GHWP Capacity Building

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Baxter Healthcare (Asia)
14 February 2023

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

Our Capacity Building Journey - Regulatory Agencies and Industries

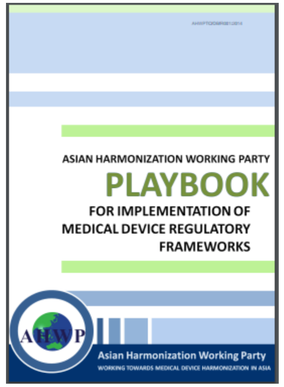
Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

10 in-country Capacity Building training /Workshop - ongoing focus on new technology & regulatory trends

- 6 Hybrid Trainings
- Webinars Curriculum whitepaper
- Capacity Building workshop

- Plan, Implement & roll-out
- Content development & curation
- Learning platform setup
- Setup of training hubs
- Launch GHWP academy and certification

2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

BỘ Y TẾ MINISTRY OF HEALTH

MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN

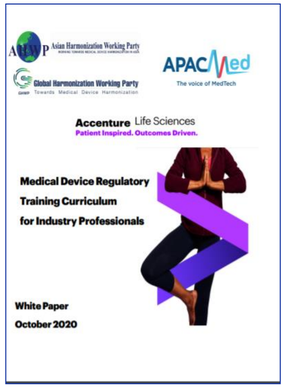
Medical Device Authority Ministry of Health Malaysia

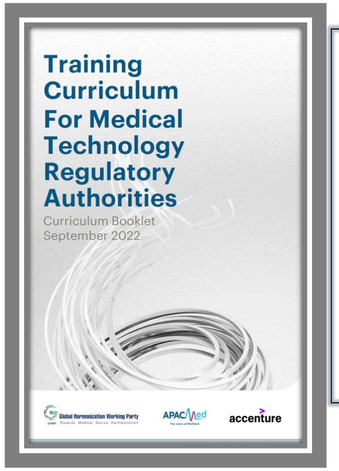
สำนักงานคณะกรรมการอาหารและยา Food and Drug Administration

FDA Food and Drug Administration PHILIPPINES

Government of India Ministry of Health & Family Welfare Department of Health & Family Welfare

AHWP-APACMed Competency Framework for Medical Technology Regulators





- Webinar on Training Curriculum for Medical Technology Regulatory authorities – well attended by 50+ regulators from multiple jurisdictions

Mission

Be the reliable training partners for global regulatory workforce in the journey towards Global Harmonization Working Party's vision

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

GHWP Capacity Building Strategies

1. Proactively **address evolving regulatory competencies** required for global professionals
2. Deliver exigent and cardinal **professional learning experiences**
3. Make complex and evolving regulatory developments **accessible to regulatory professionals**
4. **Empower a community** focused on interactions, collaboration and knowledge sharing
5. Build **partnership** that ensures operation and financial sustainability

GHWP Capacity Building Structure

GHWP Chair
Ali Al Dalaan, Saudi FDA

CB Advisor
Jiang Deyuan (ex-NMPA, China)
Lee Jeong Rim (MFDS, Korea)

CB Lead/Co-Lead
Tran Quan/Bryan So

TC Chair & Co-chair

Operation Head

Training Hub Head
Asally Razan, Saudi FDA

Training Panel Head
Salbiah Yaakop, MDA

Curriculum Head
Li Jun, NMPA, China

Online Academy Platform (outsourced)

Supported by GHWP Secretariat

Deputy Head
S. Adelheid

Deputy Head
TBC

Deputy Head
Kitty Mao

REGIONAL TRAINING HUBS
TBC - ASIA, MIDDLE EAST, AMERICAS, AFRICA

Training Panel

Task Force Team -SME

TRAINING PARTNERS (TBC)
APACMed, DITTA, ASEAN Medical Device Planning Committee, RAPS

Note:
- Head roles can be filled by current work group personnel.
- Teams can be expanded to include Deputy Head.

GHWP Capacity Building Team's Role

CB Lead/Co-Lead

- Develop **Capacity Building strategy and roadmap** in alignment with GHWP strategy, vision and mission
- Build **sustainable funding**
- Plan and oversee Capacity Building program development and implementation

Operation

- Maintain up to date training master plan & calendar
- Facilitate scheduling of training and logistics
- Manage course registration
- Manage member communication
- Budget control
- Issuance of certification

Training Hub

- Manage **Training Hubs**
- Select and establish training partners
- Manage Training Partners
- Conduct in-country/online training workshops

Training Panel

- Establish **Training Panel**
- Develop and manage **training resources** & **content** to meet the approved curriculum and training objectives
- Source and recruit trainers and speakers
- Create and maintain KPIs for trainers
- Develop and conduct **assessment of the effectiveness of training program, trainers and training partners**

Curriculum

- Identify training needs for members
- Plan and develop **up-to-date capacity building curriculum** for GHWP
- Plan and develop training curriculum for regulatory authorities / Industry across the globe
- Adapt and localize the curriculum to be country specific

GHWP ACADEMY

FACE-TO-FACE PROGRAMS @ TRAINING HUB

Workshops

Seminars

Certification Courses (With Assessment Component)

ONLINE PROGRAMS @ ONLINE ACADEMY

Real-Time /Live

Workshops

Webinars

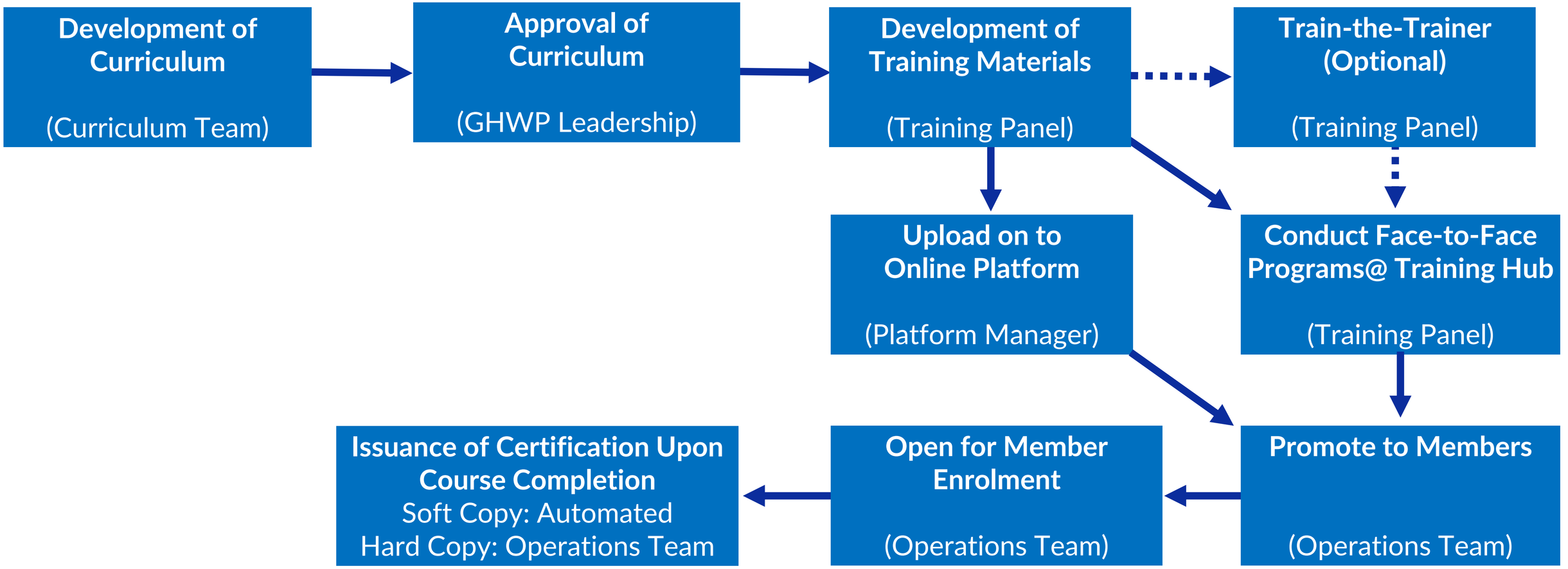
Certification Courses (With Assessment Component)

Self-Directed (Learner-Paced)

Learning Courses

Certification Courses (With Assessment Component)

GHWP ACADEMY WORK-FLOW



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Capacity Building Roadmap – Step forward

Next steps – GHWP Capacity Building for Regulators

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Curriculum	Curriculum	Training Hub/ Training Panel	Training Panel/Curriculum
Curriculum	Operation	Operation	Operation

1st step GHWP-APACMed Curriculum for Regulators launched

2nd step Identify most urgent Trainings needed – Survey

3rd step Identify Subject Matter Experts (SME) for trainings – collaborate with IMDRF, APEC, Academia, Industry Associations GMTA, APACMed etc

4th step Develop Training Table of Contents and Training Material and delivery mode

5th step Develop trainings modules for different purpose eg. RA basic, RA expert, RA Post_ Market, RA new technologies, etc

6th step Develop certification program

2023 → **2024**

Training Platform
- Curriculum, Training, Certification

Next steps – GHWP Capacity Building for Industry

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2023	2023	2024	2024	2024
Curriculum	Curriculum Operation	Training Hub/ Training Panel Operation	Training Panel/Curriculum Operation	
1st step: Update GHWP/APACMed Curriculum for Regulatory Professionals	2nd step: Identify most urgent Trainings needed – Survey	3rd step: Identify Subject Matter Experts (SME) for trainings – leverage trainings already established for regulalors	4th step: Establish additional Training not available yet Table of Contents and Training Material	5th step: Develop certification program

Training Platform
- Curriculum, Training, Certification

APACMed

The voice of MedTech

GHWP

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Training Curriculum for MedTech Regulators - Joint initiative between GHWP and APACMed

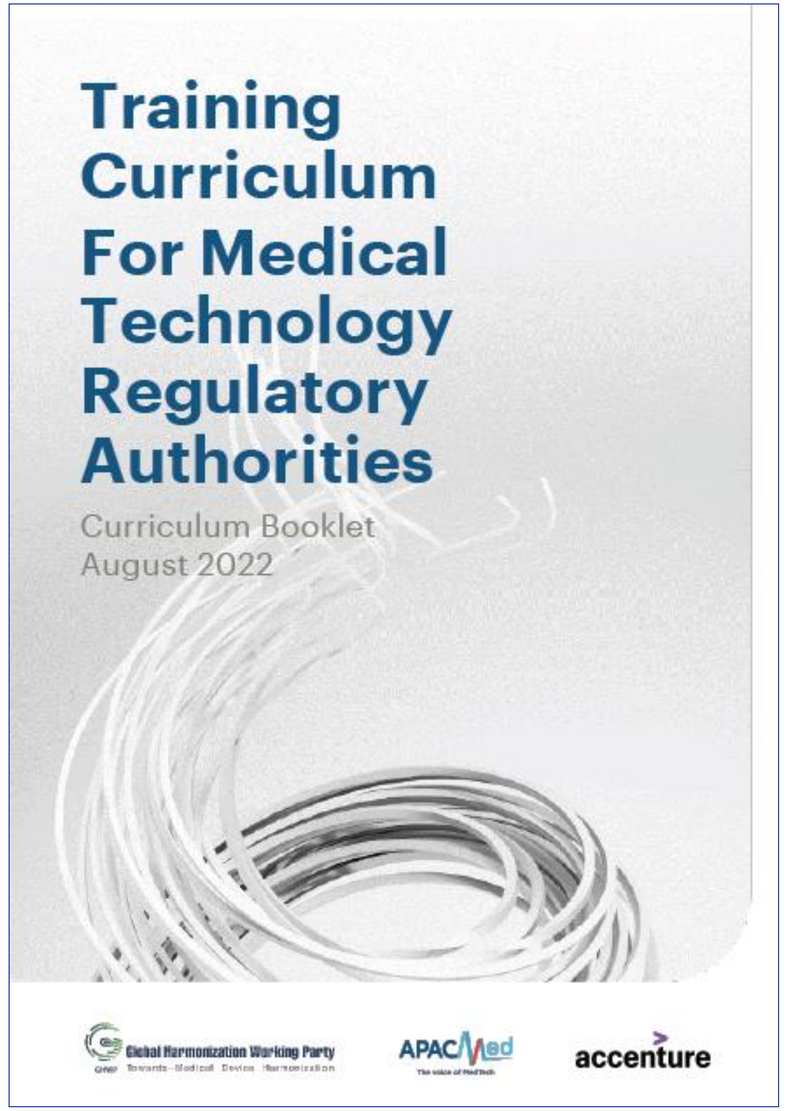
14 February 2023

Dr. Praveen Kumar
Manager, APACMed RA committee

GHWP 26th Annual Meeting

Vision

A **standardized and harmonized training curriculum for MedTech Regulators** across the globe



APACMed
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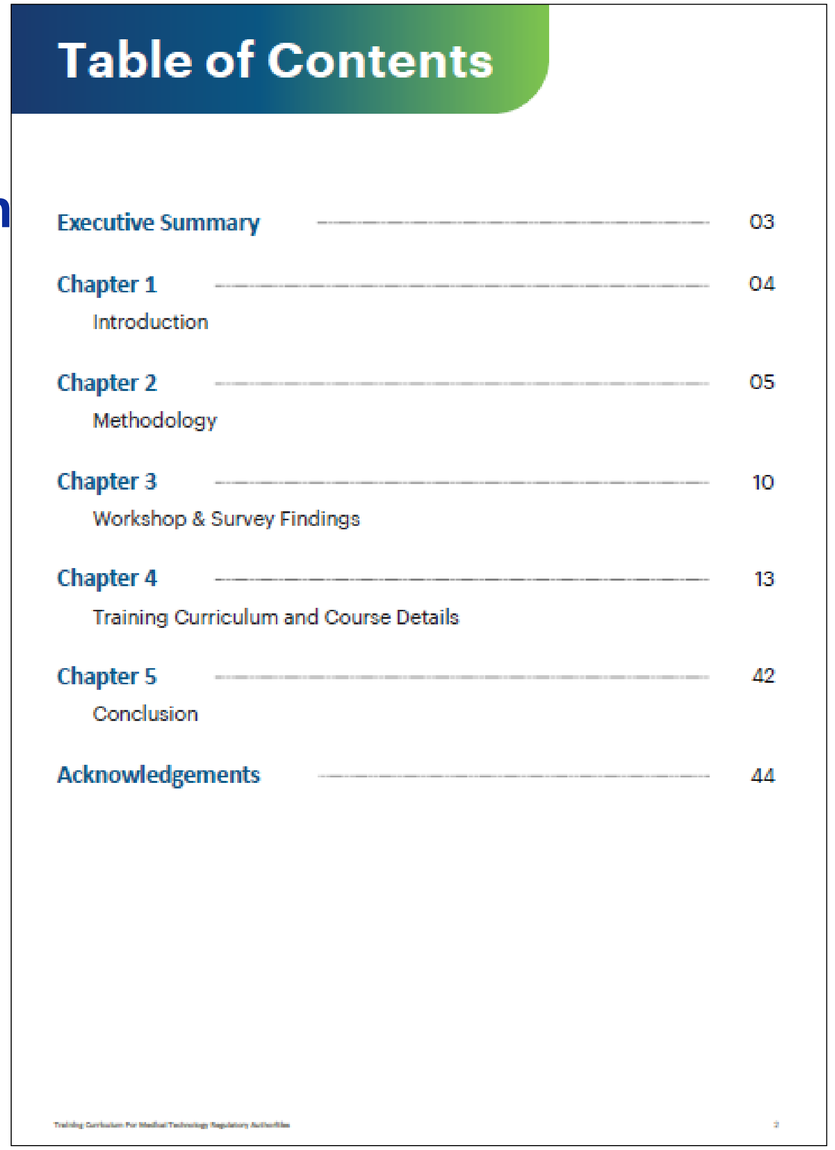
Accenture Life Sciences
Patient Inspired. Outcomes Driven.

Objectives

To come up with **standardized and harmonized trainin curriculum** cutting across different core competencies

To define ands shape the future direction of regulatory trainings for all GHWP member jurisdictions.

To develop a comprehensive curriculum to regulators to equip and enable them with the fast-evolving global regulatory landscape.



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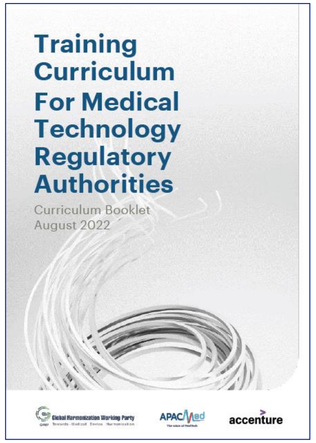
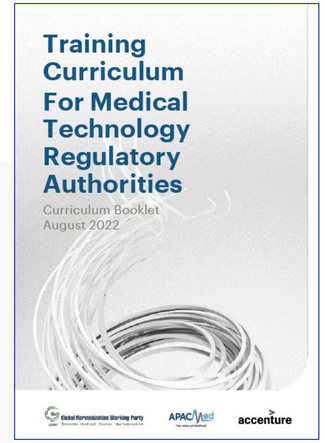


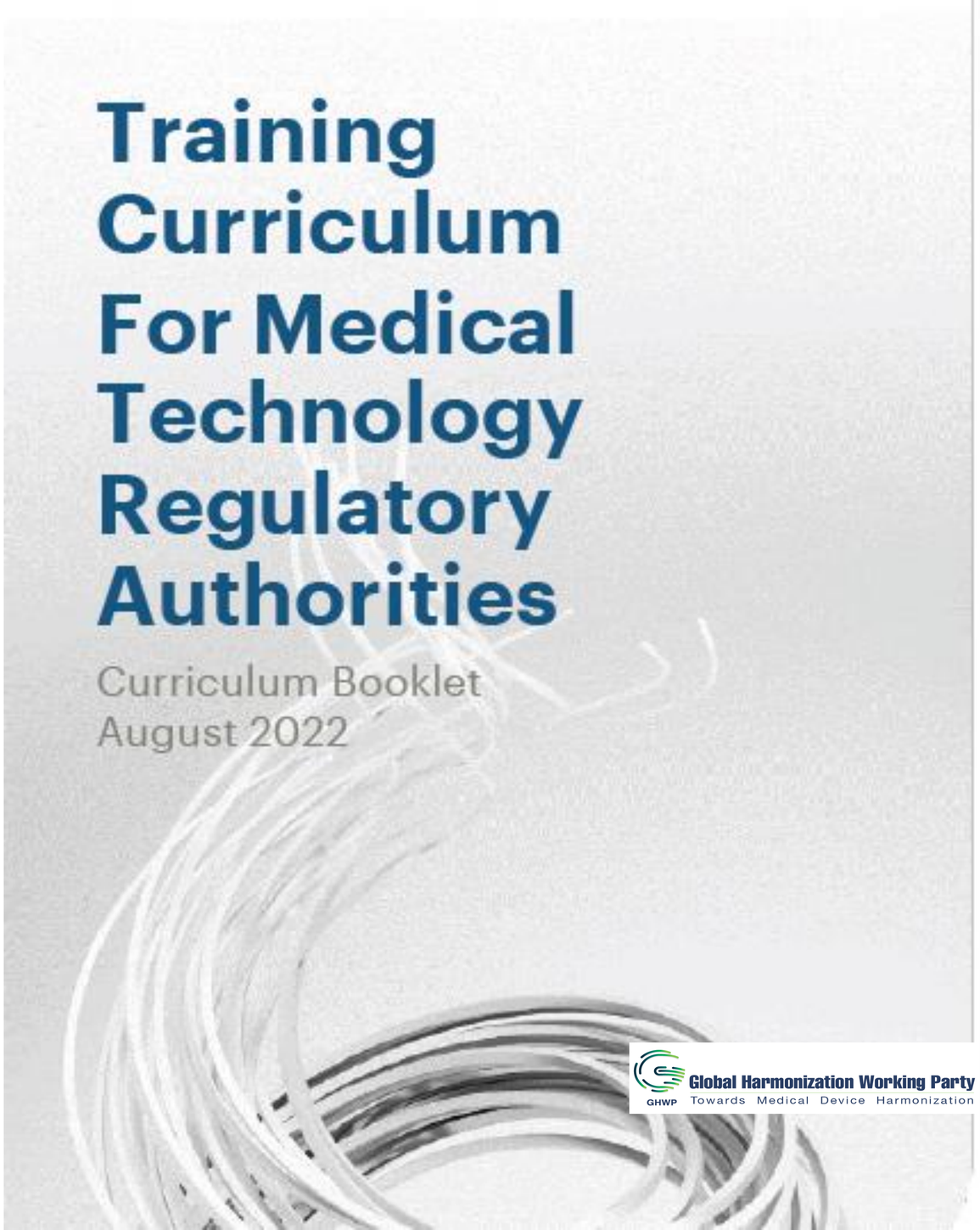
Staggered Approach



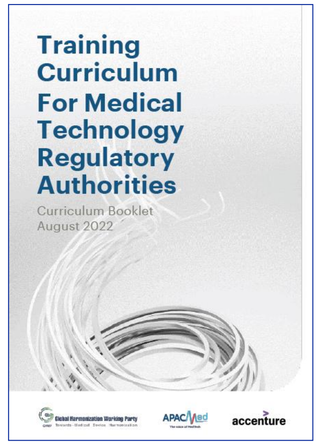
STEP 1	Re-validation of existing competency framework which was developed in 2018
STEP 2	Identification of gaps in competencies and training modules, with respect to current and emerging technologies
STEP 3	Review and updation of competency framework as per the identified gaps
STEP 4	Identification of constraints and barriers in establishing a Training Curriculum
STEP 5	Development of the courses and intentificaiton of preferred delivery modes and levels of expertise based on the competencies within the framework

Workshop, Survey & Research

- 12 Members of GHWP



Outcome – Identification of Constraints and Barriers



TRAINING CONSTRAINTS & BARRIERS

Lack of structured and harmonized curriculum

Most of the juridictions have in-house training structure in place and few others have trainings in alliance with academia. But those programs are country specific and lack harmonised and structured approach.

Resource and capacity

In most of the countries, regulators are under-resourced and stretched making it difficult for them to devote time for training.

Cost incurred in consistent training

Lack of adequate budget towards learning and development (L&D).

Lack of high quality trainings and subject matter experts (SME)

Challenges associated with accessing high quality training materials and respective SMEs which are also cost effective.

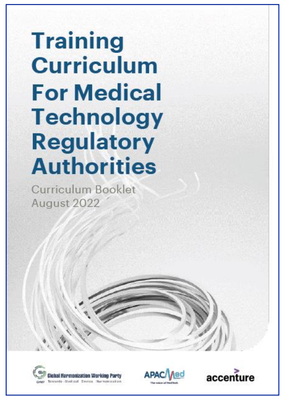
Language barrier

Preference for trainings delivered in local language.

Culture

Diverse perspectives on trainings and the way of learning.

RA Competency High Level Framework for MedTech Regulators – Building Blocks



A — **Competencies**

- Foundational
- General Technical
- Functional Technical

B — **Domain**

- Functions, roles and proficiencies across competencies

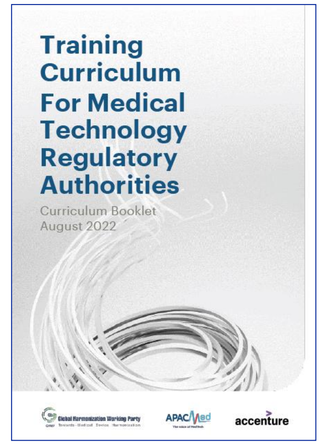
C

- **Knowledge**
  Institutional and Regulatory Professional Knowledge
- **Skills and Abilities**
  Professional and Inter-personal/business-related

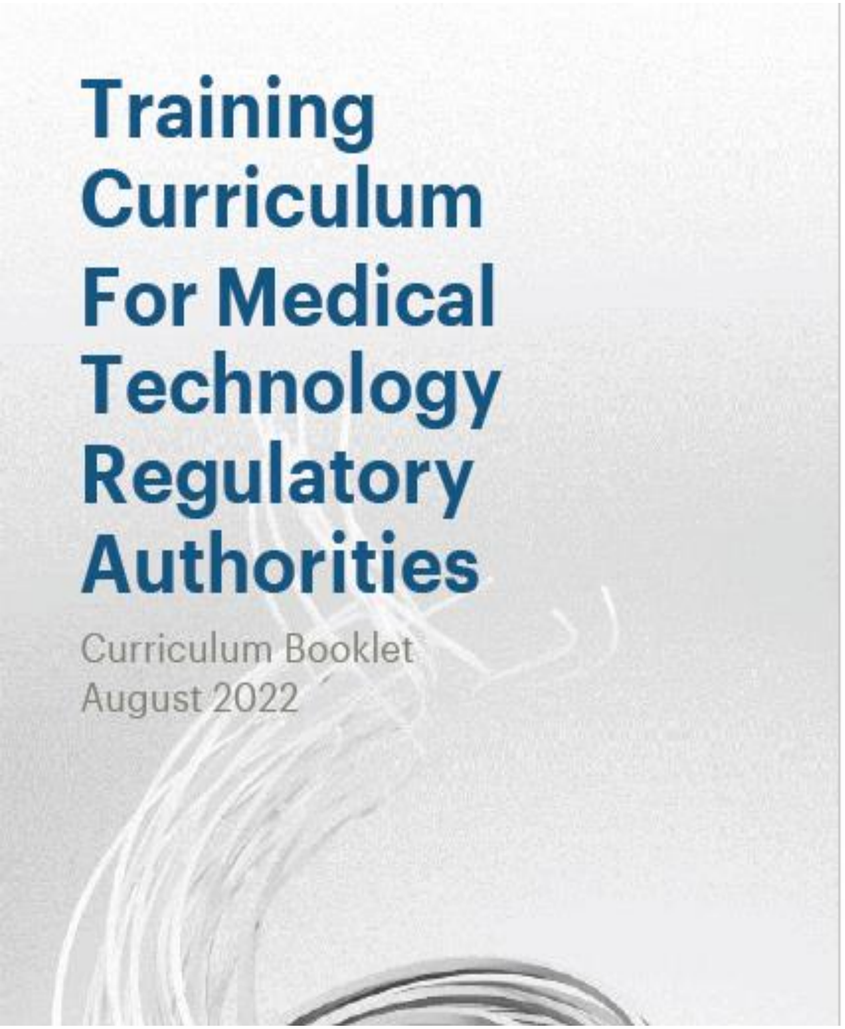
D — **Prioritization**

- Primary
- Secondary
- Tertiary

Training Curriculum and Course Details



	DOMAINS	MODULES
Foundational Competencies	Training Curriculum covers all **6 domains**	Training Curriculum covers **42 functional competencies**
General Technical Competencies	Training Curriculum covers all **2 domains**	Training Curriculum covers **21 competencies**
Functional Technical Competencies	Training Curriculum covers all **6 domains**	Training Curriculum covers **35 competencies**
		98 competencies



Course 2: Communication Competency: Foundational

Domain: Communication
Competency mapping (knowledge/skills/behaviors):

- Effective Communication (Verbal and Written)
- Interpersonal skills
- Public education
- Negotiation
- Public Speaking
- Information Dissemination and Media Strategy
- Presentation skills (updated)

Module	Outline	Delivery Mode	Duration	Professional Level
Effective Communication (Verbal and Written)	Effective communication tools and techniques Critical elements of successful planning for meetings, presentations and other types of engagement and communication	Webinar	4 hours	Beginner & Intermediate
Interpersonal skills	Introduction to the importance of soft skills Effective engagement with peers and diverse audiences such as industry professionals and cross functional stakeholders Effective conflict management Scenario analysis based on diverse organizational protocols	Interactive workshop	8 hours	Beginner
Public Education	Overview of different platforms (print, visual and social media) to communicate public on relevant important topics, as & when needed	Webinar	2 hours	All levels
Negotiation	Introduction of negotiation skills (e.g., persuasion, perseverence, diplomacy, sensitivity, clarity of thought, value creation, EQ etc) examples, templates and case studies	Interactive workshop	8 hours	Beginner & Intermediate
Public Speaking	Confidence building, Storytelling, Body language, Clarity of expression, Flow of thoughts/concepts through Clear articulation Time management	Interactive & Practice workshop	4 hours	All levels

Course 7: Scientific & Engineering Principles Competency: General Technical

Domain: Scientific & Engineering Principles
Competency mapping (knowledge/skills/behaviors):

- Human Anatomy & Physiology
- Biological Sciences
- Biomaterials
- Biochemistry
- Nanomaterials
- Biomechanics
- Bioelectronics
- Radiation and Nuclear Medicine
- Digital Technology (mobile health, telemedicine, AI, etc.)
- Electrical Safety*

Module	Outline	Delivery Mode	Duration	Professional Level
Human Anatomy & Physiology	Basics of Anatomy and Physiology Blood and Body Fluids Endocrine and Reproductive Systems Orthopedic and Musculoskeletal System Cardiovascular System Respiratory System Nervous System and Special Senses Urinary System Digestive System	Webinar	4 hours	Beginner
Biological Sciences	Introductory Biology Biophysical Chemistry Organic Chemistry Principles of Genetics Molecular & Cell Biology Microbiology Biostatistics	Webinar	2 hours	Beginner
Biomaterials	History of biomaterials General Properties of Bio-materials	Webinar	2 hours	Beginner

Course Layout and Details

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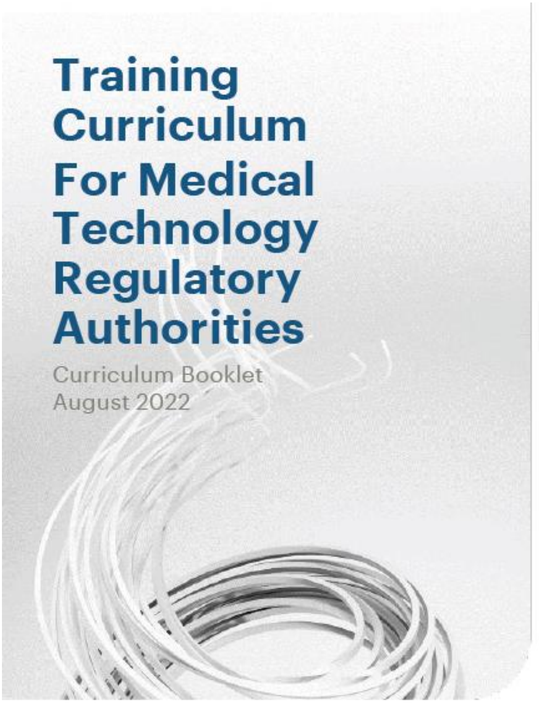
Take-Home Messages

- Overall agreement across all jurisdictions on **domains and competencies** - based on the existing framework
- Training Curriculums to be **revisited frequently for improvement**.
- Need for **trainings on ever evolving processes, products and technologies** and **international standards** (e.g. Digital Health, AI, RWE, NGS, 3D Printing)
- **Pandemic** has taught us to juggle between **virtual** and **physical** trainings.



Global Harmonization Working Party APACMed accenture

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Thank You!

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