

# **24<sup>th</sup> Asian Harmonization Working Party (AHWP) Annual Meeting**

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**AHWP Vice-Chair (Industry)**

**Vice President, Regulatory/Government Affairs/Quality Assurance**

**Asia Pacific, Align Technology**



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

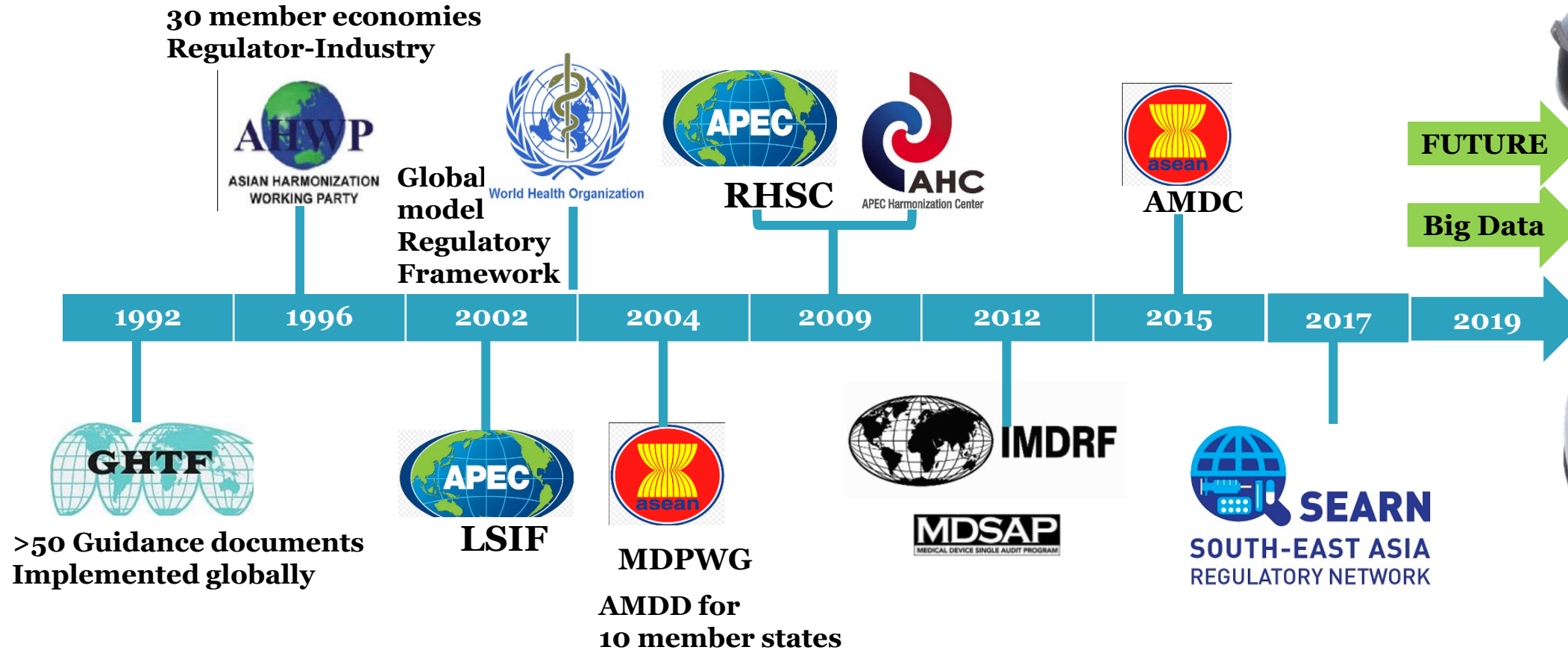
# Purpose of Medical Device Regulations

## Why Regulate Medical Devices?

- Protect and promote public health
- Block or remove unsafe and ineffective products from market
- Deter counterfeiting
- Control promotional practices

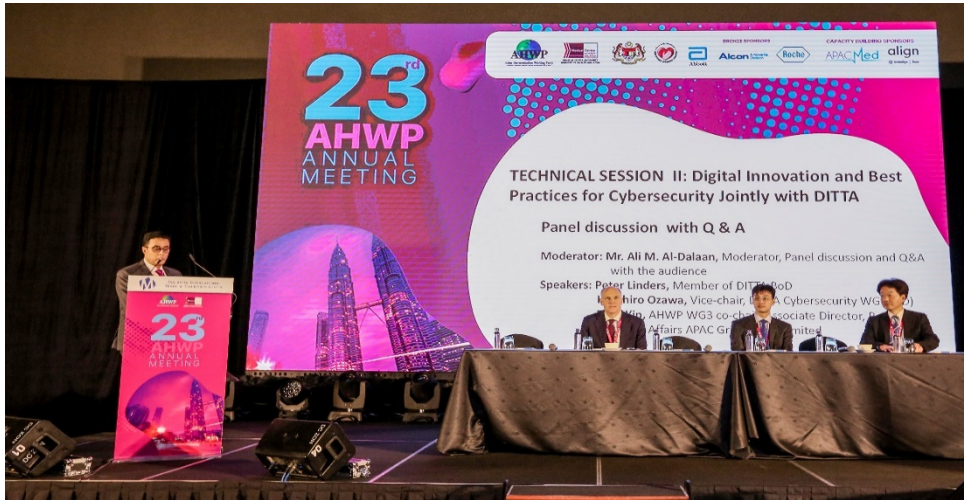


# Our Journey to Regulatory Harmonization



# 23<sup>rd</sup> AHWP Annual Meeting

October 22-25, 2018, Kuala Lumpur, Malaysia



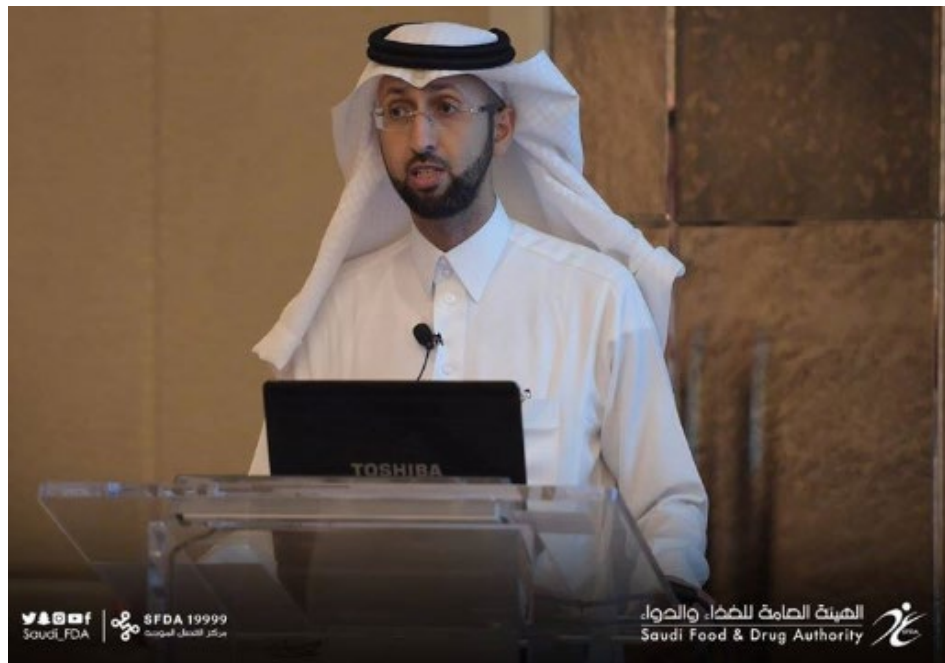
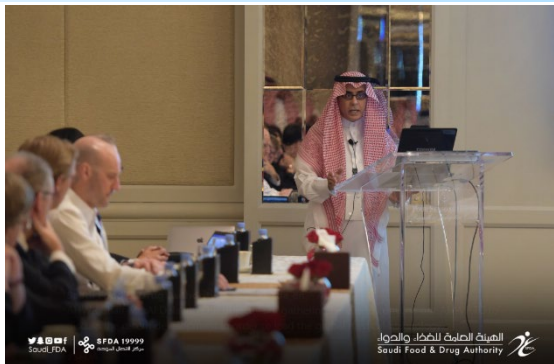
- **AHWP Annual Meeting (200+ Participants)**
  - Participation of global organizations (IMDRF, WHO, APEC, OECD, etc)
  - Joint workshop plans with liaisons
  - Strategy for Improvement of Regulatory Capacity, Enforcement and Co-operation





# 23<sup>rd</sup> AHWP TC Meeting

April 09-10, 2019, Riyadh Saudi Arabia



#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



- **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



# AHWP Goals

## 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  
24<sup>th</sup> AHWP  
Annual meeting, 2019

**Kyrgyz Republic**

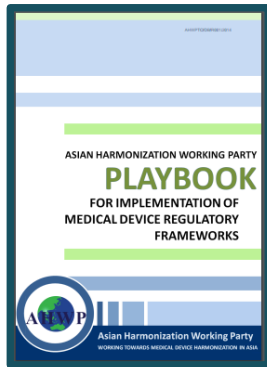


# Enhancing Regulatory Agencies and Industries

## Our Capacity Building Journey

2014 - 2017

2018 - 2019



**Competency Framework for Medical Technology Regulators**



**Thailand in-country regulator training – 35 participants**



### White Paper

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

### Webinar



# 24<sup>th</sup> AHWP Annual Meeting

November 11<sup>th</sup> – 14<sup>th</sup>, 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

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## Track 2: New Technology & Emerging Regulatory Trends



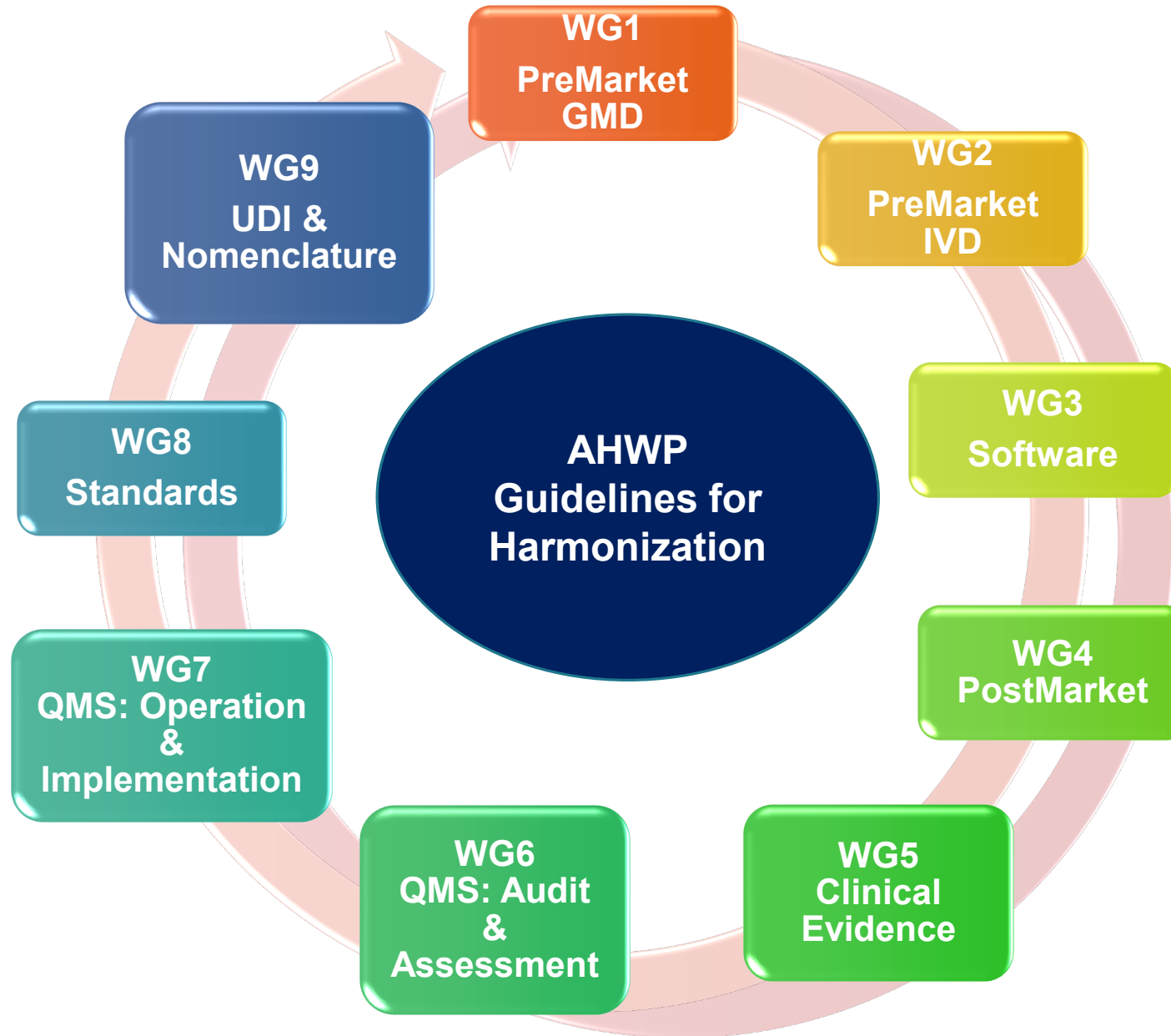
Real World  
Evidence

Companion  
Diagnostics

UDI

Digital  
Health

Artificial  
Intelligence





# 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

- Drafting: Committees of ISO14971, ISO TR24971, ISO/IEC Guide63, ISO TR20416
- Attending TC meetings: ISO TC210

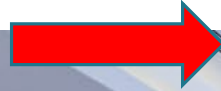


# 24<sup>th</sup> AHWP Annual Meeting - Day 1

November 11<sup>th</sup> – 14<sup>th</sup>, 2019, Sultanate of Oman, Muscat

Collaboration between  
Regulators and Industry

- Right competency
- Good Submission Practice
- Good Review Practice



Innovative/High Quality  
Medical Devices



Patients



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November 11<sup>th</sup> – 14<sup>th</sup>, 2019, Sultanate of Oman, Muscat

thank you very much

shukran jaziilan

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