



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

GHWP Capacity Building

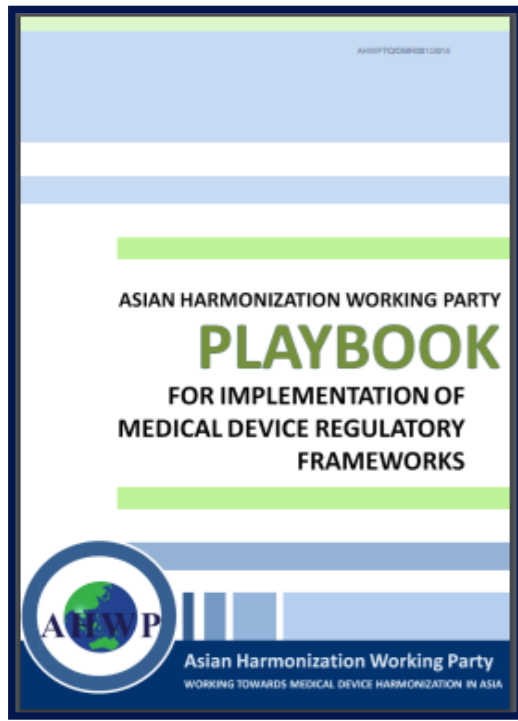
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GHWP Strategic Advisory Board member
VP, QARA, Baxter Healthcare, APAC & GEM

10 December 2024

GHWP Capacity Building Journey

--Enhancing Regulatory Agencies and Industries



Competency Framework for Medical Technology Regulators



White Paper Webinar



Thailand in-country regulator training – 35 participants



- Trainings
- Webinars
- Seminars
- Webinar curriculum whitepaper



- Setup of GHWP (Guangzhou) Academy
 - ✓ 2 training completed (total > 600 participants)
- TC WG – CB training partnership
 - ✓ 7 TC WG trainings (Total >300 participants focus on GHWP current guidelines)
 - ✓ Training event recording and/or presentation to be posted on GHWP website

2014-2017

2018-2019

2020-2023

2024



Proactively Address evolving regulatory competencies required for the global professionals

1

Make complex and evolving regulatory developments accessible to regulatory professionals

3

Build a business eco system that ensure sustainability

5

Deliver valuable and accessible professional learning and development experiences

2

Empower a community focused on interactions, collaboration, relationships and knowledge sharing

4



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Guangzhou Training Academy

Inaugural GZ Academy Training

Training Theme: Innovative Medical Devices Embrace the World

Participants: over 300 of medical device regulators & industry from 12 member countries and regions, 5 international organizations and representatives of medical device manufacturers participated

Time : June. 27th, 2024 to June 31st , 2024 (5 days)

Training Methods : face-to-face teaching / group discussion / Q&A / Case Study / Onsite Practical Training / Interactive Communication

Topics:

1. GHWP Promotes Global Medical Device Regulatory Convergence, Harmonization and Reliance
2. Innovative Trends Shaping the Future of Medical Device Industry
3. A series of Training on the Premarket Regulatory Framework of Medical Device in the Work
4. Onsite Training at Innovative Medical Device Enterprises in Guangdong
5. Case sharing: Going Global with Innovative Medical Device



创新医疗器械走向世界:首期GHWP(广州)学院培训合影
Innovative Medical Devices Embrace the World: The 1st GHWP (Guangzhou) Academy Training



- 2024 inaugural training successfully held
- Onsite training methods is established
- Closely cooperation with international organizations and regulators

2nd GZ Academy Training

Training Theme: Innovative Medical Devices Promotes Global Public Health

Participants: over 330 regulators and industry

Time : 24-26th, Nov. 2024 (3 days)

Training Methods : This training combine lectures, panel discussions, Q&A sessions, case studies, hands-on training.

Based on the needs collected by the GHWP (Guangzhou) Academy, five major training topics (Symposia) will be set, along with one hands-on training session, totaling 24 academic hours over three days. Each topic will include lectures and panel discussions.

Topics:

1. GHWP Promotion of Global Medical Device Regulatory Convergence and harmonization
2. Regulatory Requirements and Common Issues for Active Medical Devices
3. Innovation and regulatory development in the Medical Device
4. Innovation and regulatory development in the Medical Imaging and Therapeutic Equipment
5. Innovation and Regulatory development in the Artificial Intelligence and digital health





2025 Focus

- Enhanced Curriculum
- Continue to leverage GZ Academy to support training needs in Asia
- In country training in Africa & Middle East regions:
 - ❖ Focus on GHWP guidelines, adhering to GHWP training curriculum white paper and AHWP/GHWP playbook for countries developing new regulations
- Online training

Appreciation & Recognition



Asally Razan



Adelheid Schneider



Li Jun



Mike Flood



Kitty Mao



Huang Chrissy



Elizabeth CHAN



Man Kit Bryan So
CB co-lead



Yap Marianne



Yan Jing

Capacity Building Group Members



Special memory of Late Mrs. Salbiah BT Yaakop

I have the privileged to work with Salbiah , who has contributed much through her role as GHWP TC Chair and Head of Training in our GHWP Capacity Building group for many years. We will miss her dearly.

Capacity Building Group Members

