

The 23rd AHWP Annual Meeting Program

Convention Centre, Kuala Lumpur, Malaysia

22 - 25 October 2018

Day 1 Agenda: 22 October 2018 (Monday)

AHWP TC Workshop

08:00-09:15 Registration of the Delegates

TIME AHWP TC WORKSHOP OPENING (09:15 – 9:30)

09:15-09:20 Opening Address **Mr. Ali M. Al-Dalaan**, TC Chair, AHWP, Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia

09:20-09:30 Welcome Address **Mr. Zamane Abdul Rahman**, AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia

Day 1 Agenda: 22 October 2018 (Monday)

TIME **TECHNICAL SESSION I: Artificial Intelligence in Healthcare** (09:30 –12:00)
Jointly with APACMed

9:30-10:00 **Introduction to AI and latest development – setting the context**
IBM Watson Health (TBD)

10:00-10:30 **Perspectives and regulatory considerations for AI and big data in medical devices**
Dr. Seil Park, AHWP WG1 Chair, Assistant Director, High-tech Devices Division, Medical Device Evaluation Department, Korea MFDS

10:30-10:45 **Tea Break**

10:45-11:15 **Hospital case study – practical use of AI in a clinical setting**
CIO from major hospital group using AI (TBD)

11:15-12:00 **Panel discussion with Q & A**
Moderator : Fredrik Nyberg, CEO, APACMed

Speaker 1
Dr. Seil Park, AHWP WG1 Chair, Assistant Director, High-tech Devices Division, Medical Device Evaluation Department, Korea MFDS

Speaker 2

12:00-14:00 **Lunch**

TIME **TECHNICAL SESSION II: Digital Innovation and Best Practices for Cybersecurity** (14:00 –15:50)
Jointly with DITTA

14:00-14:20 **Introduction to the digital transformation of health and care**
Peter Linders, member of DITTA BoD

14:20-14:40 **Risk frameworks and international standards on cybersecurity**
Tony Yip, AHWP WG3 co-chair, Associate Director, Regulatory Affairs APAC Grifols (HK) Limited (TBD)

14:40-15:00 **Best practices and actions taken by manufacturers**
Greg LeBlanc, DITTA representative (TBD)

15:00-15:30 **Panel Discussion**
Moderator: Greg LeBlanc, DITTA representative
Speakers: Peter Linders, member of DITTA BoD
TBD, DITTA representative
Tony Yip, one of AHWP industry member, AHWP WG3 co-chair

15:30-15:50 **Tea Break**

TIME **TECHNICAL SESSION III: AHWP Leaders Sharing** (15:50 –16:30)

15:50-16:10 **National Support of Medical Device Industry and Innovation**
Dr. Hee-Kyo Jeong, AHWP Former Chair, President of National Institute of Medical Device Safety (NIDS), Korea

16:10-16:30 **Dr. V. G. Somani**, Advisor to AHWP Chair, India (TBD)

16:30-16:35 Closing Remarks **Dr. Jeong-Rim Lee**, AHWP TC Co-Chair, Director, Cardiovascular Devices Division(Former), Department of MD Evaluation, Korea Ministry of Food and Drug Safety (MFDS)

Day 2 Agenda: 23 October 2018 (Tuesday)

AHWP TC Workshop

TIME **TECHNICAL SESSION IV:** Updates on IVD regulatory requirements (TBD) (09:00-10:30)
By AHWP WG2

09:00-09:05 **Opening** **Wen-wei Tsai**, AHWP WG2 Chair

09:05-09:35 **Developing international standard – Good Clinical Study Practice for IVD**
Shelley Tang

09:35-10:05 **Change management and grouping for IVD**
Dr. Adelheid Schneider or ASEAN speaker (TBD)

10:05-10:35 **Regulatory control of IVD NGS/multiplex**
US FDA representative or Petra KAARS-WIELE (TBD)

10:35-10:50 **Tea Break**

TIME **TECHNICAL SESSION V:** Updates on Digital Health Regulations (TBD) (10:50-12:00)
By AHWP WG3

10:50-11:00 **Overview of SFDA guideline on digital health**
Dr. Abdullatif Al Watban, AHWP WG3 Chair, Director, National Center for Medical Devices Research, Medical Devices Sector, Saudi FDA

11:00-11:10 **Introduction of Guideline for VR and AR based medical devices**
Dr. Seil Park, AHWP WG1 Chair, AHWP, Assistant Director, High-tech Devices Division, Medical Device Evaluation Department, Korea MFDS

11:10-11:20 **Medical Device Software**
US FDA representative (TBD)

11:20-11:30 **Medical Devices cybersecurity**
CFDA representative (TBD)

11:30-12:00 **Panel Discussion**
(TBD)

12:00-14:00 **Lunch**

TIME **TECHNICAL SESSION VI :** Updates on UDI regulatory requirements (TBD) (14:00-16:00)
By AHWP WG9

14:00-14:05 **Opening** **Jun LI**, AHWP WG9 Chair, Director of Division of Registration I, Department of MD Registration, NMPA

14:05-14:25 **The recent development on UDI – update from IMDRF**
Ishikawa Hiroshi, PMDA, Japan (TBD)

14:25-14:45 **AHWP UDI Update (including China UDI Draft Rules for UDI System for Medical Devices)**
Li Jun, AHWP WG9 Chair, Director of Division of Registration I, Department of MD Registration, NMPA
Li Yi, Center for Medical Device Standardization Administration, NMPA

14:45-15:00 **Recent Development on UDI Rules in EU**
EC representative (TBD)

15:00-15:15 **US FDA experience in Implementation of UDI and Lessons Learned & Benefits Realized from UDI Adoption**
US FDA representative (TBD)

15:15-15:25 **Recent Development on UDI Rules in Saudi Arabia**
SFDA representative (TBD)

15:25-15:35 **Recent Development on UDI Rules in South Korea**
MFDS representative (TBD)

15:35-15:45 **Manufacturer Perspective of UDI Implementation Harmonization & Benefits Realized from UDI Adoption**
GMTA or APACMed Representative or WG9 member (TBD)

15:45-15:55 **Q & A**

15:55-16:00 **Closing Remarks and Adjourn** **Victoria Qu**, AHWP WG9 Co-chair, Director, Regulatory Affairs, Global Strategic Regulatory, Abbott

TIME **TECHNICAL SESSION VII :** Sharing on Quality System Certification & Standards (16:00-17:00)
By AHWP WG8

16:00-16:20 **EU MDR-Novel pre and post market controls as means of assurance of compliance**
Vincent Lam, AHWP WG6, co-chair, Senior Product Specialist, TUV-SUD Product Service GmbH

16:20-16:40 **WG 8 plans and progress/adoption of MS 2058**
Salbiah Yaakop, AHWP WG8 Chair, Senior Principal Assistant Director, Policy, Codes & Standards Division Medical Device Authority, Ministry of Health Malaysia

Day 2 Agenda: 23 October 2018 (Tuesday)

AHWP TC Workshop

16:40-17:00	IMDRF Work Program on Standards Scott Colburn , IMDRF WG chair on Standards
17:00-17:10	Closing Remarks for TC Workshop on Day 2 Mr Alfred Kwek , AHWP TC Co-chair (Industry), Director, Public Affairs, Edwards Lifesciences, Singapore

GALA DINNER

(19:00 ONWARDS): END OF DAY 2

Day 3 Agenda: 24 October 2018 (Wednesday)

AHWP TC Meeting

09:00-10:40	AHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting) AHWP & TC & WG Leaders & TC Advisors
10:40-11:00	Tea Break
11:00-11:05	Welcome Speech Mr. Ali M. Al-Dalaan , AHWP TC Chair, Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
11:05-11:25	Opening of TC Meeting -Roll call -Adoption of Agenda -Adoption of 21st AHWP TC Meeting Minutes Mr. Ali M. Al-Dalaan , AHWP TC Chair, Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Mr. Bryan So , AHWP Secretariat, Principal Consultant, Smart Healthcare, MedTech & Optics Unit, Hong Kong Productivity Council, Hong Kong SAR, China
TIME	WORKING GROUP UPDATES (11:25- 15:25)
11:25-13:05 (20min each)	Working Group 1 Update by Dr. Seil Park and Ms. Kate HyeongJoo Kim Working Group 2 Update by Dr. Wen-wei TSAI and Ir. Albert POON Working Group 3 Update by Dr. Abdullatif S. Al Watban and Mr. Tony Yip Working Group 4 Update by Ms. Jennifer MAK and Ms. Kitty Mao Working Group 5 Update by Ms. Yuwadee PATANAWONG and Ms. Sumati Randeo
13:05-14:05	Lunch
14:05- 15:25 (20min each)	Working Group 6 Update by Mr. Abdullah AL RASHEED and Mr. Vincent LAM Working Group 7 Update by Ms. AiJun Wang and Mr. Ee Bin Liew Working Group 8 Update by Mrs. Salbiah Yaakop and Mr. Tony Low Working Group 9 Update by Jun Li and Ms. Victoria Qu By Working Group Chair & Co-chairs
15:25-15:45	Tea Break
15:45-16:15	Highlight of AHWP Competence Project + In-country Training Ms Tran Quan , AHWP Vice-Chair (Industry), Head of Regulatory & Government Affairs and Quality Assurance Asia Pacific, Invisalign Singapore Pte Ltd. , Singapore
16:15- 16:45	Sharing of Competence Study by Malaysia Ms. Sasikala Devi Thangavelu , AHWP Secretary General Director, Policy, Codes & Standards Division, Medical Device Authority, Ministry of Health, Malaysia
16:45-17:15	Improvement of Regulatory Capacity, Enforcement and Co-operation Dr. Jeong-Rim Lee , AHWP TC Co-Chair, Director, Cardiovascular Devices Division(Former), Department of MD Evaluation, Korea Ministry of Food and Drug Safety (MFDS)
17:15-17:45	Speech by AHWP TC Advisors Representative Mr. Grant Ramaley , AHWP TC Advisor Representative
17:45-17:55	Closing Remarks Mr. Ali M. Al-Dalaan , AHWP TC Chair, Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia

Day 4 Agenda: 25 October 2018 (Thursday)

AHWP Annual Meeting

09:00-09:30	Speech by officials, Name, position, organization A. Opening Ceremony B. Congratulation Address C. Opening Speech by AHWP Chair Mr. Zamane Abdul Rahman , AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia D. Group Photograph
09:30-09:40	A. Roll Call B. Adoption of Agenda C. Adoption of 22nd AHWP Annual Meeting Minutes Mr. Zamane Abdul Rahman , AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia Supported by Mr. Bryan So , AHWP Secretariat, Principal Consultant, Smart Healthcare, MedTech & Optics Unit, Hong Kong Productivity Council, Hong Kong SAR, China
09:40-10:10	Updates by AHWP and AHWP TC Ms. Tran Quan , AHWP Vice-Chair (Industry), Head of Regulatory & Government Affairs and Quality Assurance Asia Pacific, Invisalign Singapore Pte Ltd., Singapore Mr. Ali M. Al-Dalaan , AHWP TC Chair, Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
10:10 – 10:30	Updates by IMDRF - IMDRF representative (TBD)
10:30 – 11:00	Tea Break
11:00 - 12:30 (15min each)	Updates by International Organizations WHO, PAHO, APEC, ASEAN, EU, GMDN
12:30 -14:00	Lunch
14:00-15:30 (15min each)	AHWP Member Country/Region Regulatory Updates: (Tentatively) - Malaysia - Singapore - China - Sultanate of Oman - Indonesia - Chinese Taipei Mr. Zamane Abdul Rahman , AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia Supported by Mr. Bryan So , AHWP Secretariat, Principal Consultant, Smart Healthcare, MedTech & Optics Unit, Hong Kong Productivity Council, Hong Kong SAR, China
15:30 – 15:45	Tea Break
15:45 – 16:15 (10 min each)	AHWP Liaison Member Updates - APACMed Update Mr. Fredrik Nyberg , CEO, APACMed (Tentatively) - DITTA Update TBC , Member of BoD, DITTA - GS1 Update TBC
16:15-16:30	Secretariat Updates - Secretariat Report - Financial Report Mr. Bryan So , AHWP Secretariat, Principal Consultant, Smart Healthcare, MedTech & Optics Unit, Hong Kong Productivity Council, Hong Kong SAR, China
16:30-16:50	Resolutions: A. Endorsement of New Member B. Endorsement of Resolutions from WG Mr. Zamane Abdul Rahman , AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia Supported by Mr. Bryan So , AHWP Secretariat, Principal Consultant, Smart Healthcare, MedTech & Optics Unit, Hong Kong Productivity Council, Hong Kong SAR, China
16:50-17:00	Announcement of 24th AHWP Annual Meeting Host Mr. Zamane Abdul Rahman , AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
17:00-17:10	Closing Remarks Mr. Zamane Abdul Rahman , AHWP Chair, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
17:10-17:30	Break
17:30-18:00	The 7th AHWP ASL Annual General Meeting (AGM) ASL Members only (Transfer to another room)