Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP

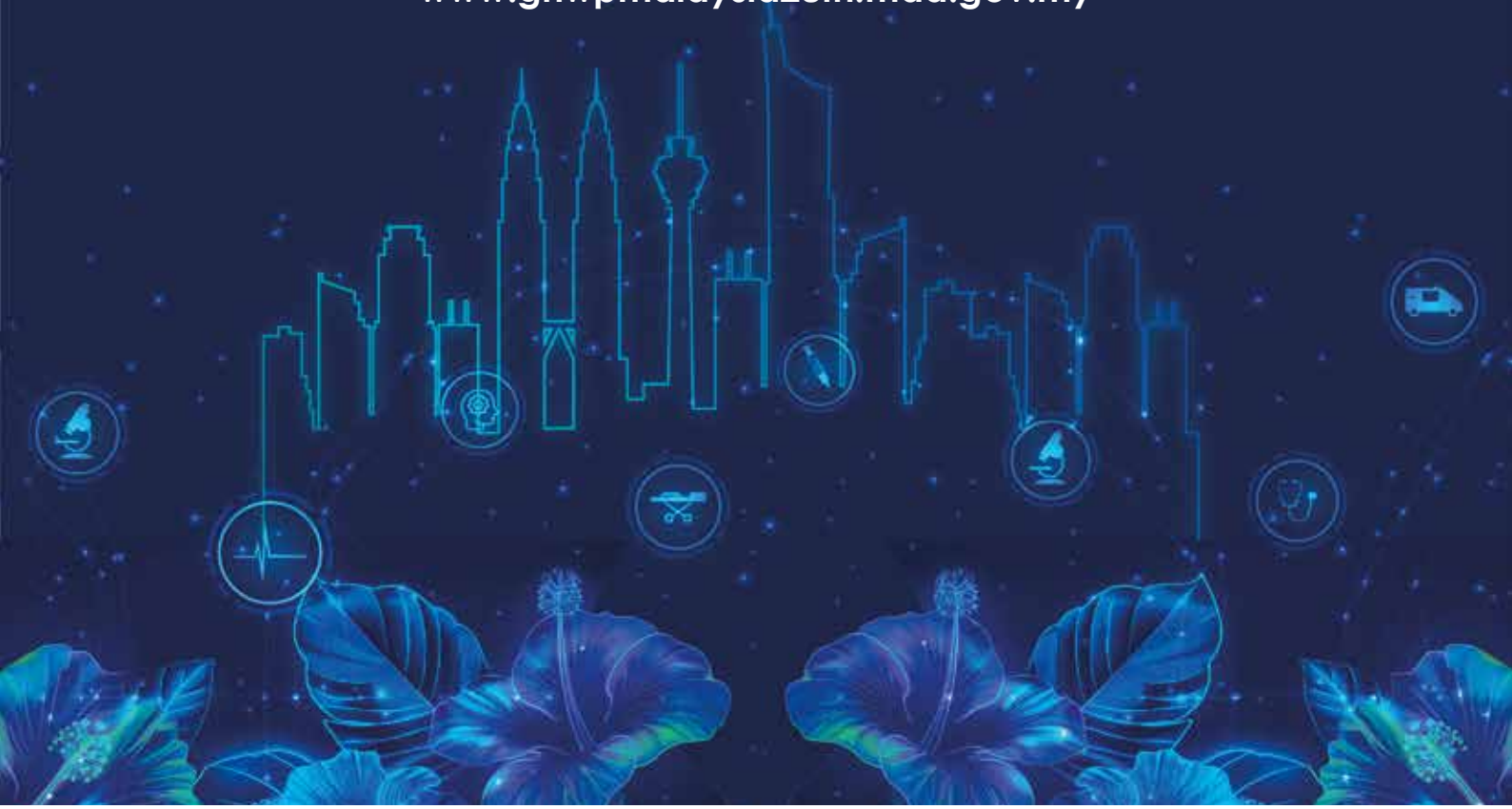
28TH GHWP ANNUAL MEETING AND TECHNICAL COMMITTEE MEETING

9-12 Dec 2024

Kuala Lumpur Convention Centre, Malaysia

PROGRAMME BOOK

www.ghwpmalaysia28th.mda.gov.my



Organised by :

Medical Device Authority Malaysia

KEMENTERIAN KESIHATAN MALAYSIA

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ABOUT GHWP

Global Harmonization Working Party (GHWP) is a non-profit organization involving the participation of medical device regulatory authorities and industry representatives across the globe. Its predecessor was the Asian Harmonization Working Party (AHWP) predominated by Asian countries and regions. With the growing number of members and increasing global impact, AHWP had transformed from an Asian organization into an international organization. In 2021, it was renamed as the GHWP, with the aim to promote global medical device regulation toward greater convergence, harmonization and reliance. It has now expanded its membership to 34 countries and regions, from Asia to the North and South Americas as well as Africa. To work in collaboration with related international organizations such as IMDRF, WHO, ISO, and IEC. Through the dialogue and communication between medical device regulatory authorities and the industry, it works towards the continuous promotion of high-quality development in global medical device regulation and industry.

EVENT HIGHLIGHTS

In conjunction with International Medical Device Exhibition & Conference (IMDEC) 2024 from 10 - 12 December 2024

Closing Ceremony, presided over by YAB Dato' Seri Anwar Ibrahim, Prime Minister of Malaysia

Inaugural ceremony by YB Datuk Seri Dr. Dzulkefly Ahmad, Minister of Health, Malaysia. Let's shape the future of medical device regulation together!

Stay up-to-date with the most recent insights and updates, where regulatory excellence and industry expertise are at the forefront

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Capacity Building Topics for 2024:

- Global Regulatory Partners (GRP) & Good Submission Practice
- Clinical Evidence & Real-world Evidence
- Cybersecurity in Medical Device
- Innovative Medical Devices Approval Pathway
- Orphan Medical Device Challenges
- Post-Market Surveillance (PMS) for Medical Devices
- Risk Management in Innovative Devices
- Regulatory Convergence & Reliance

*Please note that the above programs may be subject to change

CONFERENCE SCHEDULE

DAY 1 / 09 DEC MONDAY

THEME REGULATORY EXCELLENCE/ BEST REGULATORY PRACTICES

9:15 - 9:30AM
Welcome address by
GHWP Vice Chair

REGULATORY EXCELLENCE

9:30 - 9:45AM
Introduction to Regulatory Excellence - What is Regulatory Excellence - Defining and Assessing Regulatory Excellence
Mr. Brad Spring - Global Head of Policy and Intelligence - Roche Diagnostics

9:45 - 10:00AM
How To Regulate With Excellence - Achieving Regulatory Excellence
MDA, Malaysia, Dr. Muralitharan Paramasu

10:00 - 10:15AM
Excel Regulatory Excellence in the MedTech Industry
Ms. Diana Kaneka, Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA)

10:15 - 10:30AM
Development of the Global Benchmarking Tool (GBT)
Mr. SILLO, Hiiti Baran, Unit Head, Regulation and Safety, Department of Regulation and Prequalification, WHO

10:30 - 10:50AM **TEA BREAK**

GLOBAL REGULATORY FRAMEWORK

10:50 - 11:05AM
GHWP Playbook for Implementation of Medical Device Regulatory Frameworks and support from GHWP to establish a regulatory framework
Dr. Adelheid Schneider, GHWP WG 2 Vice Chair

11:05 - 11:20AM
WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF)
Ms. Agnes Sitta Kijo, Technical Officer, WHO

11:20 - 11:35AM
IMDRF Regulatory framework
Ms. Nicole Smith, Head of Regulatory Affairs & Policy - PSQ Regulatory Affairs, Philips

11:35 - 12:05PM
Sharing best practices of implementing a national regulatory framework
Malaysia, Bahrain

- **Experience sharing on enforcing regulatory requirements to ensure continuous compliance (Malaysia)**
  Mr. Dery Akmal bin Abdul Rahman, MDA Malaysia
- **Implementing the regulatory framework in Egypt**
  Dr. Rania Ahmed, EDA

12:05 - 12:30PM
PANEL - How does an ideal regulatory framework look like?
Moderator
Ms. Miang Tanakasemsub, Head of Regulatory Affairs (RA) Asia Pacific (AP) Johnson & Johnson Vision
Panelists
Dr. Adelheid Schneider
Ms. Agnes Sitta Kijo, Malaysia
Dr. Rania Ahmed
Ms. Nicole Smith
Mr. Dery Akmal bin Abdul Rahman, MDA Malaysia
Ms. Agnes Sitta Kijo, WHO

12:30 - 13:45PM **LUNCH**

REGULATORY SKILLS AND TALENT PIPELINE

13:45 - 14:00PM	**Insights to GHWP Regulatory Competency Framework and Curriculum for Industry and Regulators** Ms. Kitty Mao, RA Director, GE Healthcare Singapore
14:00 - 14:15PM	**Regulatory Excellence Ecosystem Industry : sharing best practise to actively support growth and development of regulatory professionals** Mr. Daniel Moeland, Johnson & Johnson MedTech
14:15 - 14:30PM	**Regulatory Excellence Ecosystem Regulators : sharing best practise to actively support growth and development of regulators** Dr. Razan Asally, Head of medical evaluation section SFDA
14:30 - 14:45PM	**Conversations That Matter - Interactions with Health Authorities** Ms. Raina E. Dauria, RAC, MS, Vice President, Global Regulatory Policy and Talent, MedTech Johnson & Johnson MedTec
14:45 - 15:15PM	**PANEL - Working in regulatory affairs - Sharing tips and experiences (beginners and mature regulatory personal of Industry and Authorities)** **Moderator** Ms. Marianne Yap, Alcon **Panelists** Mr. Muhammad Sabirrin Md Zahar, MDA Ms. Jacqueline Fok, RA Manager, Alcon Mr. Daniel Moeland, JnJ Ms. Raina E.Duaria

15:15 - 15:45AM **TEA BREAK**

CLINICAL EVIDENCE & RWE

15:45 - 16:00PM	**Acceptance of clinical oversea data for Clinical Evidence versus Local Testing** Dr. Adelheid Schneider, GHWP WG 2 Vice Chair
16:00 - 16:15PM	**Best practise on Real World Evidence Usability in Device Applications** Dr. Rama Sethuraman, Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
16:15 - 16:30PM	**Evaluating the Quality of Real-World Evidence Used to Support Regulatory Decision-Making for Medical Devices** Prof. Gao, WG - 4 Advisor
16:30 - 17:00PM	**Panel on Challenges and Opportunities on Clinical Evidence using RWE** **Moderator** - Mr. Mohammed Y. Majrashi (SFDA)
17:00 - 17:15PM	**Summary Day 1** TC Chair or Co Chair, or Capacity Building respresentative

ADJOURN

END OF DAY 1

CONFERENCE SCHEDULE

DAY 2 / 10 DEC TUESDAY

THEME REGULATORY EXCELLENCE/ BEST REGULATORY PRACTICES

8:30 - 8:45AM	**GHWP Capacity Building Initatives** Ms. Quan Tran

CYBERSECURITY AND ROBOTICS

8:45 - 9:00AM	**EU AI Act** Mr. Robert Froehlich, Head of MHS ASEAN (VP), TÜV SÜD PSB Pte Ltd
9:15 - 9:30AM	**Consideration for innovative robotic assisted Surgical Devices** Mr. Sharad Shukla, Director Regulatory Affairs, Johnson & Johnson International (Singapore) Pte. Ltd
9:30 - 9:45AM	**PANEL** **Moderator** Jennefer Ramos, Head of RA Growth Region - PSQ **Panelist** Mr. Robert Froehlich (TÜV) Mr. Sharad Shukla (Johnson & Johnson)
9:45 - 10:15AM	**TEA BREAK**

LABELING AND UDI

10:15 - 10:30AM	**Key trends on digital labeling** Mr. Shekhar Nambi, Johnson & Johnson MedTech
10:30 - 10:45AM	**Update from the MEA region on Electronic Instructions for Use (EIFU)** Ms. Heba Tork, Regulatory and Quality Manager - Roche Diagnostics (Egypt)
10:45 - 11:00AM	**Regulatory perspective on elabeling** Mr. Winson Teng (BD)- APACMed
11:00 - 11:15AM	**Industry perspective on UDI - Opportunities and challenges** Ms. Yuyi from Wego Group
11:15 - 11:30AM	**The role of UDI in whole product life cycle management** Mr. Dennis Black from BD
11:30 - 11:45AM	**The role of standards** Mr. Gite Sadanand, Abbott Associate Director, Regulatory Affairs Strategic Programs
11:45 - 12:15PM	**PANEL - Benefits, opportunities and approaches on e-labeling** Dr. Petra Kaas Wiele - TC Advisor and Consultant
12:15 - 13:30PM	**LUNCH**

QMS AND PMS

13:30 - 13:45PM	**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
13:45 - 14:00AM	**Overview of QMS implementation in GHWP member economies** Ms. Annie Yin, WG7 Secretary/ Vice President, Roche Diagnostics China
14:00 - 14:10PM	**Case sharing of QMS implementation in China** Ms. Jie Zhu, Quality Manager, Mindray Bio-Medical Electronic Co. LTD
14:10 - 14:25PM	**Guidance for Audit Supplier for Medical device Manufacturers** Ms. Ning Li, Sr. Director of Q&R, Miceo-Tech
14:25 - 14:40PM	**Industry Perspective on MDSAP** Ms. Asmaa Awad, Global Head of Eastern Europe, Middle East, and Africa Regulatory Policy Roche Diagnostics ME
14:40 - 14:55PM	**Good Distribution Practices for Medical Device GDPMD** Mr. Tony Low, Director of Human Performance and Medical QA/RA Commissioning Agents International (CAI)
14:55 - 15:10PM	**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, Executive Director, Surveillance and Biometric, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia
15:10 - 15:25PM	**Fit for purpose change management - GHWP Guideline - Change Management - Industry Perspective** Ms. Cindy Pelou (APACMed)
15:25 - 15:45PM	**PANEL - The criticality of PMS and QMS in regulatory framework.** **Moderator** Mr. Raghavan Nair Mr. Asok Kumar, Abbott Quality and Regulatory, Director - Global Strategic Regulatory Affairs

15:45 - 16:15PM **TEA BREAK**

CONVERGENCE AND RELIANCE

16:15 - 16:30PM	**Common Evaluation Reliance Practice Updates** Mr. ZHANG Shiqing, STG CERP Chair
16:30 - 16:45PM	**Good Reliance Practice** Ms. Agnes Sitta Kijo, Technical Officer, WHO
16:45 - 17:00PM	**Regulatory convergence & reliance in Africa - sharing good practice** Ms. Paulyne Wairimu, Chair of the African Medical Devices Forum
17:00 - 17:15PM	**Regulatory convergence & reliance in Asia - sharing good practice - on behalf of APACMed** Ms. Yasha Huang, Roche
17:15 - 17:30PM	**Regulatory convergence & reliance in ME - sharing good practice - MEA- MECOMED** Ms. Rana Chalhoub, Regulatory Affairs Director, MECOMED
17:30 - 17:50PM	**Panel Convergence and Reliance** **Moderator** Ms. Cindy Pelou - APACMed **Panelists** Ms. Agnes Sitta Kijo (WHO) Ms. Paulyne Wairimu (AMF) Ms. Yasha Huang (Roche) Ms. Nicole Smith (Philips) Ms. Rana Chalhoub (Mecomed)
17:50 - 18:00PM	**Closing and Summary Day 2** TC Chair or Co Chair, or Capacity Building respresentative

ADJOURN

END OF DAY 2

CONFERENCE SCHEDULE

DAY 3 / 11 DEC WEDNESDAY

MORNING: CLOSED-DOOR MEETING

KUALA LUMPUR CONVENTION CENTER

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

9:00 - 12:00PM	**GHWP TC & WG Leaders Meeting with TC Advisors (Closed-Door Meeting)**

AFTERNOON: OPEN MEETING

KUALA LUMPUR CONVENTION CENTER

MODERATOR:
MS. LI JUN
GHWP TC CO-CHAIR (REGULATORY AUTHORITY)
DEPUTY DIRECTOR GENERAL, CENTER FOR MEDICAL DEVICE EVALUATION, NMPA, PEOPLE'S REPUBLIC OF CHINA

14:00 - 14:10PM	**Opening Speech** Dr. Mohammed Y Majrashi, GHWP Acting TC Chair Executive Director, S&B, SFDA, Kingdom of Saudi Arabia
14:10 - 14:15PM	**Roll call, Adoption of Agenda** Ms. LI Jun, GHWP TC Co-Chair (Regulatory Authority) Deputy Director General, Center for Medical Device Evaluation, NMPA, People's Republic of China
14:15 - 14:20PM	**Adoption of 27th GHWP TC Meeting Minutes** Ms. Miang Tanakasemsub, GHWP TC Co-chair (Industry) Head of Regulatory Affairs, Asia Pacific Johnson & Johnson Vision, Thailand
14:20 - 15:00PM	**Work Group 1 (WG1) - Pre-Market Submission and CSDT** Work Group 1 (WG1) **Work Group 2 (WG2) - Pre-market: IVDD** Work Group 2 (WG2) **Work Group 3 (WG3) - Pre-market: Software as a Medical Device** Work Group 3 (WG3) **Work Group 4 (WG4) - Post-Market** Work Group 4 (WG4)
15:00 - 15:30PM	**TEA BREAK**

15:30 - 16:20PM	**Work Group 5 (WG5) - Clinical Evidence for Performance and Safety** Work Group 5 (WG5) **Work Group 7 (WG7) - Quality Management System** Work Group 7 (WG7) **Work Group 8 (WG8) – Standards** Work Group 8 (WG8) **Work Group 9 (WG9) – UDI & Nomenclature** Work Group 9 (WG9) **Special Task Group (STG) - Common Evaluation Reliance Practice (CERP)** STG CERP
16:20 - 16:30PM	**Q&A**
16:30 - 16:50PM	**TC Advisors Summary Report** TC Advisory Panel
16:50 - 17:00PM	**Closing Remarks for Day 3** Ms. Miang Tanakasemsub, GHWP TC Co-chair (Industry) Head of Regulatory Affairs, Asia Pacific Johnson & Johnson Vision, Thailand

ADJOURN

END OF DAY 3

18:00PM	**Gala Dinner**

CONFERENCE SCHEDULE

DAY 4 / 12 DEC THURSDAY

28TH GHWP ANNUAL MEETING (MAIN MEETING)

8:55 - 9:00AM	**Announcement by MC** Moderator: From Malaysia MDA
9:00 - 9:30AM	**Opening Ceremony** Moderator: From Malaysia MDA ◆ **Welcome Video** ◆ **Welcome Address** Dr. Muralitharan Paramasua, Chief Executive, Medical Device Authority (MDA), Ministry of Health (MOH) ◆ **Opening Address** Dr. Xu Jinghe, GHWP Chair, Deputy Commissioner, NMPA, People's Republic of China ◆ **Group Photo**
9:30 - 9:40AM	**Main Meeting** ◆ **Roll Call** ◆ **Adoption of the Agenda** Dr. Xu Jinghe, GHWP Chair, Deputy Commissioner, NMPA, People's Republic of China ◆ **Adoption of the 27th GHWP Annual Meeting Minutes** Mr. Bryan SO, GHWP Executive Secretary General, Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
9:40 - 10:25AM	**GHWP Status Reports:** ◆ **GHWP Overall Status Report** Dr. Xu Jinghe, GHWP Chair, Deputy Commissioner, NMPA, People's Republic of China ◆ **GHWP Technical Committee Status Report** Dr. Mohammed Majrashi, Acting GHWP TC Chair, Executive Director, Surveillance and Biometric, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia ◆ **GHWP Academy Status Report** GHWP Academy Representative
10:25 - 11:10AM	**International Organizations & Harmonization Efforts (10mins+5mins Q&A each)** ◆ **WHO** Mr. SILLO, Hiiti Baran Unit Head, Regulation and Safety, Department of Regulation and Prequalification, WHO ◆ **IMDRF** Dr. Miho SATO, Principal Coordinator of Pharmaceuticals and Medical Devices Agency PMDA, Japan ◆ **African Medical Devices Forum (AMDF)** Ms. Paulyne Wairimu, Chair African Medical Devices Forum (AMDF)
11:10 - 12:00PM	**PARTICIPANTS CAN PROCEED TO HALL 2 FOR THE CLOSING CEREMONY OF IMDEC**
12:00 - 13:15PM	**LUNCH**

13:15 - 14:15PM

GHWP Liaison Member Updates

- **Asia Pacific Medical Technology Association (APACMed)**
  Ms. Cindy Pelou, Lead for Regulatory Affairs, APACMed
- **Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)**
  Ms. Sunny Woo, Team Leader, Korea Medical Devices Industry Association, International Affairs Team, DITTA
- **GS1**
  Ms. Chiara Bernini, Senior Manager Healthcare Public Policy, GS1
- **Global Medical Devices Nomenclature Agency (GMDN Agency)**
  Mrs. Chinaniso Majoni, Senior Nomenclature Developer and Quality Lead
  Global Medical Devices Nomenclature Agency (GMDN Agency)
- **Global Medical Technology Alliance (GMTA)**
  Ms. Diana Kanecka, Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA)
- **Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)**
  Ms. Sandra Ligia Gonzalez, Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)

14:15 - 15:25PM

Country/Region Updates

- **Malaysia**
  Dr Muralitharan Paramasua, Chief Executive, MDA
- **Egypt**
  Dr. Rania Soliman, General manager of general administration of medical devices, Marketing authorization Egyptian Drug Authority
- **Indonesia**
  Ms. Helsy Pahlemy, Senior Health Administrator, Ministry of Health, Indonesia
- **Japan**
  Ms. Yukina Ueno, Deputy Director, Medical Devices Evaluation Division, Ministry of Health, Labour and Welfare (MHLW), Japan
- **Kingdom of Saudi Arabia**
  Eng. Abdullah Al Guriabi, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
- **People's Republic of China**
  Ms. Dong Jiangping, Director General, Department of Medical Device Regulation NMPA, People's Republic of China
- **Republic of Korea**
  Dr. Seil Park, Assistant Director, Division of High-Tech Medical Devices Ministry of Food and Drug Safety, Republic of Korea

15:25 - 16:00PM **TEA BREAK**

16:00 - 16:50PM

Resolution and Endorsement

1. Election and Endorsement of the Positions
Mr. Xu Jinghe, GHWP Chair, Deputy Commissioner, NMPA, People's Republic of China

a. TC Chair
b. WG5 Chair
c. WG8 Chair
d. STG (CERP) Chair*
e. STG (CERP) Co-Chair*

2. Endorsement of Guidance Documents from Working Groups (WG)
Mr. Bryan SO, GHWP Executive Secretary General, Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong SAR, China

3. Endorsement of New Members

a. Botswana
Mr. Batlegang Dallas Mosweu, Manager, Medical Devices, Botswana Medicines Regulatory Authority (BOMRA), Botswana

b. Ghana
Mr. Emmanuel Nkrumah, Director, Medical Devices, Cosmetics and Household Chemicals Directorate, Food and Drugs Authority (FDA), Ghana

c. Macao SAR, China
Mr. CHAN Tak In, Chief, Division of Chemical Medicines and Devices, Pharmaceutical Administration Bureau, Macao SAR, China

d. Uzbekistan
Mr. Alisher Temirov, Director, The Center for Pharmaceutical Products Safety, Uzbekistan

4. Endorsement of New Liaison Member (followed by short speech)

a. MECOMED
Ms. Rana Chalhoub, Regulatory Affairs Director MECOMED

16:50 - 16:55 PM

Announcement of the next GHWP Annual Meeting Host & Short Speech
Mr. Xu Jinghe, GHWP Chair, Deputy Commissioner, NMPA, People's Republic of China

Mr. Bryan SO, GHWP Executive Secretary General
Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China

16:55 - 17:00PM

Closing Remarks
Dr. Xu Jinghe, GHWP Chair, Deputy Commissioner, NMPA, People's Republic of China

17:00PM **ADJOURN**

END OF DAY 4

GHWP ASL ANNUAL GENERAL MEETING (17:30-18:00PM AT ANOTHER MEETING ROOM)

Johnson & Johnson
MedTech


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ADVANCING SCIENCE FOR LIFE
Hot Axios
Hot Axios Stent and Electrocautery-Enhanced Delivery System
SENTINEL
Sentinel Cerebral Protection System
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FARAWAVE Pulsed Field Ablation Catheter
FARASTAR Pulsed Field Ablation Generator System
SpyGlass DS
SpyGlass DS Digital Controller
SpyScope DS
SpyScope DS Access and Delivery Catheter
HeartLogic
HeartLogic Heart Failure Diagnostic
Eluvia
ELUVIA OVER-THE-WIRE Drug-Eluting Vascular Stent System
SpaceOAR
SpaceOAR System
VersaCross
VersaCross Access Solutions


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Professional Rapid Diagnosis & Chronic Disease Management Solution
6
R&D Centers
20+
Subsidiaries
150+
Countries/Regions
3000+
Employees
Since 1992
Immunofluorescence
Molecular Diagnostics
HPLC Hemoglobin
Electrochemistry
Pathology
Colloidal Gold
Chemiluminescence
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ISO13485 Certificate of Medical Device Quality Management System Certification in 2018
ISO9001 Certificate of Quality Management System Certification in 2017
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COMPANY PROFILE
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SPECIALTY
Pharmacy
Medical Devices
LANGUAGES (PARTLYLISTED)
English
French
German
Spanish
Portuguese
Japanese
Korean


玮沐医疗
WEIMU MEDICAL
WeilliSpheres®聚乙烯醇栓塞微球
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适用于富血管型器官肿瘤及增生性疾病的栓塞治疗
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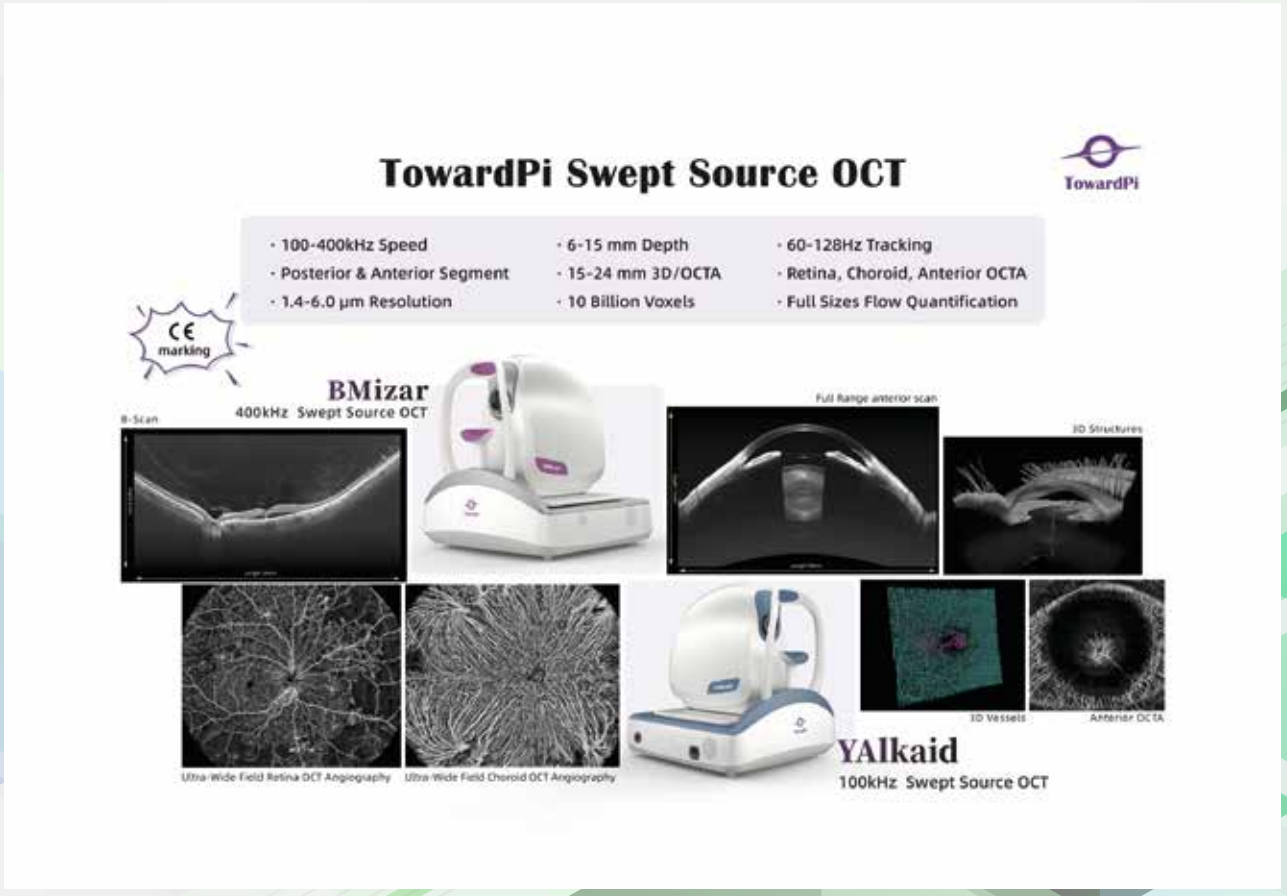
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TowardPi
· 100-400kHz Speed
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· 60-128Hz Tracking
· Posterior & Anterior Segment
· 15-24 mm 3D/OCTA
· Retina, Choroid, Anterior OCTA
· 1.4-6.0 μm Resolution
· 10 Billion Voxels
· Full Sizes Flow Quantification
CE marking
BMizar
400kHz Swept Source OCT
B-Scan
Full Range anterior scan
3D Structures
Ultra-Wide Field Retina OCT Angiography
Ultra-Wide Field Choroid OCT Angiography
3D Vessels
Anterior OCTA
YAlkaid
100kHz Swept Source OCT

Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP

In Conjunction with :

MDEC KUALA LUMPUR

INTERNATIONAL MEDICAL DEVICE EXHIBITION & CONFERENCE 2024

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Medical Device Authority Malaysia

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Malaysia Convention & Exhibition Bureau

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