



The 26th GHWP Annual Meeting Program Riyadh, Saudi Arabia 13-16 February 2023

DRAFT Program (Version 8c public)

| | | Day 1 Agenda: 13 February 2023 (Monday) | | | |
|---|---|---|---|--|--|
| ### Property of the Company of Address (Company Address (| | 0815-0900 | Venue: Crowne Plaza | | |
| Section Section 1. Sec | ITEMS | TIME | | | |
| See 1 1995 1990 Opening Address (Dates) 2 | 1 | 0900-0910 | Welcome Address (10mins) | | |
| CONTROL CAME OFFICE PLANTING TO Principle Framework (ISOming) OFFICE PLANTING CONTROL (Principle And Markets) OFFI CONTROL (P | | | | | |
| We Forcing Products, Notice (Section Products)) Notice (Section Products) Notice (Section | 2 | 0910-0920 | Opening Address (10mins) | | |
| Seed Tributed and though Captured Framework [Schmid] 8 | | | | | |
| Control Vision Class | | | | | |
| Section Processing Control | 3 | 0920-0935 | GHWP Strategic Framework (15mins) | | |
| Signature Sign | | | | | |
| Spiggers Spi | | | | | |
| Procedure Proc | 4 | 0935-1000 | Panel Discussion: GHWP Strategic Framework (20mins) + Q&A (5mins) | Moderator: Prof John Lim, Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School, | |
| Después Proposition Company of Marie Trains Control of Marie T | | | | Panelists: | |
| Section Sect | | | | a) Mr. Ali M. Al-DALAAN, (GHWP Chair), Vice Executive President, Medical Devices Sector, Saudi Food and | |
| Co. None Part Co. Colorary Co. Colorary Colorary Andrews (Description Programmers) | | | | b) Mrs. Salbiah Yaakop, (GHWPTC Chair), Director of Policy, International Affairs & Industry Facilitation | |
| Security of front and Drugs Saleste, Regulated informers of the Annual College Saleste, Regulated informers of the Annual College Saleste, Salested Saleste, Salested Salested Salested of 1900-1900 1000-1900 | | | | | |
| Section Committee Commit | | | | Ministry of Food and Drug Safety, Republic of Korea | |
| Part | | | | d) Mr. Alfred KWEK, (GHWPTC Co-Chair), Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd., Lao PDR | |
| Court Cour | | | | ej Mis. Tasila Hualig, Head of Regulatory Policy, Rocife Asia Pacific | |
| Chit Facility Chicago Control for Innovative Medicine, Paculty of Medicine, The Chicago University of News (In Section 1) | 5 | 1000-1005 | GHWP Secretariat Announcement (5mins) | Ir. Bryan SO | |
| Section Processing Proces | | | | | |
| ### **TORNEAL \$5500*** Regulatory Agiliny (Schmid) - QAA (Gmind) 7 1100-1120 Bounds of Regulatory Relaxed (15mins) - QAA (Gmind) 8 1100-1120 Record (Schmid) - QAA (Gmind) Control of Regulatory Relaxed (15mins) - QAA (Gmind) Control of Rela | | | | | |
| ### **TORNEAL \$5500*** Regulatory Agiliny (Schmid) - QAA (Gmind) 7 1100-1120 Bounds of Regulatory Relaxed (15mins) - QAA (Gmind) 8 1100-1120 Record (Schmid) - QAA (Gmind) Control of Regulatory Relaxed (15mins) - QAA (Gmind) Control of Rela | 1005-1040 | | | TEA RDEAV | |
| Sendential of Regulatory Multures (Estimola) CASA (Estimola) 7 1300-1320 Panel Discussion: Expanding Global access to Modical Devices - Related Devices, Panel Discussions: Expanding Global access to Modical Devices - Related Devices, Panel Discussion: Expanding Global access to Modical Devices - Related Devices, Panel Discussions: Expanding Global access to Modical Devices - Related Devices, Panel Expanding Global access to Modical Devices - Related Devices, Panel Selection of Panel Devices Sector, Panel Assignment of Panel Devices Sector, Panel Assignment of Panel Devices Sector, Panel Panel Panel Devices, Panel | | | | SESSION - Regulatory Agility and Reliance | |
| Total Control Part Description Part Descr | 6 | 1040-1100 | Regulatory Agility (15mins) + Q&A (5mins) | | |
| Part 120-1310 Part Discussion : Expanding Global access to Medical Devices - Relative Schematory Committed Commi | 7 | 1100-1120 | Benefits of Regulatory Reliance (15mins) + Q&A (5mins) | | |
| Cambridge Galler | | | | Director, Medical Devices, Health Sciences Authority, Singapore | |
| Section Control Cont | 8 | 1120-1150 | | | |
| Second Processing Committee Second Programmy Profiler, Rocket Also Pacific Girn Research Process Process Sections, Medical Device Sectors, 57DA, Kingdom Girn Research Processing Committee Girn Research Processing Research Resear | | Ì | (23HHIS) + Q&A (3MHS) | | |
| Soul Anaba (M. Varavoot Seminarii, Director, Medical Device Control Division, Food and Drug Administration, June 1997 (M. Varavoot Seminarii, Director, Medical Device Control Division, Food and Drug Administration, June 1997 (M. Varavoot Seminarii, Director, Medical Device Control Division, Food and Drug Administration, June 1997 (M. Varavoot Seminarii, Director, Medical Device Control Control (M. Varavoot Seminarii, Director, Medical Device Control Control (M. Varavoot Seminarii Control (M. | | Ì | | b) Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific | |
| TRIBINION AUSSION Increasing the Opportunities of Digital Health Regulatory Perspective* Inclinical Assistant Increasing and Technology [Inclinical Presentive*] | | | | | |
| TICHICAL SESSION 1. Digital Perceptodics - "Industry Perspective" (I Smine) + OAA (Smine) Or. Sean (Seong.) 3 (Jan., MN. MPH. | | | | | |
| 9 1150-1210 Olgstal Therapeutics. "Industry Perspective" (Limin) 4 ORA (Emina) Or. Asset (Security Perspective) 10 1210-1210 Olgstal Therapeutics. "Industry Perspective" (Limin) 4 ORA (Emina) Or. Asset (Security Perspective) 11 1210-1210 Olgstal Therapeutics. "Industry Perspective" (Limin) 4 ORA (Emina) 12 1210-1210 Olgstal Therapeutics. "Control of Perspective (Limin) 4 ORA (Emina) 11 1230-1250 Metavers using ARVRY/RX (Emina) - QRA (Emina) 12 12 120-1210 12 120-1210 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 12 12 120-1210 12 12 120-1210 12 12 1400-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 13 1400-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 14 14 1415-1435 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 15 1400-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 16 1400-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 17 1400-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 18 1400-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 19 1415-1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 10 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 10 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 10 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 10 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 10 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 10 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 11 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 12 1415 Olgstal Health Regulators Development in Othor (Limin) (RECCOD) 13 1415 Olgstal Health Regulators (Regulators (Regulators Olgstal Health Regulators (Regulat | | | | | |
| 9 1159-1210 Digital Pherapeutics - "Industry Perspective" (Elmina) - GBA (Smina) On Sean (Secong 3) Base, Mol. MPH. (Color MET.) 10 1220-1230 Digital Twins (Elmina) - GBA (Smina) (DREME) On Meta Palmer, Mol. Ph. 11 1230-1250 Metaverse using AN/VI/AR (ISmina) - GBA (Smina) OREA (Smina | | | | | |
| Dr. Mark Palmer, MD, PhD Besser Directs & Technical Fellow Core Technologies Meditorics Meditoric | 9 | 1150-1210 | Digital Therapeutics - "Industry Perspective" (15mins) + Q&A (5mins) | Dr. Sean (Seong-ji) Kang, MD. MPH. | |
| Research Director & Technical Fellow Cover Technologies | | | <u> </u> | | |
| Lacol Enterprise Modeling & Simulation Working Group Meditorics | 10 | 1210-1230 | Digital Twins (15mins) + Q&A (5mins) [ONLINE] | | |
| 1230-1250 Metaverse using AR/VR/XR (Ismins) + Q&A (Ismins) VBA (Ismins) V | | | | | |
| 1250-1400 TICHINCAL SESSION II : Digital Hard Parker Time | — — | | | | |
| TECHNICAL SESSION II. Digital Health Regulation Development in China (15mins) [RECORD) 12 1400-1415 Digital Health Regulation Development in China (15mins) [RECORD) 13 1415-1435 Digital Therapeutics "Exploring Regulatory Pathways of Digital Therapeutics" (15mins) + Q&A (5mins) 14 1435-1435 Digital Therapeutics "Exploring Regulatory Pathways of Digital Therapeutics" (15mins) + Q&A (5mins) 15 1435-1435 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 16 1435-1455 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 17 1435-1455 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 18 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1435-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1535-1455 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1535-1456 Panel Discussion: Digital Transformation and Connected Care in the Hospital Approaches (25mins) + Q&A (5mins) 19 1645-1645 Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator Mr. Serkan Seeze, Director of QAAA, EMTA Baster Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator Mr. Serkan Seeze, Director of QAAA, EMTA Baster Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator Mr. Serkan Seeze, Director of QAAA, EMTA Baster Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator Mr. Serkan Seeze, Director of QAAA, EMTA Ba | 11 | 1230-1250 | Metaverse using AR/VR/XR (15mins) + Q&A (5mins) | | |
| 12 1400-1415 Olgital Health Regulation Development in China (Ismins) (RECORD) Director, MD (Valuation Department II, Center for Medical Device Evaluation, MDP, Director, MD (Valuation Department II, Center for Medical Device Evaluation, MDP, Propriet Septiment (I), Center for Medical Device Evaluation, MDP, Propriet Septimics (Crisina) (Septimics) (Sep | ldash | | | | |
| 12 1405-1415 Digital Health Regulation Development in China (15mins) [RECORD] 13 1415-1435 Digital Treaspeutics "Exploring Regulatory Pathways of Digital Treaspeutics" (15mins) + Q&A (5mins) 14 1435-1435 Digital Treaspeutics "Exploring Regulatory Pathways of Digital Treaspeutics" (15mins) + Q&A (5mins) 15 1435-1455 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 16 14 1435-1455 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 17 1435-1455 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 18 1455-1525 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1455-1525 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 1455-1525 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) 19 155-1615 Testing Treaspeutics Panel Pa | 1250-1400 | | TECHNICAL SESSION II : Digit | | |
| NNPA_Popule's Republic of China | 12 | 4400 | | Dr. Guo Zhaojun. MD. | |
| Therapeutics" (15mins) + Q&A (5mins) Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea | 12 | 1400-1415 | i e | | |
| Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Koreae | 12 | 1400-1415 | | | |
| MFDS, Korea 14 1835-1855 Regulations for Artificial Intelligence (15mins) + Q&A (5mins) 15 1855-1825 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A Moderator Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corpor Panelists: 1 10 | | | Digital Therapeutics - "Exploring Regulatory Pathways of Digital | NMPA, People's Republic of China | |
| Associate Director for International Affairs Center for Devices and Radiological Health USFDA 1455-1525 Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A Gmins) Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corpor Panelists: 1) Dr. Abdullatif All Watban, Soudi FDA, Kingdom of Saudi Arabia 2) Dr. Chung Keen Lee. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea 3) Dr. Frieslul Idwans Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia (ONLINE) 4) Ms. Melisas Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TECHNICAL SESSION III: Digital Health: Advancing Healthcare Access (Government, Industry, International Org Perspectives) Dr. Abdulgader Almoneen VP. Shared Services & Advisor, Data & Digital Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Director, Organic Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Data & Digital Transformati | | | | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, (r, | |
| Center for Devices and Radiological Health USFDA | | | | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, | |
| USFDA | 13 | 1415-1435 | Therapeutics" (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres | |
| Smins Panelists: 1 | 13 | 1415-1435 | Therapeutics" (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MFDS, Korea Associate Director for International Affairs | |
| 1 3) Dr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia 2) Dr. Chung Kene. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea 3) Dr. Feisul Idzwan film Mastpha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) MS. Meliasa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TECHNICAL SESSION III : Digital Health : Advancing Healthrare Access [Government, Industry, International Org Perspectives] TECHNICAL SESSION III : Digital Health : Advancing Healthrare Access [Government, Industry, International Org Perspectives] Parability of the Patient and Product (15mins) + Q&A (5mins) Dr. Abdulgader Andrea Dr. Abdulgader Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Services & Advisor, Data & Digital Program of Services & Advisor, Data & Digital Program of Services & Advisor, Data & Digital Transformation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudards & Data Arabia Data Arabia Data & | 13 | 1415-1435 | Therapeutics" (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health | |
| 2 Dr. Chung Keun Lee. Assistant Director, Digital Health Device Evaluation Department, MFDS, Kores 3 Dr. Felstul (Dawn Bin Mustapha, Deputy Director, Disease Control Division, MoH, Malaysia [ONLINE] 4 Ms. Melisas Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Digital Services Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Digital Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Digital Transformation Program, Vision 2030 Dr. Abdulgader Almoen VP, Shared Services & Advisor, Dr. Abdulgader Almoen Dr. Abdulgader Almoen VP, Shared Services & Advisor, Dr. A | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation | |
| 3) Dr. Felsul Idxwan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONUNE] 4) MS. Mellisa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA 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. Abdulgader Almoeen VP. Shared Services & Advisor, Data & Digital Transformation Program, Vision 2030 17 1615-1645 Panel Discussion: Digital Transformation and Connected Care in the Hospital Panelists: 1 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1 Mr. Moderator: Mr. Serkan Sezer, Director, Digital Services Activation, Ministry of Health, Kingdom of Saud Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DOS Medizinprodukte GmbH 5) Ms. Alicia Chang, Country Lead, APACMed China TECHNICAL SESSION V: Standards Mr. Scott Colburn Director, CORH Standards & Conformity Assessment Program / S-CAP, USFDA 19 1705-1725 (yber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of china Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: | |
| 4) Ms. Melisas Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TECHNICAL SESSION III: Digital Health: Advancing Healthcare Access [Government, Industry, International Org Perspectives] 16 1555-1615 | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia 2) Dr. Chung Keun Lee. Assistant Director, Digital Health Devices Division, Medical Device Evaluation | |
| 1525-1555 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. Abdulgader Almoeen Vp. Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 17 1615-1645 Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1 Ms. Layla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saud Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michica Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Alicia Chang, Country Lead, APACMed China TECHNICAL SESSION III: Standards Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / S-CAP, USFDA 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Scalbiah Yaakop GNWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 | |
| TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Feissul Idawan Bim Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological | |
| TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Feissul Idawan Bim Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological | |
| TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives] | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Feissul Idawan Bim Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological | |
| 16 1555-1615 Equitable Access to the Patient and Product (15mins) + Q&A (5mins) 17 1615-1645 Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator: Mr. Serkan Searer, Director of QARA, EMEA Baxter (25mins) + Q&A (5mins) 18 1615-1645 Panel Discussion: Digital Transformation and Connected Care in the Hospital Moderator: Mr. Serkan Searer, Director of QARA, EMEA Baxter Panelists: 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | 13 | 1415-1435 1435-1455 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Feissul Idawan Bim Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological | |
| VP, Shared Services & Advisor, Date VP, Shared Services & Capacity VP, Shared Services V | 13 | 1415-1435 1435-1455 1435-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Febial Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA | |
| 17 1615-1645 Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) Was (25mins) Was | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advan | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MPDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 Idawan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA | |
| Camins + Q&A (Smins) Panelists: 1 Ms. Layla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saud Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mrs. Michied Body, DQS Medizinprodukte GmbH 5) Ms. Alicia Chang, Country Lead, APACMed China TECHNICAL SESSION IV: Standards Mrs. Solf Colburn Mrs. Saldiadrds Mrs. Solf Colburn Director, CDRH Standards & Conformity Assessment Program / 5-CAP, USFDA 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mrs. Saldiah Yaskop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia 1730 Adjourn Adjourn Adjourn Mrs. Saldiah Makapsia Mrs. Minishapsia Mrs. Malaysia Mrs. Malaysia Mrs. Minishapsia Mrs. Min | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advan | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 Idavan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ing Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen Vp. Shared Services & Advisor, | |
| Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michol Stothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Alicia Chang, Country Lead, APACIMed China TECHNICAL SESSION IV: Standards Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / 5-CAP, USFDA 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / 5-CAP, USFDA Mr. Scalbaih Yaskop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III : Digital Health : Advan Equitable Access to the Patient and Product (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MPD5, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullalif 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. Febul Idvana Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ling Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, | |
| 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Sauid Fashed, Republic of Korea 4) Mr. Alicia Chang, Country Lead, APACMed China TECHNICAL SESSION IV : Standards 18 1645-1705 Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MPDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 Idovan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ling Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen Vp., Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: | |
| Enablement Center, Kingdom of Saudi Arabia 3) Dr. Sell P.Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Alkiac Chang, Country Lead, APACMed China TECHNICAL SESSION IV: Standards Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / S-CAP, USFDA 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / S-CAP, USFDA Mr. Scalbiah Yakap GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abudilatif 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. Febial Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK TEA BREAK TEA REAK TEA | |
| 4) Mr. Alichael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms Alicia Chang, Country Lead, APACMed China TECHNICLA SESJONI V: 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 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis 21 1730 Adjourn | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Febul Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Cing Healthcare Access [Government, Industry, International Org Perspectives] TEA BREAK Cing Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Laylas Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation | |
| 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 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 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, Minis Health, Malaysia | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Folsul Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ling Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Layla Sulaiman Alsalehi, Director, Oligial Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia | |
| 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 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 20 1725-1730 Closing Remarks for Day 1 (5mins) Mrs. Salblah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Februl Advama Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Line Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Laylas Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DoS Medizinprodukte 6mbH | |
| Director, CDRH Standards & Conformity Assessment Program / S-CAP, USFDA 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 20 1725-1730 Closing Remarks for Day 1 (5mins) Mr. Sabibih Yaakop GHWPT Closing GHWPT Closing Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysla | 13 14 15 15 1525-1555 | 1415-1435 1435-1455 1435-1525 1455-1525 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital | NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Februl Advama Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Line Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Laylas Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DoS Medizinprodukte 6mbH | |
| 19 1705-1725 Cyber Security standard development (15mins) + Q&A (5mins) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 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, Minis Health, Malaysia | 13 14 15 15 1525-1555 16 17 17 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advan Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 3) Dr. Abdullatif 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. Februl Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK | |
| 20 1725-1730 Closing Remarks for Day 1 (Smins) Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia | 13 14 15 15 1525-1555 16 17 17 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advan Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MPDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 Idawan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ling Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Luyla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 3) Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Alkica Chang, Court Standards Mr. Scott Colburn | |
| GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia 21 1730 Adjourn | 13 14 15 15 1525-1535 16 17 17 18 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 1615-1645 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advan Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MPDS, Korea Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 Idwan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ling Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Luyla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 3) Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Alkica Chang, Courty Lead, APACMed China CENNICAL SESSION V : Standards Mr. Scott Colburn Director, ORM Standards & Conformity Assessment Program / S-CAP, USFDA | |
| Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Minis Health, Malaysia 21 1730 Adjourn | 13 14 15 15 1525-1555 16 17 17 18 18 19 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 1615-1645 1645-1705 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) Tusing Standards for Regulatory Purposes (15mins) + Q&A (5mins) Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MPDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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 Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Ling Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoeen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Layla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 3) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms Alicia Chang, Country Lead, APACMed China Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH | |
| 21 1730 Adjourn | 13 14 15 15 1525-1555 16 17 17 18 18 19 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 1615-1645 1645-1705 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) Tusing Standards for Regulatory Purposes (15mins) + Q&A (5mins) Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 3) Dr. Abdullatif 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. Februl Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK TE | |
| | 13 14 15 15 1525-1555 16 17 17 18 18 19 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 1615-1645 1645-1705 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advant Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) Tusing Standards for Regulatory Purposes (15mins) + Q&A (5mins) Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Febul Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Cing Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Layla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Allicic Abnag, Country Lead, APACMed China CHNICAL SESSION IV: Standards Mr. Scott Colburn Director, CROH Standards & Conformity Assessment Program / S-CAP, USFDA Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mrs. Salbiah Yaakop GHWP TC Chair | |
| END OF DAY 1 | 13 14 15 1525-1555 16 17 17 18 18 19 20 | 1415-1435 1435-1455 1435-1525 1455-1525 1555-1615 1615-1645 1645-1705 1705-1725 1725-1730 | Therapeutics" (15mins) + Q&A (5mins) Regulations for Artificial Intelligence (15mins) + Q&A (5mins) Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins) TECHNICAL SESSION III: Digital Health : Advan Equitable Access to the Patient and Product (15mins) + Q&A (5mins) Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins) Using Standards for Regulatory Purposes (15mins) + Q&A (5mins) TUsing Standards for Regulatory Purposes (15mins) + Q&A (5mins) Cyber Security standard development (15mins) + Q&A (5mins) Closing Remarks for Day 1 (5mins) | NMPA, People's Republic of China Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea MS. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif 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. Febul Idevan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA TEA BREAK Cing Healthcare Access [Government, Industry, International Org Perspectives] Dr. Abdulgader Almoen VP, Shared Services & Advisor, Data & Digital Transformation Health Sector Transformation Program, Vision 2030 Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Layla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms. Allicic Abnag, Country Lead, APACMed China CHNICAL SESSION IV: Standards Mr. Scott Colburn Director, CROH Standards & Conformity Assessment Program / S-CAP, USFDA Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH Mrs. Salbiah Yaakop GHWP TC Chair | |





| | Day 2 Agenda: 14 February 2023 (Tuesday) | | | |
|-----------------|---|---|---|--|
| | Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia | | | |
| ITEMS | TIME | TECHNICAL SESSIONS (Cont') - Increasing the Opportunities of Digital Health | | |
| 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 | |
| 2 | 0910-0930 | TECHNICAL SESSION V : Digital Health : Improving Healthcare Services (15mins) + Q&A (5mins) [ONLINE] | Clinical Applications [Industry, Hospitals and Government Perspectives] Dr. Ho Young Lee. M.D. | |
| 2 | | Improving Healthcare Services (15mins) + Q&A (5mins) [UNLINE] | Dr. no Toung tee. Mr.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) [Online] | Dr. 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) [Online] | Ms. Heather M. Colvin Director, MD Regulatory Affairs Evidence & Outcomes Policy Global Regulatory Affairs Policy Johnson and Johnson Medtech | |
| 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 | |
| 6 | 1100-1120 | Post Market Surveillance (15mins) + Q&A (5mins) | NICAL SESSION VI : New Innovations Mr. Mohd Zul hisham Junaidi, 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, Director, Medical Devices, 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. all Al-Dalaan, Vice Executive President, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Ms. Mariamanh 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 | Dr. Razan Asally, Head of Medical Devices Evaluation Section, Medical Devices Sector, SFDA, Kingdom of | |
| 1230-1345 | | (15mins) + Q&A (5mins) | Saudi Arabia 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. Praveen Kumar Manager, Regulatory Affairs, APACMed | |
| 11 | 1405-1435 | Panel Discussion on GHWP Capacity Building (25mins) + Q&A (5mins) | Moderator: Mr. Anirudh Sen, APACMed Panelists: Aprof. John Lim, Executive 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) Dr. Razan Asally, Head of Medical Devices Evaluation Section, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Mr. Yiting Cai, Chair, Capacity Building Working Group, APACMed; Regional Regulatory Affairs Director, Alcon, Singapore | |
| 12 | 1435-1455 | MDSAP Updates (15mins) + Q&A (5mins) | Ms. Michelle Noonan International Policy Analyst Center for Devices and Radiological Health U.S. Food and Drug Administration | |
| 13 1515-1545 | 1455-1515 | UDI (15mins) + Q&A (5mins) | Ms. Victoria Qu, Director, Quality and Regulatory Affairs, Asia Pacific, Cordis TEA BREAK | |
| 14 | 1545-1605 | IAF CertSearch (15mins) + Q&A (5mins) | Mr. Grant Ramaley and Mr. Nigel Johnston, IAF | |
| 15 | 1605-1625 | Internet tools kit for medical devices (15mins) + Q&A (5mins) [ONLINE] | Mr. Jeff Gren & Ms. Miang TANAKASEMSUB | |
| 16 | 1625-1630 | Closing Remarks for Day 2 (Smins) | Dr. Jeong-Rim LEE (GHWPTC Co-Chair) Director General, Medical Device Evaluation Department Ministry of Food and Drug Safety (MFDS) Republic of Korea | |
| 17 | 1630 | Adjourn | FDAY 2 | |
| | | | | |





| | | Day 3 Agenda: 15 February 2023 (Wednesday) | | |
|-------|-----------|---|--|--|
| | | Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia | | |
| ITEMS | | | P Technical Committee (GHWP TC) Meeting | |
| 1 | 0900-1045 | GHWP TC & WG Leaders Meeting with TC Advisors (1hr45mins) | Mr. Ali M. Al-Dalaan (proposed) | |
| | | (Closed-Door Meeting) | 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 | |
| | | | ministry of rood and orde safety, republic of rorea | |
| | | | | |
| | | | | |
| | | | | |

| | | | Er. Alfred KWEK GHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd. |
|-----------|--|---|---|
| | | | Supported by Ms. Miang TANAKASEMSUB GHWP TC Secretary Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision |
| | | | Ms. Carol Jirui YAN GHWP TC Secretary Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China |
| 1045-1115 | | | TEA BREAK |
| 2 | 1115-1120 | Welcome Speech (Smins) | 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 | Mrs. Salbiah Yaakop (Chair) Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia Dr. Jeong-Rim LEE (Co-Chair) Director, Cardiovascular Devices Division |
| | | | Ministry of Food and Drug Safety (MFDS) - Republic of Korea Mr. Alfred KWEK (Co-Chair) Director, Public Affairs |
| | | | Edwards Lifesciences Asia Pte. Ltd Lao PDR Supported by TC Secretary Ms. Miang TANAKASEMSUB |
| | | | Mr. Jack WONG |
| | | | Associate Vice President Regulatory Affairs, Asia Pacific, Middle East & Africa, Allergan - Hong Kong SAR, China |
| | | | Ms. Carol YAN Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China Dr. Adelheid Schneider |
| | | | Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore |
| 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 1 (WG1) Chair - Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea |
| | | Work Group 2 (WG2) - Pre-market: IVDD | 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 |
| | | Work Group 3 (WG3) - Pre-market: Software as a Medical Device Work Group 4 (WG4) | 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 |
| | | Post-Market Work Group 5 (WGS) - Clinical Evidence for Performance and Safety | Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong SAR, China Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore |
| | | Work Group 6 (WG6) - Quality Management System: Audit & Assessment | Work Group 5 (WGS) Chair -Mr. Fikriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India |
| | | Work Group 7 (WG7) - Quality Management System: Operation & Implementation | 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 |
| | | | Work Group 7 (WG7) Chair - Mrs. CHEN Yan, National Medical Products Administration, China Co-chair - Mr. Ee Bin Liew, Access-2-Healthcare, Singapore |
| 1245-1400 | | | LUNCH / PRAYER TIME |
| 5 | 1400 -1420 (5mins + 5mins Q&A each) | 26th GHW/ Working Group Updates and Next Steps (Cont'): | Technical Committee (GHWPTC) Meeting Work Group 8 (WG8) |
| | Que catily | Work Group 8 (WG8) - Standards | Chair - Mrs. Salbiah Yaakop, Ministry of Health, Malaysia Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia |
| | | Work Group 9 (WG9) - UDI & Nomenclature | Work Group 9 (WG9) Chair - Ms. Jun LJ, National Medical Products Administration, China Co-chair - Ms. Victoria Qu, Global Strategic Regulatory Abbott, China |
| 6 | 1420-1430 | TC Advisors Summary Report (10mins) | Representatives of TC Advisory Panel |
| 7 | 1430-1435 | Closing Remarks for Day 3 (5mins) | Mr. Alfred KWEK (GHWPTC Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd Lao PDR |
| 8 | 1435 | Adjourn END C | F DAY 3 |
| 1435-1515 | | | TEA BREAK |
| | | (151) | t Committee Meeting (CLOSED-DOOR) [TBC] 5-1645) |
| | GALA DINNER | | |





| | | Day 4 Agenda: 16 February 2023 (Thursday) | |
|-------|-----------|---|---|
| ITEMS | TIME | 26 th GHWP Annual Meeting (Main Meeting) | |
| 1 | 0855-0900 | Announcement by MC (SFDA) (5mins) | Master of Ceremony (MC) by Saudi FDA Announcement |
| 2 | 0900-0930 | Opening Ceremony (30mins) | Welcome Address- |
| | | - Welcome Address (7mins) | Dr. Hisham bin Saad Aljadhey |
| | | - Opening address (7mins) | Chief Executive Officer, Saudi Food and Drug Authority |
| | | - Group Photo (16mins) | Kingdom of Saudi Arabia |
| | | | |
| | | | Opening Address- |
| | | | Mr. Ali M. AL-DALAAN |
| | | | GHWP Chair |
| | | | Vice Executive President, Medical Devices Sector |
| | | | Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
| | | | , , |
| 3 | 0930-0940 | Main Meeting | Mr. Ali M. AL-DALAAN |
| | | - Roll Call (8mins) | GHWP Chair |
| | | - Adoption of Agenda (1min) | Vice Executive President, Medical Devices Sector |
| | | - Adoption of 25th GHWP Annual Meeting Minutes (1min) | 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 |
| | | | |
| | | | |

| 16 | 1720-1725 | Closing Remarks (5mins) Adjourn | 27th GHWP Annual Meeting Host Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
|----------------|-----------|--|--|
| 16 | 1720-1725 | Closing Remarks (5mins) | 27th GHWP Annual Meeting Host Mr. Ali M. AL-DALAAN GHWP Chair |
| | | | and |
| 15 | 1715-1720 | Announcement of next GHWP Annual Meeting Host & Short Speech (Smins) | and GHWP Chair-Elect Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia |
| 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 |
| 13 | 1645-1655 | Speech by GHWP Chair-Elect (10mins - including any translation) | Hong Kong SAR, China (onsite confirmation) |
| 12 | 1550-1645 | Election and Endorsement of GHWP Office Bearers (5Smins) [including Iminute self-introduction by each candidate before election and endorsement (25mins)] - Briefing on Election and Endorsement Procedures - Election of GHWPTC Chair and Vice Chairs - Election of GHWPTC Chair and Co-Chairs - Election of GHWPTC 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 CVH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong |
| 11 | 1545-1550 | Short Speech by New Member (5mins) | Mr TAKAHATA Masahiro Director, Office of Regnerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan |
| | | 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 | |
| | | - Global Harmonization Working Party Strategic Framework towards 2026 3. Endorsement of White Paper - Medical Device Regulatory Authorities Training Curriculum White Paper | GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China |
| 10 | 1530-1545 | 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 | 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 |
| 1500-1530 | | | TEA BREAK |
| | | c) Japan d) Kingdom of Saudi Arabia e) People's Republic of China f) Republic of Korea g) Thailand h) United States of America | c) Ms. TOGASHI Mika, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan d) feng Abdullah AlGuraibi, Saudi Food and Drug Authority (SFDA), Kingdom of Saudi Arabia e) Dr. Xu Jinghe, Deputy Comissioner, National Medical Products Administration (NMPA), People's Republic of China for China in the Common of China for Chi |
| 1245-1400 9 | 1400-1500 | Country/Region Updates (Cont') (5mins+5mins Q&A each) | LUNCH / PRAYER TIME |
| 8 | 1225-1245 | Country/Region Updates (Smins+Smins 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) Ms. Nada Alkhayat, Policy Officer, Directorate-General for Health and Food Safety (DG SANTE) European Commission |
| | | 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) | b) Mr. Yuji Yanagida, GRP WG Vice chair, DITTA () Ms. Géraldine Lissalde-Bonnet, Vice-President Healthcare, GS1 Global Office, GS1 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, Genic Medical Technology Alliance (GMT) d) Ms. Sandra Ligia Gonzalee, Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) |
| 7 | 1125-1225 | b) ASEAN GHWP Liaison Member Updates (5mins + 5mins Q&A each) a) Asia Pacific Medical Technology Association (APACMed) | b) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, MDA, Ministry of Health , Malaysia, ASEAN a) Mr. Anirudh Sen, Director, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) |
| 6 | 1055-1125 | International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) APEC Harmonization Center (AHC) | a) Dr. Jeewon Joung Ph.D., Director, Pre-submission Consultation Team, Ministry of Food & Drug Safety(MFDS), Republic of Korea, APEC Harmonization Center (AHC) |
| 5 | 1040-1055 | IMDRF Status Updates (10mins+5mins) | Dr. Andrzej Rys IMORF Chair 2023 Principal Scientific Adviser Directorate-General for Health and Food Safety (DG SANTE) European Commission |
| 1010-1040 | | - GHWPTC Status Report (10mins + 5mins Q&A) | Mrs. Salbiah Yaakop GHWPTC Chair Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health , Malaysia TEA REFAK |
| | | | Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia |