

The 26th GHWP Annual Meeting Program

Riyadh, Saudi Arabia
13-16 February 2023

DRAFT Program (Version 6f - Public)

| 0815-0900 | | Registration | |
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| Day 1 Agenda: 13 February 2023 (Monday) | | | |
| ITEMS | TIME | | |
| 1 | 0900-0910 | Welcome Address (10mins) | Dr. Hisham bin Saad Aljadhey Chief Executive Officer Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
| 2 | 0910-0920 | Opening Address (10mins) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
| 3 | 0920-0935 | GHWP Strategic Framework (15mins) | Ms. Quan Tran GHWP Vice-Chair Vice President, QARA, APAC, Baxter Singapore |
| 4 | 0935-1000 | Panel Discussion: GHWP Strategic Framework (20mins) + Q&A (5mins) | Moderator: Ms. Quan Tran, (GHWP Vice-Chair), Vice President, QARA, APAC, Baxter, Singapore Panelists: a) Mr. Ali M. AL-DALAAN, (GHWP Chair), Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia b) Mrs. Salbiah Yaakop, (GHWP TC Chair), Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia c) Dr. Jeong-Rim LEE, (GHWP TC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea d) Mr. Alfred KWEEK, (GHWP TC Co-Chair), Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd., Lao PDR e) Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific |
| 5 | 1000-1005 | GHWP Secretariat Announcement (5mins) | Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China |
| 1005-1040 TEA BREAK | | | |
| TECHNICAL SESSION - Regulatory Agility and Reliance | | | |
| 6 | 1040-1100 | Regulatory Agility (15mins) + Q&A (5mins) | Ms. Yasha Huang Head of Regulatory Policy, Roche Asia Pacific |
| 7 | 1100-1120 | Benefits of Regulatory Reliance (15mins) + Q&A (5mins) | Dr. Rama Sethuraman Deputy Director, Health Sciences Authority, Singapore |
| 8 | 1120-1150 | Panel Discussion : Expanding Global access to Medical Devices – Reliance (25mins) + Q&A (5mins) | Moderator : Ms. Miang Tanakasemsub Panelists: a) Dr. Rama Sethuraman, Deputy Director, HSA, Singapore b) Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific c) Dr. Razan Asally, Saudi Food and Drug Authority, Kingdom of Saudi Arabia d) Mr. Varavoot Sermisinsiri, Director, Medical Device Control Division, Food and Drug Administration, Thailand |
| TECHNICAL SESSIONS - Increasing the Opportunities of Digital Health | | | |
| TECHNICAL SESSION I : Digital Health : Innovation and Technology (Industry Perspective) | | | |
| 9 | 1150-1210 | Digital Therapeutics - "Industry Perspective" (15mins) + Q&A (5mins) [ONLINE] | Sean (Seong-ji) Kang, MD. MPH. Co-founder, CEO of WELT |
| 10 | 1210-1230 | Digital Twins (15mins) + Q&A (5mins) [ONLINE] | Mark Palmer, MD, PhD Research Director & Technical Fellow Core Technologies Lead Enterprise Modeling & Simulation Working Group Medtronic |
| 11 | 1230-1250 | Metaverse using AR/VR/XR (15mins) + Q&A (5mins) | Joy Sacmar VP Regulatory Affairs, Digital Surgery Johnson & Johnson |
| 1250-1400 LUNCH / PRAYER TIME | | | |
| TECHNICAL SESSION II : Digital Health : Regulatory Approaches (Government perspectives) | | | |
| 12 | 1400-1415 | Digital Health Regulation Development in China (15mins) [RECORD] | Guo Zhaojun. MD. Director, MD Evaluation Department II, Center for Medical Device Evaluation, NMPA, People's Republic of China |
| 13 | 1415-1435 | Digital Therapeutics - "Exploring Regulatory Pathways of Digital Therapeutics" (15mins) + Q&A (5mins) | Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea |
| 14 | 1435-1455 | Regulations for Artificial Intelligence (15mins) + Q&A (5mins) | Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA |
| 15 | 1455-1525 | Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) | Moderator: Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullahatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia 2) Dr. Chung Keun Lee. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea 3) Dr. Feisul Idzwan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] |
| 1525-1555 TEA BREAK | | | |
| TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access (Government, Industry, International Org Perspectives) | | | |
| 16 | 1555-1615 | Equitable Access to the Patient and Product (15mins) + Q&A (5mins) | Dr. Wisam Haddadin Director Market Access Abbott, UAE |
| 17 | 1615-1645 | Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) | Moderator: Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 2) Dr. Hani Alharbi, Chief Governance, Risk, and Compliance Officer Seha Virtual Hospital SVH, Kingdom of Saudi Arabia 3) Sigrid Uhlemann Managing Director, DQS Medizinprodukte GmbH 4) Ms. Glenda Teng, Head, Government Affairs and Market Access APAC 5) Dr. Wisam Haddadin, Director Market Access, Abbott, UAE |
| TECHNICAL SESSION IV : Standards | | | |
| 18 | 1645-1705 | Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) | Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / S-CAP, USFDA |
| 19 | 1705-1725 | Updates on ISO14155 and ISO20916 (15mins) + Q&A (5mins) | Ms. Shelley Tang, Principal, Stellar Consulting |
| 20 | 1725-1730 | Closing Remarks for Day 1 (5mins) | Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia |
| 21 | 1730 | Adjourn | |
| END OF DAY 1 | | | |

| Day 2 Agenda: 14 February 2023 (Tuesday) | | | |
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| TECHNICAL SESSIONS (Cont.) - Increasing the Opportunities of Digital Health | | | |
| ITEMS | TIME | | |
| 1 | 0900-0910 | Opening Address for Day 2 (10mins) | Mr. Guobiao Gao GHWP Vice Chair Secretary of Leading Party Group, Center for Medical Device Evaluation, National Medical Products Administration People's Republic of China |
| TECHNICAL SESSION V : Digital Health : Clinical Applications [Industry, Hospitals and Government Perspectives] | | | |
| 2 | 0910-0930 | Improving Healthcare Services (15mins) + Q&A (5mins) [ONLINE] | Ho Young Lee, M.D. Professor: Nuclear Medicine, CIO, Digital Medicine & Office of eHealth Research & Business, Seoul National University Bundang Hospital, South Korea |
| 3 | 0930-0950 | Artificial Intelligence Clinical Application in Hospital (15mins) + Q&A (5mins) | Chong Jai KIM, MD Professor of Pathology Asan Medical Center Seoul, Korea |
| 4 | 0950-1010 | New Approaches to Post-market Clinical Follow-Ups (15mins) + Q&A (5mins) | J&J (To be confirmed) |
| 5 | 1010-1030 | Real World Evidence - Using Real-world Data (15mins) + Q&A (5mins) | Mr. Kenneth Cavanaugh Deputy Director, Officer of Cardiovascular Devices, USFDA Center for Devices and Radiological Health |
| 1030-1100 TEA BREAK | | | |
| TECHNICAL SESSION VI : New Innovations | | | |
| 6 | 1100-1120 | Post Market Surveillance (15mins) + Q&A (5mins) | Mr. Mohd Zul hisham Junaedi, Post Market & Enforcement Division, Medical Device Authority, Malaysia |
| 7 | 1120-1140 | Regulatory Pathways for Innovative Products (15mins) + Q&A (5mins) | Mr. Kenneth Cavanaugh Deputy Director, Officer of Cardiovascular Devices, USFDA Center for Devices and Radiological Health |
| 8 | 1140-1210 | Panel : Fit-for-Purpose Change Management (25mins) + Q&A (5mins) | Moderator: Ms. Adelheid Schneider Panelists: a) Dr. Rama Sethuraman, Deputy Director, Health Sciences Authority, Singapore b) Dr. KUSAKABE Tetsuya, PhD, MPH, Director, Office of Manufacturing Quality and Vigilance for Medical Devices, International Coordination Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan c) Mr. Ali Al-Dalaan, Vice Executive President, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Ms. Marlanmah Krishnasamy, Malaysia MOH e) Mr. Kenneth Cavanaugh, Deputy Director, Officer of Cardiovascular Devices, Center for Devices and Radiological Health, USFDA |
| 9 | 1210-1230 | Biotech Applications in Medical Device from the Authority Perspective (15mins) + Q&A (5mins) | Dr. Razan Asally, SFDA, Saudi |
| 1230-1345 LUNCH / PRAYER TIME | | | |
| Capacity Building | | | |
| 10 | 1345-1405 | GHWP Capacity Building Journey and Training Curriculum (15mins) + Q&A (5mins) | Ms. Quan Tran Vice President, QARA, APAC, Baxter Singapore Dr. Adelheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore |
| 11 | 1405-1435 | Panel Discussion on GHWP Capacity Building (25mins) + Q&A (5mins) | Moderator: Mr. Anirudh Sen, APACMed Panelists- a) Prof John Lim, Director, Centre of Regulatory Excellence, Duke-NUS Medical School, Singapore b) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia c) Praveen Kumar, APACMed d) Mr Armando Dumindin, Engineer, Ministry of Health, Philippines (TBC) |
| 12 | 1435-1455 | MDSAP Updates (15mins) + Q&A (5mins) | (TBC) |
| 13 | 1455-1515 | UDI (15mins) + Q&A (5mins) | Ms. Victoria Qu, Global Strategic Regulatory Abbott, China |
| 1515-1545 TEA BREAK | | | |
| 14 | 1545-1605 | IAF CertSearch (15mins) + Q&A (5mins) | Mr. Grant Ramaley and Mr. Nigel Johnston |
| 15 | 1605-1625 | Internet tools kit for medical devices (15mins) + Q&A (5mins) [ONLINE] | Mr. Jeff Gren & Miang |
| 16 | 1625-1630 | Closing Remarks for Day 2 (5mins) | Dr. Jeong-Rim LEE (GHWP TC Co-Chair) Director General, Medical Device Evaluation Department Ministry of Food and Drug Safety (MFDS) Republic of Korea |
| 17 | 1630 | Adjourn | |

| Day 3 Agenda: 15 February 2023 (Wednesday) | | | |
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| Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia | | | |
| 26th GHWP Technical Committee (GHWP TC) Meeting | | | |
| ITEMS | TIME | | |
| 1 | 0900-1045 | GHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting) | Mr. Ali M. Al-Dalaan (proposed) GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia Mr. Guobiao Gao (proposed) GHWP Vice-Chair Secretary of Leading Party Group, Center for Medical Device Evaluation, NMPA, People's Republic of China Ms. Quan Tran (proposed) GHWP Vice-Chair Vice President, QARA, APAC, Baxter, Singapore Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia Dr Jeong-Rim LEE GHWP TC Co-Chair Ministry of Food and Drug Safety, Republic of Korea |

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| | | | <p>Er. Alfred KWEK GHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd.</p> <p>Supported by Ms. Miang TANAKASEMSUB GHWP TC Secretary Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision</p> <p>Ms. Carol Jirui YAN GHWP TC Secretary Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China</p> |
| 1045-1115 | | | TEA BREAK |
| 2 | 1115-1120 | Welcome Speech (5mins) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
| 3 | 1120-1135 | Opening of TC Meeting (15mins) -Roll call -Adoption of Agenda -Adoption of 25th GHWP TC Meeting Minutes | <p>Mrs. Salbiah Yaakop (Chair) Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia</p> <p>Dr. Jeong-Rim LEE (Co-Chair) Director, Cardiovascular Devices Division Ministry of Food and Drug Safety (MFDS) - Republic of Korea</p> <p>Mr. Alfred KWEK (Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR</p> <p><i>Supported by TC Secretary</i> Ms. Miang TANAKASEMSUB Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision</p> <p>Mr. Jack WONG Associate Vice President Regulatory Affairs, Asia Pacific, Middle East & Africa, Allergan - Hong Kong SAR, China</p> <p>Ms. Carol YAN Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China</p> <p>Dr. Adelheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore</p> |
| 4 | 1135 – 1245 (5mins + 5mins Q&A each) | Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 3 (WG3) - Pre-market: Software as a Medical Device Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 6 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation | <p>Work Group 1 (WG1) Chair - Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea</p> <p>Work Group 2 (WG2) Chair - Mr. Wen-wei TSAI, Food and Drug Administration, Chinese Taipei Co-chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong SAR, China</p> <p>Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong SAR, China</p> <p>Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong SAR, China Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore</p> <p>Work Group 5 (WG5) Chair - Mr. Fikriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India</p> <p>Work Group 6 (WG6) Chair - Mr. Abdullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Vincent Chee-Choong Lam, TUV SUD Product Service, Malaysia</p> <p>Work Group 7 (WG7) Chair - Mrs. CHEN Yan, National Medical Products Administration, China Co-chair - Mr. Ee Bin Liew, Access-2-Healthcare, Singapore</p> |
| 1245-1400 | | | LUNCH / PRAYER TIME |
| 26th GHWP Technical Committee (GHWP TC) Meeting | | | |
| 5 | 1400 -1420 (5mins + 5mins Q&A each) | Working Group Updates and Next Steps (Cont'): Work Group 8 (WG8) - Standards Work Group 9 (WG9) - UDI & Nomenclature | <p>Work Group 8 (WG8) Chair - Mrs. Salbiah Yaakop, Ministry of Health, Malaysia Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia</p> <p>Work Group 9 (WG9) Chair - Ms. Jun LI, National Medical Products Administration, China Co-chair - Ms. Victoria Qu, Global Strategic Regulatory Abbott, China</p> |
| 6 | 1420-1440 | TC Advisors Summary Report (20mins) | Representatives of TC Advisory Panel |
| 7 | 1440-1445 | Closing Remarks for Day 3 (5mins) | Mr. Alfred KWEK (GHWP TC Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR |
| 8 | 1445 | Adjourn | |
| 1445-1515 | | | TEA BREAK |
| GHWP Leadership and IMDRF Management Committee Meeting (CLOSED-DOOR) [TBC] (1515-1645) | | | |
| GALA DINNER (Dinner starts at 1900) | | | |



| Day 4 Agenda: 16 February 2023 (Thursday) | | |
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| ITEMS | TIME | |
| 26th GHWP Annual Meeting (Main Meeting) | | |
| 1 | 0855-0900 | Announcement by MC (SFDA) (5mins) |
| 2 | 0900-0930 | <p>Opening Ceremony (30mins) - Welcome Address (7mins) - Opening address (7mins) - Group Photo (16mins)</p> <p>Master of Ceremony (MC) by Saudi FDA Announcement</p> <p>Welcome Address- Dr. Hisham bin Saad Aljadhey Chief Executive Officer, Saudi Food and Drug Authority Kingdom of Saudi Arabia</p> <p>Opening Address- Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia</p> |

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| 3 | 0930-0940 | Main Meeting - Roll Call (8mins) - Adoption of Agenda (1min) - Adoption of 25th GHWP Annual Meeting Minutes (1min) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China |
| 4 | 0940-1010 | GHWP Status Reports - GHWP Overall Status Report (10mins + 5mins Q&A) - GHWPTC Status Report (10mins + 5mins Q&A) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Mrs. Salbiah Yaakop GHWPTC Chair Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health, Malaysia |
| 1010-1040 | | TEA BREAK | |
| 5 | 1040-1055 | IMDRF Status Updates (10mins+5mins) | Dr. Andrzej Rys IMDRF Chair 2023 Principal Scientific Adviser Directorate-General for Health and Food Safety (DG SANTE) European Commission |
| 6 | 1055-1125 | International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) APEC Harmonization Center (AHC) b) ASEAN | a) Jeewon Joung Ph.D., Director, Pre-submission Consultation Team, Ministry of Food & Drug Safety(MFDS), Republic of Korea, APEC Harmonization Center (AHC) [ONLINE] b) Mrs. Salbiah Yaakop (GHWPTC Chair), Director of Policy, International Affairs & Industry Facilitation Division, MDA, Ministry of Health, Malaysia, ASEAN [TBC] |
| 7 | 1125-1225 | GHWP Liaison Member Updates (5mins + 5mins Q&A each) a) Asia Pacific Medical Technology Association (APACMed) b) Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association (DITTA) c) GS1 d) Global Medical Devices Nomenclature Agency (GMDN Agency) e) Global Medical Technology Alliance (GMTA) f) Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) | a) Mr. Anirudh Sen, Director, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) b) Mr. Yuji Yanagida, GRP WG Vice chair, DITTA c) Ms. Géraldine Lissalde-Bonnet, Vice-President Healthcare, GS1 Global Office, GS1 [TBC] d) Mrs. Deniz Bruce, Chief Executive Officer, Global Medical Devices Nomenclature Agency (GMDN Agency) e) Ms. Diana Kanecka, Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA) f) Ms. Sandra Ligia Gonzalez, Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) [TBC] |
| 8 | 1225-1245 | Country/Region Updates (5mins+5mins Q&A each) a) Australia [Online] b) European Commission | a) Ms. Tracey Duffy, First Assistant Secretary, Medical Devices & Product Quality, Therapeutic Goods Administration (TGA), Australia [Online] b) Andrzej Rys, Principal Scientific Adviser, Directorate-General for Health and Food Safety (DG SANTE), European Commission |
| 1245-1400 | | LUNCH / PRAYER TIME | |
| 9 | 1400-1510 | Country/Region Updates (Cont') (5mins+5mins Q&A each) c) Japan d) Kingdom of Saudi Arabia e) People's Republic of China f) Philippines g) Republic of Korea h) Thailand i) United States of America | c) Ms. TOGASHI Milka, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan d) Eng. Abdullah AlGurailb, Saudi Food and Drug Authority (SFDA), Kingdom of Saudi Arabia e) Dr. Xu Jinghe, Deputy Commissioner, National Medical Products Administration (NMPA), People's Republic of China f) Mr Armando Dumindin, Engineer, Ministry of Health, Philippines [TBC] g) Dr. Jeong-Rim LEE, (GHWPTC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety (MFDS), Republic of Korea h) Mr. Varavoot Sermsinsiri, Director, Medical Device Control Division, Food and Drug Administration, Thailand i) Ms. Melissa Torres, Associate Director for International Affairs, The United States Food and Drug Administration (US FDA), United States of America |
| 1500-1530 | | TEA BREAK | |
| 10 | 1540-1555 | Resolution and Endorsement (15mins) 1. Resolutions - Amendment 8 to the Global Harmonization Working Party House Rules on GHWP Strategic Advisory Board (SAB) 2. Endorsement of Strategic Framework - Global Harmonization Working Party Strategic Framework towards 2026 3. Endorsement of White Paper - Medical Device Regulatory Authorities Training Curriculum White Paper 4. Endorsement of Guidance Documents from Working Groups (WG) - WG8 - Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance 5. Endorsement of New Member - Japan | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China |
| 11 | 1555-1600 | Short Speech by New Member (5mins) | Mr TAKAHATA Masahiro Director, Office of Regenerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan |
| 12 | 1600-1645 | Election and Endorsement of GHWP Office Bearers (45mins) <i>[including 1minute self-introduction by each candidate before election and endorsement (24mins)]</i> - Briefing on Election and Endorsement Procedures - Election of GHWP Chair and Vice Chairs - Election of GHWPTC Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong |
| 13 | 1645-1655 | Speech by GHWP Chair-Elect (10mins - including any translation) | (onsite confirmation) |
| 14 | 1655-1715 | Recognition Awards and Certificates Presentations on Stage (20mins) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia and GHWP Chair-Elect |
| 15 | 1715-1720 | Announcement of next GHWP Annual Meeting Host & Short Speech (5mins) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia and 27th GHWP Annual Meeting Host |
| 16 | 1720-1725 | Closing Remarks (5mins) | Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
| 17 | 1725 | Adjourn | |
| END OF DAY 4 | | | |
| GHWP ASL Annual General Meeting [For ASL Members only] (1800-1830 at another meeting room) | | | |