



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Insight to Regulatory Competency and Curriculum

Kitty Mao

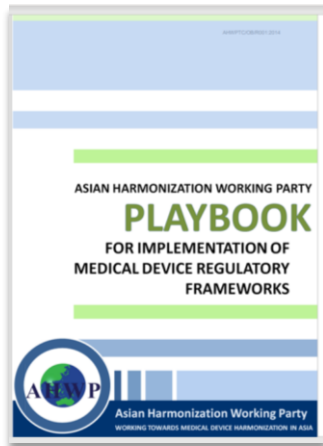
GHWP WG4 – Co-Chair

GHWP Capacity Building Curriculum – Co-Lead

ANZ, Korea & ASEAN GE HealthCare

Journey to the GHWP Training Curriculum

2014
Playbook



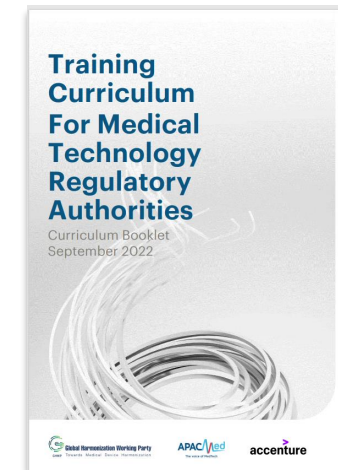
Chapter 5: Manpower
“Prospective staff with medical or scientific qualifications may, at present, be easier to find than staff with prior regulatory expertise...As such, training programs may need to be established...to educate new staff on basic regulatory science, the current regulatory framework...and a fundamental understanding of the legal framework...”

2018 - 2021
Competency Framework
& Workshop



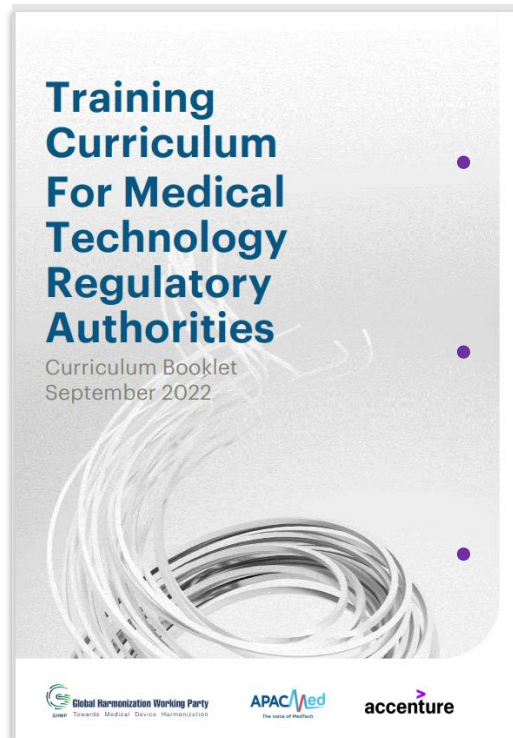
As part of the curriculum development exercise, an initial workshop with MedTech regulators was conducted where different jurisdictions including Chinese Taipei, Malaysia, South Korea, Indonesia, China, Hong Kong SAR, Kyrgyzstan, Saudi Arabia, Jordan and Pakistan participated. Findings from that workshop were further evaluated through a survey that was designed to gather additional insights from more regulatory authorities such as Singapore, State of Kuwait, Sultanate of Oman and Thailand.

2022
Training Curriculum





Training Curriculum | Category



- **Foundational Competencies**
- **General Technical Competencies**
- **Functional Technical Competencies**

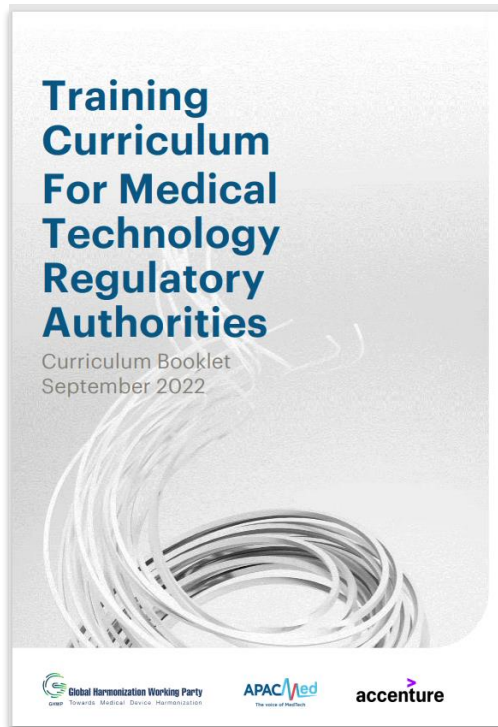


- Basic essential competencies - regarded as universal for regulators in different economies



- Additional core competencies - depending on local regulatory requirements

Training Curriculum | Domain and Modules



Competency	Domains (Courses)	Modules
Foundational	6 domains: Legal, Communication, Multisector Partnership, Industry Insight, Operations, Management	42
General Technical	2 domains: Scientific & Engineering Principles, Regulatory Principles	21
Functional Technical	6 domains: Post-market, Distribution Control, Manufacturing Control, Good Laboratory Testing, Clinical Oversight	35
Total Modules:		98



Training Curriculum | Course Details

Course 1: Legal Competency: Foundational						Course 8: Regulatory Principles Competency: General Technical						Course 9: Pre-Market Competency: Functional Technical							
Domain: Legal Competency mapping (Knowledge/skills/behaviors)						Domain: Regulatory Principles Competency mapping (Knowledge/skills/behaviors)						Domain: Pre-Market Competency mapping (Knowledge/skills/behaviors)							
<ul style="list-style-type: none"> Legal Documents (Local & International) Technical Documents (Local & International) 		<ul style="list-style-type: none"> Legislative Process Legal Writing 				<ul style="list-style-type: none"> Differences between Pharmaceuticals, General MDs and IVDs Combination & Borderline Products Risk Classification Essential Principles of Safety & Performance 		<ul style="list-style-type: none"> Device Nomenclature Device Labeling & Unique Device Identifier Conformity Assessment Concepts and Principles Post-marketing Surveillance System 		<ul style="list-style-type: none"> Supply Chain Integrity Local Standards International Standards 				<ul style="list-style-type: none"> International Medical Device Requirements Device Registration Grouping Principles Submission Dossier Format and Content 		<ul style="list-style-type: none"> Declaration of Conformity Requirements General Device Safety and performance 			
Module	Outline	Delivery Mode	Duration	Professional Level		Module	Outline	Delivery Mode	Duration	Professional Level		Module	Outline	Delivery Mode	Duration	Professional Level			
Legal Documents (Local & International)	In-depth local & international legal document requirements pertaining to medical devices	Interactive workshop	8 hours	All levels		Differences between Pharmaceuticals, General MDs and IVD	Provide definition of different Pharmaceuticals, General MDs and IVDs Case studies and determination of products	Webinar	1 hour	All levels		International Medical Device Requirements	MDRF Regulatory Framework MDRF Risk based Classification System MDRF Conformity Assessment System MDRF Dossier requirement - Regulatory Product Submission (RPS) structure	Webinar	2 hours	Intermediate			
Technical Documents (Local & International)	Technical documentation requirements as specified in the local/ regional and global regulations Interpret the applicable regulations & different standards in relation to the technical documentation to comply with conformance	Webinar	8 hours	All levels		Combination & Borderline products	The Manual on Borderline and Classification Definition of medical device combination products How to regulate a combination product with characteristics of a medical device and a drug Special medical devices (cosmetic/aesthetic devices) Examples cases of borderline products and their correct classification	Webinar	2 hours	Beginner & Intermediate		Device Grouping	Guidance on grouping of Medical Devices for product registration General grouping criteria Sharing best practices through case studies	Interactive workshop	4 hours	Beginner			
Legislative Process	Overview of legislative process flow for respective APAC markets, regulating medical devices, IVDs and new technologies Aspects of the preparation process and promulgation of legislation	Webinar	4 hours	All levels		Risk Classification	General classification system (MDRF and AMDD) Risk based classification scheme Classification Rules Case Studies	Interactive workshop	2 hours	Beginner & Intermediate		Submission Dossier Format and Content	Understand submission template (MDRF RPS & CSOT) for all products classes for both MDD & IVD	Webinar	2 hours	Beginner			
Legal Writing	Overview of basic elements of legal arguments and legal writing, using case studies Introduction to legal research and how to interpret basic legal text	Interactive workshop	4 hours	All levels		Risk Classification IVD Medical Devices	General IVD classification system (MDRF and AMDD) Risk based IVD classification scheme Classification Rules Research use only products Case Studies	Interactive workshop	2 hours	Beginner & Intermediate		Declaration of Conformity Requirements	Role of Declaration of conformity requirements and template	Webinar	1 hour	Beginner & Intermediate			
						Conformity Assessment & Essential Principles (Medical Devices)	Conformity Assessment Elements MDs Conformity Assessment System MDs Declaration of Conformity General Essential Principles MDs Case Studies	Interactive workshop	2 hours	Beginner & Intermediate		Device Safety and Performance	Understand the safety of Medical Devices, based on Pre-Market evaluation, assessment, and analysis of clinical data to verify clinical safety and performance when used as intended by the manufacturer	Webinar	1 Day	Beginner			

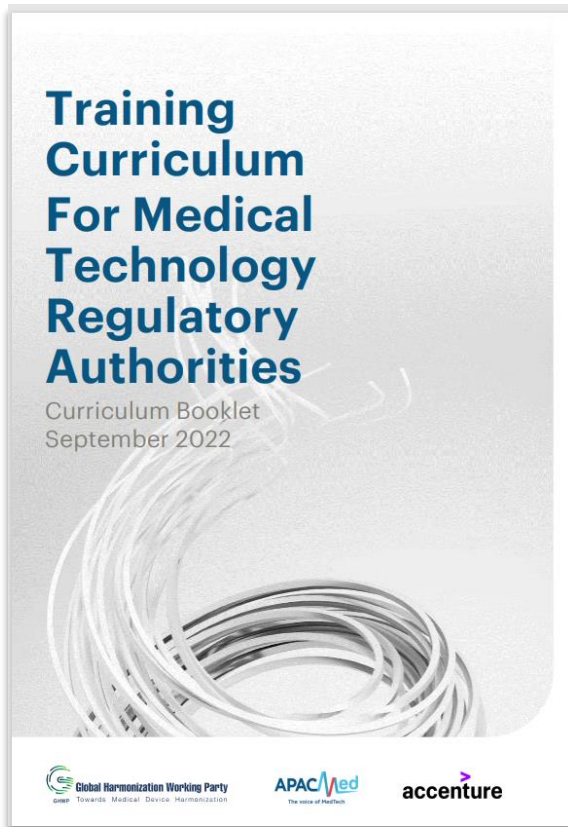
Delivery mode

Duration

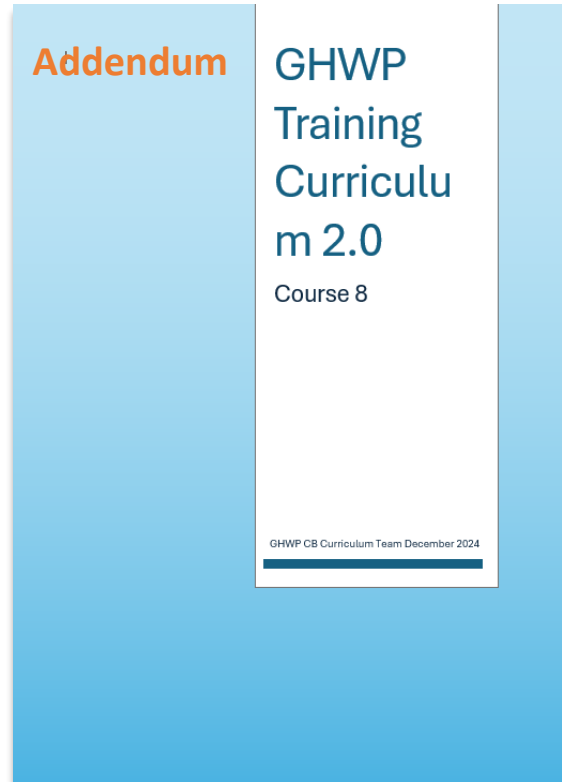
Professional Level



What's the Next ...



+



Addendum to 2022 Training Curriculum

- Enhance the training process
- Define the outline for each module
- Currently course 8 addendum has been completed ... on-track for release soon ... Stay tuned!



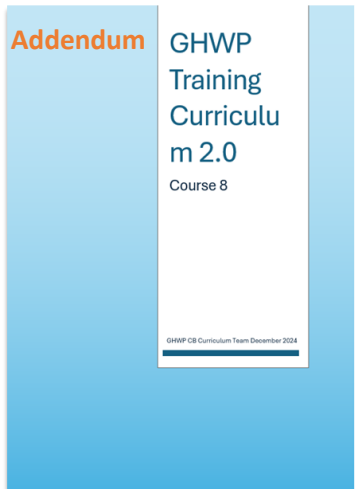
Training Curriculum | Course 8

- 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



Training Curriculum 2024 | Course 8

Sneak Preview



1 Suggested pre-requisites

2 Learning Elements & Sub-elements

3 Key learning objectives

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

4 Practical Exercises

5 Reference material

6 Assessment



Conclusion

- The GHWP Competency Framework and Training Curriculum provide the necessary knowledge and structure to enhance MedTech regulators and industries' competencies.
- A standardized, harmonized training framework and detailed course outline are key developments.
- The curriculum will continue to expand and improve over time.
- Stakeholder feedback is encouraged to ensure the ongoing success of this process.
- Collaboration is essential for the continued refinement and effectiveness of the curriculum.



Thanks to ALL who Contributed to the GHWP Training Curriculum!

GHWP Capacity Building Lead
GHWP SAB Member

Tran Quan, Baxter

GHWP Capacity Building Co-Lead
GHWP Executive Secretary General

Bryan So

GHWP Capacity Building Training
Academy Group Lead

Asally Razan, Saudi FDA

GHWP Capacity Building Training
Academy Group Co-Lead

S. Adelheid

Ex-GHWP Panel Group Lead

*Remembering Salbia
Yaakop*

GHWP Panel Group Co-Lead

Mike Flood, Locus

GHWP Capacity Building
Curriculum Group Lead
GHWP TC Co-Chair

Li Jun, China NMPA

GHWP TC Co-Chair

Miang Tanakasemsub, J&J Vision

GHWP Capacity Building
Curriculum Group Co-Lead
GHWP WG4 Co-Chair

Kitty Mao, GE HealthCare

GHWP Secretariat

Elizabeth Chan

GHWP WG4 Member

Elva Shang, Allergan

APAC Med

Huang YaSha, Roche, and APAC
Med Team



感谢

Баярлалаа

شكريه

Salamat

Asante

감사합니다

Dankie

Asante sana

Cảm ơn bạn

Maita basa

Thank you

អរគុណ

Gracias

شكراً

ありがとうございます

Рақмем

Paxmam

ຂອບໃຈ

ขอบคุณ

Email Address: Kitty.mao@gehealthcare.com