

27th GHWP Annual Meeting and 27th GHWP TC Meeting

27–30 November 2023
Shanghai International Convention Center, China

Venue: Grand Ballroom I , 7F, Shanghai International Convention Center

| Time | Content | Responsible Person (s) |
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| 08:55-09:00 | Announcement by MC (5mins) | Moderator: Dong Jiangping Director General, CCFDIE, People's Republic of China |
| 09:00-09:30 | Opening Ceremony (30mins) - Welcome Video (5mins) - Welcome Addresses (5mins+5mins) - Opening Address (5mins) - Group Photo (10mins) | Moderator: Dong Jiangping Director General, CCFDIE, People's Republic of China Welcome Addresses Li Li Commissioner, NMPA, People's Republic of China Chen Jie Vice Mayor, Shanghai Municipal People's Government, People's Republic of China Opening Address Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China |
| TEA BREAK (09:30-10:00) | | |
| 10:00-10:10 | Main Meeting - Roll Call (8mins) - Adoption of the Agenda (1min) - Adoption of the 26 th GHWP Annual Meeting Minutes (1min) | Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China |
| 10:10-10:40 | GHWP Status Reports: a) GHWP Overall Status Report (15mins) b) GHWP TC Status Report (10mins + 5mins Q&A) | Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Abdullatif S. AlWatban GHWP TC Chair Executive Director, Medical Devices Evaluation, Saudi Food & Drug Authority, Kingdom of Saudi Arabia |
| 10:40-10:55 | IMDRF Updates (15mins) | Chloe Spathari Nada Alkhatat Policy Officers, Medical Devices, Directorate-General for Health and Food Safety, European Commission, IMDRF |
| 10:55-11:25 | International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) WHO b) African Medical Devices Forum (AMDF) | a) Agnes Sitta Kijo Technical Officer, WHO b) Paulyne Wairimu Chair, African Medical Devices Forum (AMDF) |

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| 11:25-12:25 | <p>GHWP Liaison Member Updates (5mins + 5mins Q&A each)</p> <p>a) Asia Pacific Medical Technology Association (APACMed)</p> <p>b) Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association (DITTA)</p> <p>c) GS1</p> <p>d) Global Medical Devices Nomenclature Agency (GMDN Agency)</p> <p>e) Global Medical Technology Alliance (GMTA)</p> <p>f) Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)</p> | <p>a) Cindy Pelou Lead for Regulatory Affairs, APACMed</p> <p>b) Sunny Woo, Team Leader Korea Medical Devices Industry Association, International Affairs Team, DITTA</p> <p>c) Géraldine Lissalde-Bonnet Vice President Healthcare, GS1</p> <p>d) Deniz Bruce Chief Executive Officer, Global Medical Devices Nomenclature Agency (GMDN Agency)</p> <p>e) Diana Kanecka Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA)</p> <p>f) Sandra Ligia Gonzalez Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)</p> |
| 12:25-12:55 | <p>Country/Region Updates (5mins+5mins Q&A each)</p> <p>a) Chile</p> <p>b) European Commission</p> <p>c) Indonesia</p> | <p>a) Maria Cecilia Lopez Head of the Authorization and Registration of Medical Devices Subdepartment - ANDID/ISP Department, Chile</p> <p>b) Graeme Tunbridge Senior Vice President, Global Regulatory and Quality, Medical Devices at BSI</p> <p>c) Ismiyati Surata Senior Health Administrator, Ministry of Health, Indonesia</p> |
| LUNCH (12:55-14:00) | | |
| 14:00-15:20 | <p>Country/Region Updates (Cont') (5mins+5mins Q&A each)</p> <p>d) Japan</p> <p>e) Kingdom of Saudi Arabia</p> <p>f) Laos PDR</p> <p>g) Malaysia</p> <p>h) People's Republic of China</p> <p>i) Republic of Korea</p> <p>j) Thailand</p> <p>k) Vietnam</p> | <p>d) Miho Sato Coordinator, Office of International Programs Pharmaceuticals and Medical Devices Agency (PMDA), Japan</p> <p>e) Abdullah Alghuraibi Director of Regulation and Standard, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia</p> <p>f) Bounxou Keohavong Director General, Food and Drug Department, Ministry of Health, Laos PDR</p> <p>g) Muralitharan Paramasua Chief Executive, Medical Device Authority, Ministry of Health, Malaysia</p> <p>h) Lyu Ling Director General, Department of Medical Devices Registration, NMPA, People's Republic of China</p> <p>i) Ahn Young Wook Deputy Director, In-vitro Diagnostic Devices Division at NIFDS of MFDS, Republic of Korea</p> <p>j) Lertchai Lertvut Deputy Secretary-General, Food and Drug Administration, Thailand</p> <p>k) Nguyen Tu Hieu Deputy Director, Infrastructure and Medical Device Administration, Ministry of Health, Vietnam</p> |

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| <p>15:20-15:45</p> | <p>Resolution and Endorsement (25mins)</p> <ol style="list-style-type: none"> 1. Endorsement of Vice-Chair (Regulatory Authority) and WG5 Chair positions 2. Endorsement of Guidance Documents from Working Groups (WG) <ol style="list-style-type: none"> a) WG1-WG2-WG3 "Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)" b) WG2 "Guidance for Additional Considerations to Support Conformity Assessment of In vitro Companion Diagnostic Medical Devices" c) WG4 "Post Market Resource Center" d) WG7 "Guidance document on the risk based approach to quality management system aspects: ISO13485:2016" e) WG7 "Guidance for Auditing Supplier to Medical Device Manufacturers" f) WG7 "A Guide to Understanding Presently Available Audit Duration Determination Systems" g) WG7 "A Guide to Understanding Best Practices in Audit Life Cycle Management" h) WG9 "GHWP UDI Rule" 3. Endorsement of New Members, followed by short speeches <ol style="list-style-type: none"> a) Egypt [Speech by Rania Soliman, General Manager Of General Administration Of Medical Devices Marketing authorization, Egyptian Drug Authority, Egypt] b) Cuba [Speech by Yadira Alvarez Rodriguez, Specialist of Medical Devices Department, CECMED, Cuba] 4. Endorsement on Membership Withdrawal USA | <p>Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China</p> <p>Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China</p> |
| <p>TEA BREAK (15:45-16:10)</p> | | |
| <p>16:10-16:25</p> | <p>Presentation of Certificates of Appointment to the Members of GHWP Strategic Advisory Board (SAB) [15mins]</p> | <p>Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China</p> <p>Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China</p> |



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| 16:25-16:40 | Presentation of Bronze Plaque to GHWP (Guangzhou) Academy and Short Presentation [15mins] | <p>Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China</p> <p>Yong XU Vice President of South China University of Technology People's Republic of China</p> <p>Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China</p> |
| 16:40-16:45 | Ceremony on Strategic Cooperation between GHWP and Reed Sinopharm Exhibitions on CMEF [5mins] | <p>EunHee Cho GHWP Vice-Chair (Industry) Regulatory Affairs Director, Abbott Medical Korea, Republic of Korea</p> <p>Li Chao Managing Director, Reed Sinopharm Exhibitions</p> <p>Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China</p> |
| 16:45-17:00 | Presentation of Souvenirs to Company Sponsors [15mins] | <p>Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China</p> <p>Eka Purnamasari Director for Medical Devices Control, Ministry of Health, Indonesia GHWP Vice-Chair (Regulatory Authority)</p> <p>Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China</p> |
| 17:00-17:05 | Announcement of the next GHWP Annual Meeting Host & Short Speech (5mins) | <p>Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China</p> <p>Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China</p> |
| 17:05-17:10 | Closing Remarks (5mins) | <p>Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China</p> |
| 17:10 | Adjourn | |

END OF DAY 4

