese Taipei
- Hong Kong SAR, China
- India
- Indonesia
- Jordan
- Kazakhstan
- Kingdom of Bahrain

- Kingdom of Saudi Arabia
- Republic of Korea
- Laos
- Malaysia
- Mongolia
- Myanmar
- Pakistan
- People’s Republic of China
- Philippines
- Republic of Kenya

- Singapore
- South Africa
- State of Kuwait
- Sultanate of Oman
- Tanzania
- Thailand
- United Arab Emirates
- Vietnam
- Yemen
- Zimbabwe

To be endorsed at 24th AHWP Annual meeting, 2019

Kyrgyz Republic
# Enhancing Regulatory Agencies and Industries
## Our Capacity Building Journey

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<tr>
<td>Competency Framework for Medical Technology Regulators</td>
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<td>Thailand in-country regulator training – 35 participants</td>
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### White Paper

1. Approach to Develop the Competency Framework
2. Survey Findings
3. Introducing Framework
4. Guidelines on Use of Framework

**Webinar**
24th AHWP Annual Meeting
November 11th – 14th, 2019, Sultanate of Oman, Muscat

Track 1: Regulatory Fundamentals

- Conformity Assessment
- Essential Principles of Safety & Performance
- Risk Classification
- Product Grouping
- Expedited Routes (Referencing/Reliance)
- Post market surveillance/investigation/change management
24th AHWP Annual Meeting
November 11th – 14th, 2019, Sultanate of Oman, Muscat

Track 2: New Technology & Emerging Regulatory Trends

Real World Evidence  Companion Diagnostics  UDI  Digital Health  Artificial Intelligence
AHWP Guidelines for Harmonization

- WG1: PreMarket GMD
- WG2: PreMarket IVD
- WG3: Software
- WG4: PostMarket
- WG5: Clinical Evidence
- WG6: QMS: Audit & Assessment
- WG7: QMS: Operation & Implementation
- WG8: Standards
- WG9: UDI & Nomenclature

AHWP Guidelines for Harmonization
Continuous Efforts for Global Harmonization

APEC LSIF RHSC/ Medical Device Vigilance
- Join the Project ‘Roadmap to Promote Convergence’ and training workshops

IMDRF WG/ UDI & Standards
- Join the International Workshop on UDI, Feb 2018, Brussels
- Participated IMDRF meeting in March, Shanghai, September Beijing

IMDRF WG/ Personalized Medical Devices
- Attended IMDRF face to face meeting for Personalized Medical Devices
  * Personalized Medical Devices definitions N49 is approved by MC
  * Now working on another documents for Personalized Medical Devices conformity pathways

IMDRF WG/ Principles of IVD Medical Devices Classification
- Working on revision of GHTF / SG1 / N045: 2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
- Provided AHWP experience and comments on IVD Classification
- Attend IMDRF IVD WG F2F meeting in Aug, Moscow, Russia

IEC/ISO Works
- Attending TC meetings: ISO TC210
Collaboration between Regulators and Industry
- Right competency
- Good Submission Practice
- Good Review Practice

Innovative/High Quality Medical Devices

Patients
24th AHWP Annual Meeting
November 11th – 14th, 2019, Sultanate of Oman, Muscat

thank you very much

shukran jaziilan

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