AHWP UPDATE

Ali M. Aldalaan

Vice Executive President, Medical Devices Sector
AHWP Chair

IMDRF – 15. 19-21 March 2019 Moscow, Russia
AHWP Member Country or Region: 30 (as of Mar 2019)

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
# AHWP TC Strategic Plan

<table>
<thead>
<tr>
<th>Collaborating Activities</th>
<th>• Harmonization in key areas based on IMDRF Principles and AHWP Guidance</th>
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<tbody>
<tr>
<td>Working Group Tasks</td>
<td>• Development of AHWP Guidance</td>
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<td></td>
<td>• Pre- and post-market control, UDI</td>
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<td>• QMS, Clinical evidence, Standards</td>
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<td>Capacity Building Projects</td>
<td>• In-country trainings</td>
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<td>• Implementation of Guidance</td>
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<td>• Regulatory Competency Handbook</td>
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AHWP Leadership Team

AHWP Chair:
Mr. Ali Al dalaan,
Vice Executive President, Medical Devices Sector, Saudi Arabia

AHWP Vice-chair:
Mr. Guobiao Gao,
Deputy Director General, National Medical Product Administration, China

AHWP Vice-chair:
Ms. Tran Quan, Industry
# AHWP TC Team

## TC Office Bearers

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
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<tbody>
<tr>
<td>Chair</td>
<td>Ms. Sasikala Devi Thangavelu</td>
</tr>
<tr>
<td>Co-Chair</td>
<td>Dr. Jeong-Rim Lee</td>
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<tr>
<td>Co-Chair</td>
<td>Mr. Alfred Kwek</td>
</tr>
<tr>
<td>Secretary</td>
<td>Mr. Jack Wong</td>
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<tr>
<td></td>
<td>Ms. Chadaporn Tanakasemsub (Miang)</td>
</tr>
<tr>
<td></td>
<td>Ms. Carol Yan</td>
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<td>Ms. Soo-Kyeong Shin</td>
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## Work Groups

<table>
<thead>
<tr>
<th>Work Group</th>
<th>Positions</th>
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</thead>
</table>
| WG1: Pre-market | Chair - Mr. Se-il Park  
Co-Chair - Ms. Kate Hyeong Joo Kim |
| WG2: Pre-market - IVDD  | Chair - Mr. Wen-Wei TSAI  
Co-Chair - Mr. Albert POON |
| WG3: Pre-market - Software as a Medical Device  | Chair - Dr. Abdullatif Alwatban  
Co-Chair - Mr. Tony Yip |
| WG4: Post-market  | Chair - Ms. Jennifer MAK  
Co-Chair - Ms. Kitty Mao |
| WG5: Clinical Evidence for performance & safety | Chair - Ms. Yuwadee PATANAWONG  
Co-Chair - Ms. Sumati Randeo |
| WG6: Quality Management Systems: Audit & assessment | Chair - Mr. Abdullah AL RASHEED  
Co-Chair - Mr. Vincent LAM Chee-Choong |
| WG7: Quality Management Systems: Operation & implementation | Chair - Ms. Wang Aijun  
Co-Chair - Mr. Ee Bin Liew |
| WG8: Standards  | Chair - Mrs. Salibiah Yaakop  
Co-Chair - Mr. Tony Low |
| STC (UDI & Nomenclature)  | Chair - Mr. Jun LI  
Co-Chair - Ms. Victoria Qu |
AHWP TC PLAN

2018 - 2020
## WG Plans for 2018 - 2020 (1)

<table>
<thead>
<tr>
<th>WG</th>
<th>Tasks</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG1</td>
<td>• E-labeling/e-IFU guideline (collaboration with WG2 &amp; WG3)</td>
<td>Q4, 2018</td>
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<tr>
<td></td>
<td>• 3D printing handbook update</td>
<td>TBD</td>
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<td>• Change management for medical device registration guideline</td>
<td>Q4, 2019</td>
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<tr>
<td></td>
<td>(collaboration with WG2 &amp; WG3)</td>
<td></td>
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<td></td>
<td>• AI guidance in consideration</td>
<td>TBD</td>
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<tr>
<td>WG2</td>
<td>• E-labeling/e-IFU guideline (collaboration with WG1 and WG3)</td>
<td>Q4, 2018</td>
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<tr>
<td></td>
<td>• Change management for medical device registration guideline</td>
<td>Q4, 2019</td>
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<tr>
<td></td>
<td>(collaboration with WG1 &amp; WG3)</td>
<td>Q4, 2020</td>
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<td>• Guidance document for approval of reagent for instrument family</td>
<td>Q4, 2020</td>
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<td>• Future trend study &amp; survey: Bridging LDT and IVD</td>
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<tr>
<td>WG3</td>
<td>• White paper on pre-market initial submission format for SaMD</td>
<td>Q4, 2018</td>
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<tr>
<td></td>
<td>• E-labeling/e-IFU guideline (collaboration with WG2 &amp; WG3)</td>
<td>Q4, 2018</td>
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<td></td>
<td>• White paper on cybersecurity for SaMD</td>
<td>Q1, 2019</td>
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<tr>
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<td>• Change management for medical device registration guideline</td>
<td>Q4, 2019</td>
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<tr>
<td></td>
<td>(collaboration with WG2 &amp; WG3)</td>
<td></td>
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<tr>
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<td>• Guidance document for pre-market submission format for SaMD (draft)</td>
<td>Q3, 2019</td>
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<tr>
<td>WG4</td>
<td>• Updating the post-market resource centre</td>
<td>Ongoing</td>
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<td></td>
<td>• Gap analysis on the implementation of AHWP guidance among AHWP members</td>
<td>Ongoing</td>
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<td></td>
<td>• Participation in the development works of ISO TC210/WG6</td>
<td>Ongoing</td>
</tr>
<tr>
<td>WG</td>
<td>Tasks</td>
<td>Timeline</td>
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</table>
| **WG5** | • Annual review SWOT analysis of WG5 framework  
• Guidance document on general principles of clinical investigation audit & inspection for medical devices  
• Training: WG5 & AHWP members  
• Survey: country regulations/guidelines and implementation | Q4, 2018  
Q4, 2018  
Q4, 2018  
Q4, 2019 |
| **WG6** | • Guidance document on understanding the roles of IMDRF documents concerning auditing (draft)  
• Guidance document on the current best practice in determination of regulatory audit duration (draft) | Q4, 2018  
Q2, 2019 |
| **WG7** | • Comparison study of new ISO13485 vs QMS requirements in each country  
• QMS consideration for manufacturers and importers for localization | Q2, 2020  
Q4, 2020 |
| **WG8** | • Guidance document on code of practice for good engineering maintenance management of medical devices  
• Collecting a list of standards used for medical device regulatory purposes that are recognized by AHWP member countries | TBD  
TBD |
| **WG9** | • AHWP UDI report  
• AHWP UDI rule | TBD  
TBD |
Development & Implementation of AHWP Guidance

AHWP WG Achievements:
Guidance documents were endorsed
- 12 in 2015
- 15 in 2016
- 3 in 2017
- 5 in 2018 (planned)
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

**IEC/ISO Works**
- Attending TC meetings: ISO TC210
Collaboration with the OECD

Title: The Contribution of Trans-Governmental Networks of Regulators to International Regulatory Co-operation

A Case Study of the AHWP on Medical Devices

1. Overview
- History
  - Intended objectives of regulatory co-operation
  - Landscape of regulatory actors
  - Collaboration with other IOs

2. Governance & Operational Modalities
- AHWP Membership
- Structure and governance
- Institutional setup
- The range of AHWP instruments
- Implementation mechanism (CBP)
- Quality mechanism of instruments

3. Assessment
- Benefits
- Challenges

- Participation in drafting the 2nd OECD Report (2017 - 2018)
- Published as an OECD report (September, 2018)
• **AHWP Technical Committee**

**Short-term & long-term Plans**
- Guideline topics and development plans by each WG
- Development of Competency Handbook by AHWP TC
- In-country training plans

• **AHWP Annual Meeting**

- Participation of global organizations (IMDRF, WHO, APEC, OECD, etc)
- Joint workshop plans with liaisons
- Strategy for Improvement of Regulatory Capacity, Enforcement and Co-operation
AHWP Capacity Building Projects

3 Capacity Building Workshops & 4 In-country Trainings (2015-2017)

- CB Workshops: Thailand Nov’15; Philippines Nov’16; India Dec’17
- In-country Trainings: Indonesia ’16; Vietnam ’16; Malaysia ’17; Kazakhstan ’17
- Topics: CSDT for pre-market registration submission, Risk classification, Good distribution practice, QMS audit, SW, Information technology, Post-market considerations

2018

- In-country trainings
- Republic of Kenya
- Thailand

Launch Competency Framework for MedTech Regulators

A joint initiative of AHWP, APACMed and Deloitte
AHWP Capacity Building
Bangkok, Thailand
Feb 22-23, 2019
Capacity Building in Thailand

Day 1:

✓ AMDD- Areas of harmonization in place in ASEAN states- summary update
✓ Definition of a Medical Device (Recap)
✓ Risk Management
✓ Risk classification and grouping
✓ CSDT
✓ Discussion on 1 application for product registration received by TFDA (Optional)

• 35 Regulators attended training

Day 2:

✓ Essential Principles - what and why this is necessary
✓ Standards - application of standards in the context of Essential Principles
✓ Post Market (articles in AMDD)
✓ Areas of Post market to be applied.
Capacity Building in Thailand

• Training met my expectation?  ~92% Strongly Agree and Agree

<table>
<thead>
<tr>
<th>Part I: AMDD Summary</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
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<table>
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<tr>
<th>Part II: Premarket</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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<table>
<thead>
<tr>
<th>Part III: Post market</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
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<tbody>
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Note: 22 attendees participated after-training feedback
COMPETENCY HANDBOOK FOR MEDITECH REGULATORS

PROJECT SCOPE:
- AHWP survey for regulators among its 30 member countries and regions
- APACMed launching similar survey among companies to assess satisfaction & expectation

High-Level Competency Framework for MedTech Regulators

A. Domain
   - Sub-domain 1: Foundational Competencies
   - Sub-domain 2: General Technical Competencies
   - Sub-domain 3: Functional Technical Competencies

B. Competency
   - Knowledge: Institutional, scientific & regulatory professional knowledge
   - Skill/Abilities: Professional, technical & interpersonal skills/abilities

C. Six Functions
   - Premarket Evaluation
   - Clinical Oversight
   - Lab Testing
   - Manufacturing Control
   - Distribution Control
   - PMS/Vigilance

D. Clusters of Competencies for capacity building
   - Basic
   - Advanced
   - Expert
   - Mastery

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- AHWP survey for regulators among its 30 member countries and regions
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Thank you