25th AHWP/GHWP Online Annual Meeting and 25th TC Online Meeting
30th Nov & 1st Dec 2021
DRAFT Program (Version 9.6)

Day ONE: 30th Nov 2021| 1pm to 4.35pm KSA Time/ 6pm to 9.35pm Beijing Time

Estimated Time	Opening, Keynotes and Highlights on Capacity Building Program
1300 (KSA) 1800 (BJ/HKT) [5mins]	**Welcome Address** **H.E. Prof. Hisham S. Aljadhey** Executive President, Saudi FDA, Kingdom of Saudi Arabia
1305(KSA) 1805(BJ/HKT) [5mins]	**Opening Address** **Mr. Ali M. Al-Dalaan**, AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
1310(KSA) 1810(BJ/HKT) [1mins]	**Group Photos Taking (cap screen photos)**
1311(KSA) 1811(BJ/HKT) [15mins]	**Keynote Speech** **Hepatitis C virus elimination: laying the foundation for achieving 2030 targets** **Dr. Hishamshah**, Deputy Director General (Research & Technical Support), Malaysia MOH
1326(KSA) 1826 (BJ/HKT) [35mins]	**Global Medical Device Regulatory Framework – New Regulations & the Way Forward** **Panel Discussion [35mins]** **Moderator: Mr. Mike Flood,** Chair, Biomedical College, Engineers Australia **Panellists:** 1. **Saudi FDA - Mr. Ali M. Al-Dalaan**, Vice Executive President, Medical

	Devices Sector, Saudi FDA, Kingdom of Saudi Arabia 2. **China NMPA - Mr. ZHANG Hua**, Deputy Director General, Department of Medical Device Registration, National Medical Products Administration, China 3. **South Korea MFDS - Dr. Seil Park**, Assistant Director, Cardiovascular and Imaging Devices Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, South Korea 4. **Malaysia MOH - Ms. Mariammah Krishnasamy**, Senior Principal Assistant Director, Registration, Licensing and Enforcement Division, Medical Device Authority, Ministry of Health, Malaysia 5. **WHO - Ms. Agnes Sitta Kijo**, Technical Officer, Regulation and Safety Unit (REG), Regulation and Prequalification Department (RPQ), World Health Organization 6. **Australia TGA- Ms. Tracey Duffy,** First Assistant Secretary, Medical Devices & Product Quality Division, Health Products Regulation Group, Department of Health, Australia
1401 (KSA) 1901 (BJ/HKT) [15mins]	**AHWP/GHWP Capacity Building Program- Bringing It Together** **Ms. Quan TRAN**, AHWP/GHWP Vice-Chair | Lead of Capacity Building | Vice President, Regulatory, Government Affairs, and Quality Assurance, Asia Pacific, Align Technology

Estimated Time	Emergency Use Authorization (EUA)
1416 (KSA) 1916 (BJ/HKT) [70mins]	**EUA Experience Sharing by AHWP/GHWP Country/Region** [5mins each x 10]: 1. **Saudi FDA - Dr. Razan Asally,** Head of Medical Device Evaluation Section, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia 2. **China NMPA – Mr. YUAN Peng**, Director, Department of Medical Device Registration, National Medical Products Administration, China 3. **South Korea MFDS- Mr. Young-Wook Ahn,** Deputy Director, In-Vitro

Diagnostic Devices Division, NIFDS, MFDS, South Korea

4. **Malaysia MOH and ASEAN- Mrs. Salbiah Yaakop,** Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health, Malaysia
5. **Chinese Taipei TFDA- Dr. Wen Wei Tsai,** Division of Medical Devices & Cosmetics, Food & Drug Administration, Ministry of Health & Welfare
6. **India MOH- Dr. V. G. Somani**, Drugs Controller General
7. **Kenya MOH - Ms. Paulyne Wairimu,** Head of Medical Devices, Ministry of Health, Republic of Kenya
8. **Chile ISP- Ms. Maria Cecilia Lopez,** Professional Medical Devices Office, Public Health Institute of Chile
9. **USFDA- Ms. Melissa Torres,** Associate Director for International Affairs, Center for Devices and Radiological Health, US Food and Drug Administration
10. **Japan PMDA- Ms Mika Togashi,** Deputy Division Director, Division of Regulatory Cooperation, Office of International Programs

Panel Discussion on EUA [20mins]

Moderator: Dr. Adelheid Schneider, APACMed | Head of Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd

Panellists:

1. **Saudi FDA - Dr. Razan Asally,** Head of Medical Device Evaluation Section, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
2. **China NMPA – Mr. YUAN Peng**, Director, Department of Medical Device Registration, National Medical Products Administration, China
3. **South Korea MFDS- Mr. Young-Wook Ahn,** Deputy Director, In-Vitro Diagnostic Devices Division, NIFDS, MFDS, South Korea
4. **Malaysia MOH and ASEAN- Mrs. Salbiah Yaakop,** Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health,

	Malaysia 5. **Chinese Taipei TFDA- Dr. Wen Wei Tsai,** Division of Medical Devices & Cosmetics, Food & Drug Administration, Ministry of Health & Welfare 6. **India MOH- Dr. V. G. Somani,** Drugs Controller General 7. **Kenya MOH - Ms. Paulyne Wairimu,** Head of Medical Devices, Ministry of Health, Republic of Kenya 8. **Chile ISP- Ms. Maria Cecilia Lopez,** Professional Medical Devices Office, Public Health Institute of Chile 9. **USFDA- Ms. Melissa Torres,** Associate Director for International Affairs, Center for Devices and Radiological Health, US Food and Drug Administration 10. **Japan PMDA- Ms. Mika Togashi,** Deputy Division Director, Division of Regulatory Cooperation, Office of International Programs
1526 (KSA) 2026 (BJ/HKT) [4mins]	Break (4 mins) and sponsors' commercials

Estimated Time	25th AHWP/GHWP TC Meeting and TECHNICAL SESSION
1530 (KSA) 2030 (BJ/HKT) [5mins]	**Opening** **Mrs. Salbiah Yaakop**, Acting AHWP/GHWP TC Chair | Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health, Malaysia
1535 (KSA) 2035 (BJ/HKT) [15mins]	**Summary of TC Work Progress (WG1-9)** **Mr. Alfred KWEK,** AHWP/GHWP TC Co-Chair | Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd., Lao PDR
1550 (KSA) 2050 (BJ/HKT)	**Highlight from Joint WG 1, 2 & 3 on EUA** From Joint WGs **Dr. Wen Wei Tsai,** WG2 IVDD Chair

[5mins]	
1555(KSA) 2055(BJ/HKT) [5mins]	**General Overview on Cybersecurity trends around the Globe** **Mr. Ben Kokx,** Director Product Security, Philips
1600 (KSA) 2100 (BJ/HKT) [5mins]	**UDI Rules for Medical Devices, and Implementation Experience and Health Records?** **Ms. LI Jun,** Division Director of Medical Device Registration, Medical Device Registration Department, China Food and Drug Administration
1605 (KSA) 2105 (BJ/HKT) [15mins]	**Post-Market Surveillance, investigation and change management** **Panel Discussion** Moderator: **Ms. Miang Tanakasemsub**, TC Secretary | Head of QA Commercial and Regulatory Affairs, APAC, Cardinal Health **Panellists:** **Ms. Joanna KOH**, Principal Consultant at MDNet. Regulatory Consultants **Ms. Tracey Duffy**, First Assistant Secretary, Medical Devices & Product Quality Division, Health Products Regulation Group, Department of Health, Australia (Video-recorded for Ms. Tracey Duffy TBC)
1620 (KSA) 2120 (BJ/HKT) [15mins]	**Panel Discussion & TC Closing Remarks** **Moderator: Mr. Alfred KWEK**, AHWP/GHWP TC Co-Chair | Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd., Lao PDR **Panellist:** **Ms. Cheng-Ning Emily Wu,** Senior Technical Specialist, Division of Medical Devices and Cosmetics at TFDA and current Primary AHWP/GHWP TC Representative of Chinese Taipei

- END of DAY ONE –

Day TWO: 1st Dec 2021 | 1pm to 5pm KSA time / 6pm to 10pm Beijing Time

Estimated Time	25th AHWP Annual Meeting (Main Meeting)	
1300 (KSA) 1800(BJ/HKT) [5mins]	**Opening Address** **Mr. Ali M. Al-Dalaan**, AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia	
1305(KSA) 1805(BJ/HKT) [15mins]	**Keynote Speech - Highlight of "Outcome of AHWP Strategic Framework 2020" and the Formulation of GHWP Strategic framework** **Ms. Quan TRAN**, AHWP/GHWP Vice-Chair Vice President, Regulatory, Government Affairs and Quality Assurance, Asia Pacific, Align Technology	
1320 (KSA) 1820 (BJ/HKT) [5mins]	**Main Meeting** - Roll Call - Adoption of Agenda - Adoption of 24th AHWP/GHWP Annual Meeting Minutes	**Mr. Ali M. Al-Dalaan,** AHWP/GHWP Chair | Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia *Supported by* **Ir. Bryan So,** AHWP/GHWP Executive Secretary General | CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong
1325 (KSA) 1825 (BJ/HKT) [20mins]	**AHWP/GHWP Status Reports** - Overall Status Report	**Ms. Quan TRAN**, AHWP/GHWP Vice-Chair | Vice President, Regulatory, Government Affairs and Quality Assurance, Asia Pacific, Align Technology

	- TC Status Report	**Er. Alfred KWEK**, AHWP/GHWP TC Co-Chair | Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd.
1345 (KSA) 1845 (BJ/HKT) [10mins]	**IMDRF Status Update** **Dr. LEE Jeong-Rim**, IMDRF Chair | Director General, Medical Device Evaluation Department, National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS), South Korea	
1355 (KSA) 1855 (BJ/HKT) [10mins]	**IMDRF Member Country Harmonization Efforts and WGs updates** **Dr. Chung Keun Lee**, IMDRF Secretariat | Assistant Director from High-Tech Medical Devices Division, NIFDS, MFDS, South Korea	
1405 (KSA) 1905(BJ/HKT) [25mins]	**International Organizations Updates [5mins each x 5]** 1. **APEC LSIF-RHSC: Ms. Cheng-Ning Emily Wu**, Senior Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, Chinese Taipei 2. **ASEAN: Ms Mia Ulfa**, Standards and Conformance Officer, Standards and Conformance Division, Market Integration Directorate, ASEAN Secretariat 3. **African Medical Devices Forum (former PAHWP): by Ms Paulyne Wairimu**, Interim Chair, Africa Medical Device Forum 4. **WHO: Ms. Adriana Velazquez Berumen**, Team Lead, Medical Devices and In Vitro Diagnostics, Health Product Policy and Standards Department, Access to Medicines and Health Products Division, World Health Organization 5. **Global Medical Technology Alliance (GMTA): Mr. Jesús Rueda Rodríguez,** Director General Strategies, Special Projects & International Affairs, MedTech Europe	
1430 (KSA) 1930 (BJ/HKT) [15mins]	**AHWP/GHWP Joint Efforts with International Organizations [5mins each x 3]:** 1. Updates from Joint Advisory Group 5 (JAG5) of IEC TC 62 and ISO/TC 210 **Mr. Nicklas Christian Funk,** Sustainability Engineer, AMBU 2. Highlight on ISO16142 Recognized essential principles of safety and performance of medical devices	

	Mrs. Salbiah Yaakop, Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health, Malaysia 3. ISO13485 and other updates by ISO/TC210 **Dr. Peter Linders**, Chairman, ISO/TC210 | Director, Global Regulations & Standards, Philips
1445 (KSA) 1945 (BJ/HKT) [20mins]	**AHWP/GHWP Liaison Member Updates [5mins each x 4]** 1. **APACMed Update - Ms. Miang Tanakasemsub**, Regulatory Affairs Committee Chair | Head of QA Commercial and Regulatory Affairs, APAC, Cardinal Health 2. **DITTA Update - Dr. Peter Linders**, Member of the DITTA Board of Directors | Director, Global Regulations & Standards, Philips 3. **GS1 Update - Mr. Géraldine Lissalde-Bonnet**, Director Public Policy - Global Healthcare 4. **GMDN Agency Update - Mr. Mark Wasmuth**, CEO, GMDN AGENCY
1505 (KSA) 2005 (BJ/HKT) [5mins]	**IAF Updates on CertSearch** **Mr. Matt Gantley**, Chief Executive of UKAS
1510 (KSA) 2010 (BJ/HKT) [40mins]	**AHWP/GHWP Member Country/Region Updates [10mins each x 4]** 1. **China NMPA – Mr. ZHANG Hua**, Deputy Director General, Department of Medical Device Registration, National Medical Products Administration, China 2. **Saudi SFDA - Eng. Abdullah Alghuraibi,** Director of Regulations and Registration Support, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia **3. South Korea MFDS - Dr. LEE Jeong-Rim,** Director General, Medical Device Evaluation Department, National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS), South Korea 4. **Chinese Taipei TFDA - Ms. Cheng-Ning Wu Emily**, Senior Technical Specialist, Division of Medical Devices and Cosmetics, Food and Drug

	Administration, Ministry of Health and Welfare, Chinese Taipei	
1550 (KSA) 2050 (BJ/HKT) [20mins]	**Panel Discussion (20mins): Global Convergence on Medical Device Regulations** **Moderator: Mr. Emmett Devereux**, Chair, MedTech Europe | Director, Government and Regulatory Affairs, EMEA., Cook Medical EMEA Group Ltd **Panellist:** **Mr. Jesús Rueda Rodríguez,** Director General Strategies, Special Projects & International Affairs, MedTech Europe	
1610 (KSA) 2110 (BJ/HKT) [30mins]	**Digital Transformation in Device Regulatory: AI, Software and Cybersecurity** 1. **South Korea MFDS (5mins) - Dr. Young-Woo Bae**, Assistant Director, Digital Health Device TF, NIFDS, MFDS, South Korea 2. **China NMPA (5mins) - Mr. PENG Liang**, Deputy Director, Center for Medical Device Evaluation, National Medical Products Administration, China **Panel Discussion (20mins)** **Moderator: Dr. Peter Linders**, Member of the DITTA Board of Directors| Director, Global Regulations & Standards, Philips **Panellists:** 1. **China NMPA – Mr. PENG Liang**, Deputy Director, Center for Medical Device Evaluation, National Medical Products Administration, China **2. South Korea MFDS - Dr. Young-Woo Bae** **3. Saudi FDA - Mr. Abdullatif Alwatban** 4. **Mr. Koen Cobbaert**, Senior Manager, Quality, Standard & Regulations, Philips 5. **Mr. Carlos Arglebe**, Vice President, Health Services QM, Siemens Healthcare	
1640 (KSA) 2140 (BJ/HKT) [2 mins]	**AHWP/GHWP Secretariat Updates** - Secretariat Report - Financial Report	**Ir. Bryan So,** AHWP/GHWP Executive Secretary General | CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong
1642 (KSA) 2142 (BJ/HKT)	**Endorsements** 1. Endorsement on the appointment of	**Mr. Ali M. Al-Dalaan,** AHWP/GHWP Chair |Vice Executive President,

[15 mins]	TC Chair for the remaining term until next election 2. Endorsement on Guidance Document(s): a) Emergency Use Authorization for Medical Devices and In Vitro Diagnostic Medical Devices (by WG1, WG2 & WG3) b) Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices (by WG2 & WG5) c) Replacement Reagent and Instrument Family Policy (by WG2) 3. Endorsement on rebranding of AHWP into GHWP 4. Endorsement on change of Terms of Reference and House Rules 5. Endorsement on the admission of new Member(s) - US Food and Drug Administration (5min speech before endorsement) 6. Endorsement on the admission of new Liaison Member(s) - Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (IACRC) (3min speech before endorsement)	Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia *Supported by* **Ir. Bryan So,** AHWP/GHWP Executive Secretary General | CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong

1657 (KSA) 2157 (BJ/HKT) [1min]	**Announcement on AHWP/GHWP Face-to-Face Annual Meeting**	**Mr. Ali M. Al-Dalaan**, AHWP/GHWP Chair | Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
1658 (KSA) 2158 (BJ/HKT) [2mins]	**Closing Remarks**	**Mr. Ali M. Al-Dalaan**, AHWP/GHWP Chair | Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia

- END of DAY TWO -