

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

Day ONE: 30th Nov 2021 | 12noon to 3.35pm KSA Time/ 5pm to 8.35pm Beijing Time

Estimated Time	Opening, Keynotes and Highlights on Capacity Building Program
1200 (KSA) 1700 (BJ/HKT) [5mins]	Welcome Address H.E. Prof. Hisham S. Aljadhey Executive President, Saudi FDA, Kingdom of Saudi Arabia
1205(KSA) 1705(BJ/HKT) [5mins]	Opening Address Mr. Ali M. Al-Dalaan , AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
1210(KSA) 1710(BJ/HKT) [15mins]	Keynote Speech Hepatitis C virus elimination: laying the foundation for achieving 2030 targets Speaker Dr Hishamshah, Deputy Director General (Research & Technical Support), Malaysia MOH
1225(KSA) 1725 (BJ/HKT) [30mins]	Global Medical Device Regulatory Framework – New Regulations and the Way Forward Panel Discussion [30mins] Moderator: Mr Mike Flood , Chair, Biomedical College, Engineers Australia Panellist: 1. Saudi FDA 2. China NMPA 3. South Korea MFDS 4. Malaysia MOH
1255 (KSA)	AHWP/GHWP Capacity Building Program- Bringing It Together

1755 (BJ/HKT) [15mins]	Speaker: Ms. Quan TRAN , AHWP/GHWP Vice-Chair Lead of Capacity Building Vice President, Regulatory, Government Affairs, and Quality Assurance, Asia Pacific, Align Technology
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Estimated Time	Emergency Use Authorization (EUA)
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1310 (KSA) 1810 (BJ/HKT) [75mins]	<p>EUA Experience Sharing by AHWP/GHWP Country/Region [5mins each x 11]:</p> <ol style="list-style-type: none"> 1. Saudi FDA 2. China NMPA 3. South Korea MFDS 4. Malaysia MOH and ASEAN- Speaker: Mrs. Salbiah Yaakop 5. Chinese Taipei TFDA- Speaker: Mr. Wen Wei Tsai 6. India MOH 7. Kenya MOH - Speaker: Ms. Paulyne Wairimu 8. Chile ISP- Speaker: Ms. Maria Cecilia Lopez 9. USFDA- Speaker: Ms. Melissa Torres 10. Australia TGA 11. Japan PMDA- Speaker: Ms Mika Togashi <p>Panel Discussion on EUA [20mins]</p> <p>Moderator: Dr. Adelheid Schneider, APACMed Head of Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd</p>
1425 (KSA) 1925 (BJ/HKT) [5mins]	Break (5 mins) and sponsors' commercials

Estimated Time	25 th AHWP/GHWP TC Meeting and TECHNICAL SESSION
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1430 (KSA) 1930 (BJ/HKT)	<p>Opening</p> <p>Mrs. Salbiah Yaakop, Acting AHWP/GHWP TC Chair </p>
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[5mins]	Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health, Malaysia
1435 (KSA) 1935 (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
1450 (KSA) 1950 (BJ/HKT) [5mins]	Highlight from Joint WG 1, 2 & 3 on EUA Speaker: From Joint WGs (TBC) Mr. Wen Wei Tsai WG2 IVDD Chair
1455(KSA) 1955(BJ/HKT) [5mins]	General Overview on Cybersecurity trends around the Globe? Mr. Ben Kokx (Speaker recommended by Dr. Peter Linders, DITTA)
1500 (KSA) 2000 (BJ/HKT) [5mins]	UDI Rules for Medical Devices, and Implementation Experience and Health Records? Speaker TBC
1505 (KSA) 2005 (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 TBC
1520 (KSA) 2020 (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

Day TWO: 1st Dec 2021 | 12noon to 3.45pm KSA time / 5pm to 8.45pm Beijing Time

Estimated Time		25th AHWP Annual Meeting (Main Meeting)	
1200 (KSA) 1700(BJ/HKT) [5mins]	<p>Opening Address</p> <p>Mr. Ali M. Al-Dalaan, AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p>		
1205(KSA) 1705(BJ/HKT) [15mins]	<p>Keynote Speeches</p> <p>Keynote ONE</p> <p>Highlight of GHWP Strategy</p> <p>Ms. Quan TRAN, AHWP/GHWP Vice-Chair Vice President, Regulatory, Government Affairs and Quality Assurance, Asia Pacific, Align Technology</p>		
1220 (KSA) 1720 (BJ/HKT) [5mins]	<p>Main Meeting</p> <ul style="list-style-type: none"> - Roll Call - Adoption of Agenda - Adoption of 24th AHWP/GHWP Annual Meeting Minutes 	<p>Mr. Ali M. Al-Dalaan, AHWP/GHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p> <p><u>Supported by</u></p> <p>Ir. Bryan So, AHWP/GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong</p>	
1225 (KSA) 1725 (BJ/HKT) [20mins]	<p>AHWP/GHWP Status Reports</p> <ul style="list-style-type: none"> - Overall Status Report - TC Status Report 	<p>Ms. Quan TRAN, AHWP/GHWP Vice-Chair Vice President, Regulatory, Government Affairs and Quality Assurance, Asia Pacific Align Technology</p> <p>Er. Alfred KWEK, AHWP/GHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd.</p>	

<p>1245 (KSA) 1745 (BJ/HKT) [10mins]</p>	<p>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</p>
<p>1255 (KSA) 1755 (BJ/HKT) [10mins]</p>	<p>IMDRF Member Country Harmonization Efforts -International Regulatory Corporations or other topics? Speaker TBC - IMDRF WGs updates Speaker: IMDRF Secretariat Tentative speaker Dr. Chung Keun Lee</p>
<p>1305 (KSA) 1805(BJ/HKT) [25mins]</p>	<p>International Organizations Updates [5mins each x 5]</p> <ol style="list-style-type: none"> 1. APEC LSIF-RHSC: Speaker: Ms. Cheng-Ning Emily Wu, a Senior Technical Specialist from the Division of Medical Devices and Cosmetics at TFDA and current Primary AHWP/GHWP TC Representative of Chinese Taipei 2. ASEAN: ASEAN Medical Device Committee (ASEAN Secretariat: Ms Mia Ulfa, Standards and Conformance Officer, Standards and Conformance Division – Market Integration Directorate, The ASEAN Secretariat 70 A Jl Sisingamangaraja, Jakarta 12110 Indonesia , Tel +62-21 7262991 Ext 1270 Fax +62-21 7398234) 3. African Medical Devices forum (former PAHWP): by Ms. Paulyne Wairimu, TC Secondary Representative of Kenya from the Regulator Authority (will share updates for both Kenya MOH and also AMDF as slotted in the agenda item) 4. WHO: Ms. Adriana Velazquez Berumen 5. MedTech Europe: Speaker TBC
<p>1330 (KSA) 1830 (BJ/HKT) [15mins]</p>	<p>AHWP/GHWP Joint Efforts with International Organizations [5mins each x 3]:</p> <ol style="list-style-type: none"> 1. Sharing from AHWP/GHWP Experts in Joint Advisory Group 5 (JAG5) under the leadership of IEC TC 62 and ISO/TC 210 Speaker TBC

	<p>2. Highlight on ISO16142 Recognized essential principles of safety and performance of medical devices</p> <p>Speaker TBC</p> <p>3. ISO13485 and other updates (standard/post market?) by ISO TC210</p> <p>Speaker TBC</p>
<p>1345 (KSA)</p> <p>1845 (BJ/HKT)</p> <p>[20mins]</p>	<p>AHWP/GHWP Liaison Member Updates [5mins each x 4]</p> <p>1. APACMed Update: Speaker TBC</p> <p>2. DITTA Update: By Dr. Peter Linders</p> <p>3. GS1 Update: Speaker Director Mr Géraldine Lissalde-Bonnet</p> <p>4. GMDN Agency Update: Speaker TBC</p>
<p>1405 (KSA)</p> <p>1905 (BJ/HKT)</p> <p>[40mins]</p>	<p>AHWP/GHWP Member Country/Region Updates [10mins each x 4]</p> <p>1. China NMPA</p> <p>2. Saudi SFDA</p> <p>3. South Korea MFDS</p> <p>4. Chinese Taipei TFDA, Speaker: 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</p>
<p>1445 (KSA)</p> <p>1945 (BJ/HKT)</p> <p>[20mins]</p>	<p>Panel Discussion (20mins): Global Convergence on Medical Device Regulations</p> <p>Moderator: Mr. Emmett Devereux, Chair, MedTech Europe Director, Government and Regulatory Affairs, EMEA., Cook Medical EMEA Group Ltd</p> <p>Panellists: TBC</p>
<p>1505 (KSA)</p> <p>2005 (BJ/HKT)</p> <p>[30mins]</p>	<p>Digital Transformation in Device Regulatory: AI, Software and Cybersecurity</p> <p>1. South Korea MFDS (5mins)</p> <p>2. China NMPA (5mins)</p> <p>Panel Discussion (20mins)</p> <p>Moderator: Dr. Peter Linders, Member of the DITTA Board of Directors Director, Global Regulations & Standards, Philips</p> <p>Panellists:</p> <p>1. China NMPA</p>

	<ol style="list-style-type: none"> 2. South Korea MFDS 3. Saudi FDA: Abdullatif Alwatban (Aswatban@sfda.gov.sa) 4. Mr. Koen Cobbaert, Senior Manager, Quality, Standard and Regulations, Philips 5. Mr.Carlos Arglebe, Vice President ,Health Services QM, Siemens Healthcare 	
<p>1535 (KSA) 2035 (BJ/HKT) [2 mins]</p>	<p>AHWP/GHWP Secretariat Updates</p> <ul style="list-style-type: none"> - Secretariat Report - Financial Report 	<p>Ir. Bryan So AHWP/GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong</p>
<p>1537 (KSA) 2037 (BJ/HKT) [5 mins]</p>	<p>Endorsements</p> <ol style="list-style-type: none"> 1. Endorsement on the appointment of TC Chair for the remaining term until next election 2. Endorsement on the admission of new member(s) 3. Endorsement on Guidance Documents: <ul style="list-style-type: none"> a) WG1, 2 & 3 on EUA GN b) Others TBC 	<p>Mr. Ali M. Al-Dalaan, AHWP/GHWP Chair Vice Executive President Medical Devices Sector Saudi FDA, Kingdom of Saudi Arabia</p> <p><u>Supported by</u> Ir. Bryan So AHWP/GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong</p>
<p>1542 (KSA) 2042 (BJ/HKT) [1min]</p>	<p>Announcement on AHWP/GHWP Face-to-Face Annual Meeting</p>	<p>Mr. Ali M. Al-Dalaan, AHWP/GHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p>
<p>1543 (KSA) 2043 (BJ/HKT) [2mins]</p>	<p>Closing Remarks</p>	<p>Mr. Ali M. Al-Dalaan, AHWP/GHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p>