# Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

## Day 1 Agenda: 9 December 2024
## Venue: Kuala Lumpur Convention Centre

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| | | **Theme Regulatory Excellence/ Best regulatory practices** | |
| | **TIME** | | |
| **1** | **0915-0930** | **Welcome address** | **GHWP Vice Chair** |
| | | **Regulatory Excellence** | |
| **2** | **0930-0945** | Introduction to Regulatory Excellence - What is Regulatory Excellence - Defining and Assessing Regulatory Excellence | Mr. Brad Spring - Global Head of Policy and Intelligence -Roche Diagnostics |
| **3** | **0945-1000** | How To Regulate With Excellence- Achieving Regulatory Excellence | MDA, Malaysia<br>Dr. Muralitharan Paramasu |
| **4** | **1000-1015** | Excel Regulatory Excellence in the MedTech Industry | Ms. Diana Kaneka<br>Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA) |
| **5** | **1015-1030** | Development of the Global Benchmarking Tool (GBT) | Mr. SILLO, Hiiti Baran<br>Unit Head, Regulation and Safety,<br>Department of Regulation and Prequalification, WHO |
| | **1030-1050** | TEA BREAK | |
| | | **Global Regulatory Framework** | |
| **6** | **1050-1105** | GHWP Playbook for Implementation of Medical Device Regulatory Frameworks and support from GHWP to establish a regulatory framework | Dr. Adelheid Schneider,<br>GHWP WG 2 Vice Chair |
| **7** | **1105-1120** | WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF) | Ms. Agnes Sitta Kijo, Technical Officer, WHO |
| **8** | **1120-1135** | IMDRF Regulatory framework | Ms. Nicole Smith, Head of Regulatory Affairs & Policy - PSQ Regulatory Affairs, Philips |
| **9** | **1135-1205** | Sharing best practices of implementing a national regulatory framework<br>(1)Experience sharing on enforcing regulatory requirements to ensure continuous compliance (Malaysia)<br>(2)Implementing the regulatory framework in Egypt<br>(3) Implementing the regulatory framework in Bahrain | Malaysia, Egypt, Bahrain - 10 minutes each<br>Mr. Dery Akmal bin Abdul Rahman, MDA Malaysia<br>Dr.Rania Ahmed, EDA<br>Eng.Nada Al Sayegh, NHRA Bahrain |
| **10** | **1205-1230** | PANEL - How does an ideal regulatory framework look like? | Moderator- Ms. Miang Tanakasemsub Head of Regulatory Affairs (RA) Asia Pacific (AP)<br>Johnson & Johnson Vision<br>Panelists - Dr. Adelheid Schneider, Ms Agnes Sitta Kijo, Malaysia, Dr. Rania Ahmed and Eng. Nada Al Sayegh |

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| | **1230-1345** | LUNCH | |
| | | **Regulatory Skills and Talent Pipeline** | |
| **11** | **1345-1400** | Insights to GHWP Regulatory Competency Framework and Curriculum for Industry and Regulators | Ms. Kitty Mao<br>RA Director<br>GE Healthcare<br>Singapore |
| **12** | **1400-1415** | Regulatory Excellence Ecosystem Industry : sharing best practise to actively support growth and development of regulatory professionals | Mr. Daniel Moeland<br>Johnson & Johnson MedTech |
| **13** | **1415-1430** | Regulatory Excellence Ecosystem Regulators : sharing best practise to actively support growth and development of regulators | Dr. Razan Asally<br>Head of medical evaluation section<br>SFDA |
| **14** | **1430-1445** | Conversations That Matter - Interactions with Health Authorities | Ms. Raina E. Dauria, RAC, MS<br>Vice President, Global Regulatory Policy and Talent, MedTech<br>Johnson & Johnson MedTec |
| **15** | **1445-1515** | PANEL - Working in regulatory affairs - Sharing tips and experiences (beginners and mature regulatory personal of Industry and Authorities ) | Moderator Ms. Marianne Yap, Alcon<br>Mr. Muhammad Sabirrin Md Zahar, MDA<br>Ms. Jacqueline Fok, RA Manager, Alcon<br>Mr. Sharad Shukla, J&J,<br>Dr. Razan Asally, SFDA<br>Ms. Raina E Duaria |
| | **1515-1545** | TEA BREAK | |
| | | **Clinical Evidence & RWE** | |
| **16** | **1545-1600** | How to demonstrate Clinical Evidence | Mr. Rajakumaran Karnagaran (BSI)- confirmed |
| **17** | **1600-1615** | Acceptance of clinical oversea data for Clinical Evidence versus Local Testing | Dr. Adelheid Schneider<br>GHWP WG 2 Vice Chair (confirmed) |
| **18** | **1615-1630** | Best practise on Real World Evidence Usability in Device Applications | Dr. Rama Sethuraman<br>Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd |
| **19** | **1630-1645** | Evaluating the Quality of Real-World Evidence Used to Support Regulatory Decision-Making for Medical Devices | Prof. Gao<br>WG-4 Advisor |
| **20** | **1645-1715** | Panel on Challenges and Opportunities on Clinical Evidence using RWE | Moderator Mr. Mohammed Y. Majrashi (SFDA) confirmed Panelists Presenters |
| | **1715-1730** | **Summary Day 1** | TC Chair or Co Chair, or Capacity Building respresentative |
| | | **Adjourn** | |
| **END OF DAY 1** | | | |

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| | **Day 2 Agenda: 10 December 2024**<br>**Venue: Kuala Lumpur Convention Centre** | |
| | **Theme Regulatory Excellence/ Best regulatory practices** | |
| | **TIME** | |
| | **Welcome DAY 2** | |
| **1** | **0830-0845** | GHWP Capacity Building Initatives | Ms. Quan Tran |
| | **Cybersecurity and Robotics** | |
| **2** | **0845-0900** | EU AI Act | Mr. Robert Froehlich<br>Head of MHS ASEAN (VP)<br>TÜV SÜD PSB Pte Ltd |

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| **3** | **0900-0915** | Cybersecurity: Integrating Medical Device Cybersecurity in the Quality Management System | Ms. Jennifer Khow Chui Ping (Synapxe)Deputy Director - Synapxe (Subsidiary of Singapore MOH) (Video) |
| **4** | **0915-0930** | Consideration for innovative robotic assisted Surgical Devices | Mr. Sharad Shukla<br>Director Regulatory Affairs<br>Johnson & Johnson International (Singapore) Pte. Ltd |
| **5** | **0930-0945** | PANEL | Moderator Jennefer Ramos Head of RA Growth Region – PSQ<br>Panelist-Mr. Robert Froehlich (TÜV)<br>Mr. Sharad Shukla (Johnson & Johnson) |
| | **0945-1015** | TEA BREAK | |
| | | **Labeling and UDI** | |
| **6** | **1015-1030** | Key trends on digital labeling | Mr. Shekhar Nambi<br>Johnson & Johnson MedTech |
| **7** | **1030-1045** | Update from the MEA region on Electronic Instructions for Use (EIFU) | Ms. Heba Tork- Regulatory and Quality Manager - Roche Diagnostics ( Egypt) |
| **8** | **1045-1100** | Regulatory perspective on elabeling | Mr. Winson Teng (BD)- APACMed |
| **9** | **1100-1115** | Industry perspective on UDI - Opportunities and challenges | Ms. Yuyi from Wego Group |
| **10** | **1115-1130** | The role of UDI in whole product life cycle management | Mr. Dennis Black from BD |
| **11** | **1130-1145** | The role of standards | Mr. Gite Sadanand, Abbott Associate Director, Regulatory Affairs Strategic Programs |
| **12** | **1145-1215** | PANEL - Benefits, opportunities and approaches on e-labeling | Dr. Petra Kaas Wiele - TC Advisor and Consultant |
| | **1215-1330** | LUNCH | |
| | | **QMS and PMS** | |
| **13** | **1330-1345** | Briefing of ISO/TC 210 progress on ISO13485 | Dr. Ir. Peter W.J. Linders, GHWP TC Advisor/Former Director, Global Standards & Regulations, Former Philips Healthcare (Video) |
| **14** | **1345-1400** | Overview of QMS implementation in GHWP member economies | Ms. Annie Yin, WG7 Secretary/Vice President, Roche Diagnostics China |
| **15** | **1400-1410** | Case sharing of QMS implementation in China | Ms. Jie Zhu, Quality Manager, Mindray Bio-Medical Electronic Co. LTD |
| **16** | **1410-1425** | Guidance for Audit Supplier for Medical device Manufacturers | Ms. Ning Li, Sr. Director of Q&R, Miceo-Tech |
| **17** | **1425-1440** | Industry Perspective on MDSAP | Ms. Asmaa Awad<br>Global Head of Eastern Europe, Middle East, and Africa Regulatory Policy<br>Roche Diagnostics ME |
| **18** | **1440-1455** | Good Distribution Practices for Medical Device GDPMD | Mr. Tony Low<br>Director of Human Performance and Medical QA/RA Commissioning Agents International (CAI) |
| **19** | **1455-1510** | Reporting and investigating adverse events and complaints of medical devices or Safety alerts and field safety corrective action (FSCA) for medical devices | Dr. Mohammed Majrashi<br>Executive Director<br>Surveillance and Biometric<br>Saudi Food & Drug Authority (SFDA)<br>Kingdom of Saudi Arabia |
| **20** | **1510-1525** | Fit for purpose change management - GHWP Guideline (draft) - Change Management - Industry Perspective | Ms. Cindy Pelou (APACMed) |
| **21** | **1525-1545** | PANEL - The criticality of PMDA and QMS in regulatory framework. | Moderator Mr. Raghavan Nair, Mr. Asok Kumar, Abbott Quality and Regulatory<br>Director - Global Strategic Regulatory Affairs |
| | **1545-1615** | TEA BREAK | |
| | | **Convergence and Reliance** | |

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| **22** | **1615-1630** | Common Evaluation Reliance Practice Updates | Mr. ZHANG Shiqing,<br>STG CERP Chair |
| **23** | **1630-1645** | Good Reliance Practice | Ms. Agnes Sitta Kijo<br>Technical Officer, WHO |
| **24** | **1645-1700** | Regulatory convergence & reliance in Africa - sharing good practice | Ms. Paulyne Wairimu<br>Chair of the African Medical Devices Forum |
| **25** | **1700-1715** | Regulatory convergence & reliance in Asia - sharing good practice - on behalf of APACMed | Ms. Yasha Huang<br>Roche |
| **26** | **1715-1730** | Regulatory convergence & reliance in ME - sharing good practice - MEA- MECOMED | Ms. Rana Chalhoub<br>Regulatory Affairs Director, MECOMED |
| **27** | **1730-1750** | Panel Convergence and Reliance | Moderator Ms. Cindy Pelou -APACMed (confirmed)<br>Panelists-Ms. Agnes Sitta Kijo (WHO)<br>Ms. Paulyne Wairimu (AMF)<br>Ms. Yasha Huang (Roche)<br>Ms. Nicole Smith (Philips)<br>Ms. Rana Chalhoub (Mecomed) |
| **28** | **1750-1800** | Closing and Summary Day 2 | TC Chair or Co Chair, or Capacity Building respresentative |
| | | **Adjourn** | |

# Day 3 Agenda: 11 December 2024
# Morning: Closed-door Meeting
# Venue: Kuala Lumpur Convention Centre

## 28th GHWP Technical Committee (GHWP TC) Meeting
## Attendees: GHWP LT, TC LT, TC Advisor, TC Secretariat, WG Chair/Co-chair

**Moderator: Dr. Mohammed Y Majrashi**
**GHWP Acting TC Chair**
**Executive Director, S&B, SFDA, Kingdom of Saudi Arabia**

| No. | TIME | ITEM | SPEAKER |
|---|---|---|---|
| **1** | **0900-1200** | GHWP TC & WG Leaders Meeting with TC Advisors<br>(Closed-Door Meeting) | |
| **Day 3 Agenda: 11 December 2024<br>Afternoon: Open Meeting<br>Venue: Kuala Lumpur Convention Centre** | | | |
| **2** | **1400-1410** | Opening Speech | Dr. Mohammed Y Majrashi<br>GHWP Acting TC Chair<br>Executive Director, S&B, SFDA, Kingdom of Saudi Arabia |
| **3** | **1410-1415** | Roll call<br>Adoption of Agenda | Ms. LI Jun<br>GHWP TC Co-Chair (Regulatory Authority)<br>Deputy Director General, Center for Medical Device Evaluation, NMPA, People's Republic of China |

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| **4** | **1415-1420** | Adoption of 27th GHWP TC Meeting Minutes | Ms. Miang Tanakasemsub<br>GHWP TC Co-chair (Industry)<br>Head of Regulatory Affairs, Asia Pacific Johnson & Johnson Vision, Thailand |
| **5** | **1420-1500** | Work Group 1 (WG1) - Pre-Market Submission and CSDT | Work Group 1 (WG1) |
| **6** | | Work Group 2 (WG2) - Pre-market: IVDD | Work Group 2 (WG2) |
| **7** | | Work Group 3 (WG3) - Pre-market: Software as a Medical Device | Work Group 3 (WG3) |
| **8** | | Work Group 4 (WG4) - Post-Market | Work Group 4 (WG4) |
| **1500-1530** | | **TEA BREAK** | |
| **9** | **1530-1620** | Work Group 5 (WG5) - Clinical Evidence for Performance and Safety | Work Group 5 (WG5) |
| **10** | | Work Group 7 (WG7) - Quality Management System | Work Group 7 (WG7) |
| **11** | | Work Group 8 (WG8) – Standards | Work Group 8 (WG8) |
| **12** | | Work Group 9 (WG9) – UDI & Nomenclature | Work Group 9 (WG9) |
| **13** | | Special Task Group (STG) - Common Evaluation Reliance Practice (CERP) | STG CERP |
| **14** | **1620-1630** | Q&A | |
| **15** | **1630-1650** | TC Advisors Summary Report | TC Advisory Panel |
| **16** | **1650-1700** | Closing Remarks for Day 3 | Ms. Miang Tanakasemsub<br>GHWP TC Co-chair (Industry)<br>Head of Regulatory Affairs, Asia Pacific Johnson & Johnson Vision, Thailand |
| **17** | **1700** | **Adjourn** | |
| **END OF DAY 3** | | | |
| **1800** | | **Gala Dinner** | |

# Day 4 Agenda: 12th Dec 2024

## Venue: Kuala Lumpur Convention Centre

| ITEMS | TIME | 28th GHWP Annual Meeting (Main Meeting) | |
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| 1 | 0855-0900 | Announcement by MC (5mins) | Moderator: From Malaysia MDA (TBC) |
| 2 | 0900-0930 | Opening Ceremony (30mins)<br>- Welcome Video (5mins)<br>- Welcome Address (5mins)<br>- Opening Address (5mins)<br>- Group Photo (15mins) | Moderator: From Malaysia MDA (TBC)<br><br>Welcome Address-<br>DR. MURALITHARAN PARAMASUA<br>Chief Executive, Medical Device Authority (MDA), Ministry of Health (MoH)<br><br>Opening Address-<br>Xu Jinghe<br>GHWP Chair<br>Deputy Commissioner, NMPA, People's Republic of |
| 3 | 0930-0940 | Main Meeting<br>- Roll Call (8mins)<br>- Adoption of the Agenda (1min)<br>- Adoption of the 27th GHWP Annual Meeting Minutes (1min) | Dr. Xu Jinghe<br>GHWP Chair<br>Deputy Commissioner, NMPA, People's Republic of China<br><br>Mr. Bryan SO<br>GHWP Executive Secretary General<br>Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China |

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| 4 | 0940-1025 | GHWP Status Reports: (45mins)<br>a) GHWP Overall Status Report (10mins + 5mins Q&A)<br>b) GHWP Technical Committee Status Report (10mins + 5mins Q&A)<br>c) GHWP Academy Status Report (10mins + 5 mins Q&A) | Dr. Xu Jinghe<br>GHWP Chair<br>Deputy Commissioner, NMPA, People's Republic of China<br><br>Dr. Mohammed Majrashi<br>Acting GHWP TC Chair<br>Executive Director, Surveillance and Biometric, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia |
| 5 | 1025-1110 | International Organizations & Harmonization Efforts (10mins+5mins Q&A each)<br>a) WHO<br>b) IMDRF<br>c) African Medical Devices Forum (AMDF) | a) Mr. SILLO, Hiiti Baran<br>Unit Head, Regulation and Safety,<br>Department of Regulation and Prequalification, WHO<br><br>b) b) Dr. Miho SATO<br>Principal Coordinator of Pharmaceuticals and Medical Devices Agency PMDA, Japan<br><br>c) MS. Paulyne Wairimu<br>Chair, African Medical Devices Forum (AMDF) |
| 1110-1200 | | Participants can proceed to Hall 2 for the Closing Ceremony of IMDEC | |
| 1200-1300 | | LUNCH | |
| 6 | 1300-1400 | GHWP Liaison Member Updates (5mins + 5mins Q&A each)<br>a) Asia Pacific Medical Technology Association (APACMed)<br>b) Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association (DITTA)<br>c) GS1<br>d) Global Medical Devices Nomenclature Agency (GMDN Agency)<br>e) Global Medical Technology Alliance (GMTA)<br>f) Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) | a) Ms. Cindy Pelou<br>Lead for Regulatory Affairs, APACMed<br><br>b) Ms. Sunny Woo<br>Team Leader, Korea Medical Devices Industry Association, International Affairs Team, DITTA<br><br>c) Ms. Chiara Bernini<br>Senior Manager Healthcare Public Policy, GS1<br><br>d) Mrs. Chinaniso Majoni<br>Senior Nomenclature Developer and Quality Lead, Global Medical Devices Nomenclature Agency (GMDN Agency)<br><br>e) Ms. Diana Kanecka<br>Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA)<br><br>f) Ms. Sandra Ligia Gonzalez<br>Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) (Video) |

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| 7 | 1400-1530 | Country/Region Updates (5mins+5mins Q&A each)<br><br>a) Malaysia<br>b) Egypt<br>c) Indonesia<br>d) Japan | a) Dr Muralitharan Paramasuaaidahwaty m.olaybal change with Dr.murali for country updare<br>Chief Executive, MDA<br><br>b) Dr. Rania Soliman<br>General manager of general administration of medical devices, Marketing authorization<br>Egyptian Drug Authority<br><br>c) Ms. Helsy Pahlemy<br>Senior Health Administrator, Ministry of Health, Indonesia<br><br>d) Ms. Yukina Ueno<br>Deputy Director, Medical Devices Evaluation Division<br>Ministry of Health, Labour and Welfare (MHLW), Japan |
| | | e) Kingdom of Saudi Arabia<br>f) People's Republic of China<br>g) Republic of Korea | e) Eng. Abdullah Al Guriabi<br>Medical Devices Sector, SFDA, Kingdom of Saudi Arabia<br><br>f) Ms. Dong Jiangping<br>Director General, Department of Medical Device Regulation<br>NMPA, People's Republic of China<br><br>g) Dr. Seil Park<br>Assistant Director, Division of High-Tech Medical Devices, Ministry of Food and Drug Safety<br>Republic of Korea |
| 1530-1600 | | TEA BREAK | |
| 8 | 1600-1650 | Resolution and Endorsement (50mins)<br><br>1. Election and Endorsement of the Positions<br>a) TC Chair<br>b) WG5 Chair<br>c) WG8 Chair<br>d) STG (CERP) Chair* [Conversion of STG to WG TBC ]<br>e) STG (CERP) Co-Chair* [Conversion of STG to WG TBC ]<br><br>2. Endorsement of Amendments to TOR and House Rules, and New WG Guidance Documents<br><br>3. Endorsement of New Members (followed by short speeches)<br>a) Botswana<br>b) Ghana<br>c) Macao SAR, China<br>d) Uzbekistan<br><br>4. Endorsement of New Liaison Member (followed by short speech)<br>a) MECOMED | Mr. Xu Jinghe<br>GHWP Chair<br>Deputy Commissioner, NMPA, People's Republic of China<br><br>Mr. Bryan SO<br>GHWP Executive Secretary General<br>Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China<br><br>3. New Members<br>a) Mr. Batlegang Dallas Mosweu<br>Manager, Medical Devices, Botswana Medicines Regulatory Authority (BOMRA), Botswana<br><br>b) Mr. Emmanuel Nkrumah<br>Director, Medical Devices, Cosmetics and Household Chemicals Directorate, Food and Drugs Authority (FDA), Ghana<br><br>c) Mr. CHAN Tak In<br>Chief, Division of Chemical Medicines and Devices, |

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| | | | Pharmaceutical Administration Bureau, Macao SAR, China<br><br>d) Mr. Alisher Temirov<br>Director, The Center for Pharmaceutical Products Safety, Uzbekistan<br><br>4. Ms. Rana Chalhoub |
| 9 | 1650-1655 | Announcement of the next GHWP Annual Meeting Host & Short Speech (5mins) | Mr. Xu Jinghe<br>GHWP Chair<br>Deputy Commissioner, NMPA, People's Republic of China<br><br>Mr. Bryan SO<br>GHWP Executive Secretary General<br>Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China |
| 10 | 1655-1700 | Closing Remarks (5mins) | Dr. Xu Jinghe<br>GHWP Chair<br>Deputy Commissioner, NMPA, People's Republic of China |
| 11 | 1700 | Adjourn | |
| **END OF DAY 4** | | | |
| **GHWP ASL Annual General Meeting<br>(1730-1800 at another meeting room)** | | | |