

# GHWP Capacity Building Status Report

By Tran Quan

GHWP Strategic Advisory Board member

GHWP Capacity Building Lead

4 Dec 2025

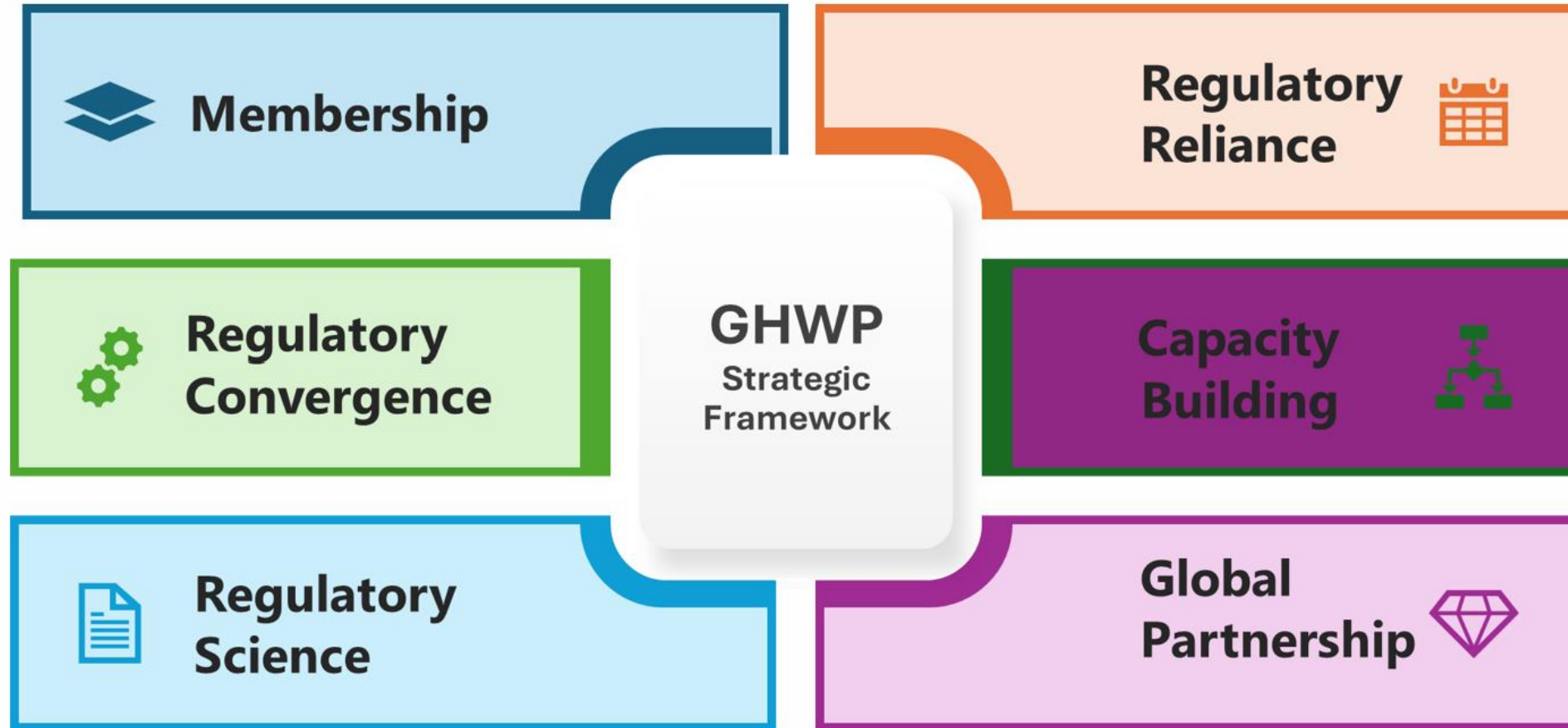


**Global Harmonization Working Party**

GHWP

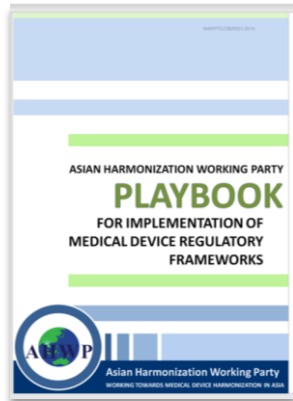
Towards Medical Device Harmonization

# GHWP Strategic Framework | Capacity Building



# GHWP Training Curriculum

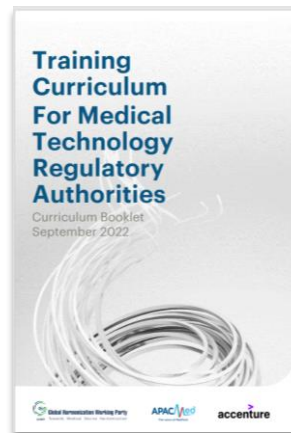
2014



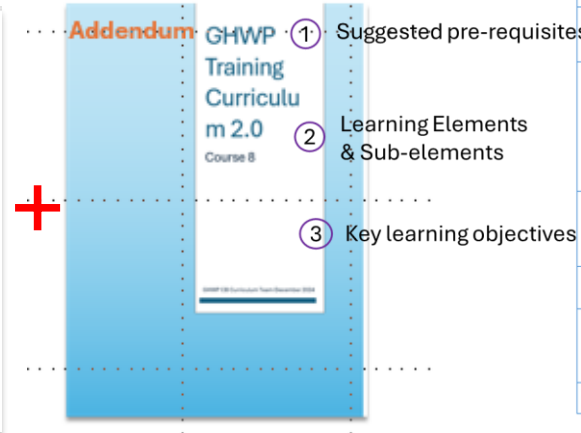
2018 - 2021



2022



2023 - 2025  
(Development)



2026

- Collect Feedback
- Enhance
- Keep it current

Core Topic Group	Subject/Topic
Course 8: Regulatory Principles	The Conformity Assessment Concepts and Principles
<b>Suggested pre-requisites</b>	
<ul style="list-style-type: none"> <li>The GHWP global regulatory Model</li> <li>Establishment and implementation of a Quality Management System</li> <li>Essential principles</li> </ul>	
<b>Learning Elements &amp; Sub-elements</b>	
<ul style="list-style-type: none"> <li>Linkages of device classification to conformity assessment</li> <li>Conformity assessment for the different classifications of medical devices</li> <li>The role of –                             <ul style="list-style-type: none"> <li>the manufacturer in applying a conformity assessment procedure</li> <li>the CAB in assessing the correct application, by the manufacturer of a conformity assessment procedure</li> </ul> </li> <li>Assessment of the QMS</li> <li>Design &amp; production QMS v/s production only QMS</li> <li>Assessment of device safety and performance – the role of the CSDT</li> <li>The Declaration of Conformity</li> </ul>	
<b>Key learning objectives</b>	
<ul style="list-style-type: none"> <li>Understanding of the linkage between classification and allowable Conformity Assessment processes</li> <li>Knowledge to allow assessment of the application, by a manufacturer, of an appropriate conformity assessment process</li> </ul>	
<b>Practical Exercises</b>	
By examples through training documents	
<b>Reference material</b>	
GHTF/SG1/N78:2012 – Principles of conformity assessment for medical devices GHTF/SG1/N046:2008- Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	
<b>Assessment</b>	<b>Duration</b>
Multiple choice questionnaire	0.5 hours

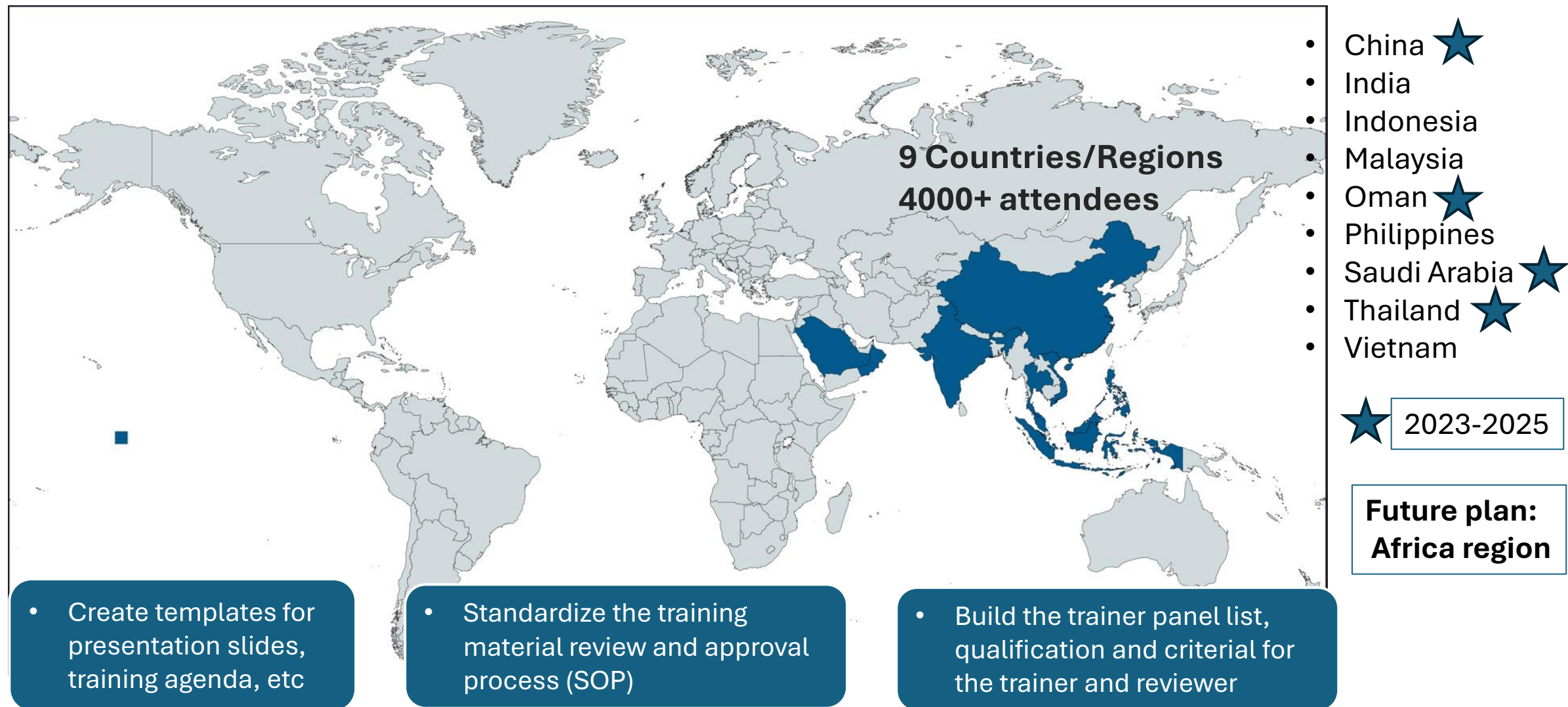
- 4 Practical Exercises
- 5 Reference material
- 6 Assessment

- Difference between Pharmaceuticals, General MDs and IVDs
- Combination & Borderline Products
- Risk Classification
- Essential Principles of Safety and Performance
- Device Nomenclature
- Device Labelling & Unique Device Identifier

- Conformity Assessment Concepts and Principles
- Post-marketing Surveillance System
- Supply Chain Integrity
- Local Standards
- International Standards

Course 8

# Capacity Building | Training Footprint



# GHWP Innovative Medical Device Symposium

The 1st GHWP  
Innovative Medical  
Device Symposium

April 2024

The 2nd GHWP  
Innovative Medical  
Device Symposium > 200 Participants

April 2025





# Capacity Building | Training Academy

- Core capacity-building initiatives with the aim of accelerating the convergence, harmonization, and reliance of global medical device regulation.
- Established the First GHWP Training Academy in China in partnership with South China University of Technology
- Successfully held 4 sessions in 2024 -2025
- Continue to expand academy in member countries/regions.



# Acknowledgement

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Asally Razan



Adelheid  
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Yap Marianne



Yan Jing



Man Kit Bryan So



Ծնորհակալություն

Teşekkür ederim

Terima kasih

Merci

ขอบคุณ

Gratiam ago

Cảm ơn

Grazie

धन्यवाद।

شكراً

Спасибо

நன்றி

Mulțumesc

多謝

To-siā

Danke

धन्यवाद।

Asante

Děkuji

Ďakujem

Dankie

nanri Köszönöm

Tak

Gràcies

Thank

Tack

you

唔該

Dankon

謝謝

Hvala

Takk

dhanyavaad

Diolch

Kiitos

谢谢

Faleminderit

감사합니다

Obrigado

Paldies

Bedankt

ありがとう

Dziękujemy

Mèsi

Ви

благодарам

Gracias

Lóo-lát

Σας ευχαριστούμε