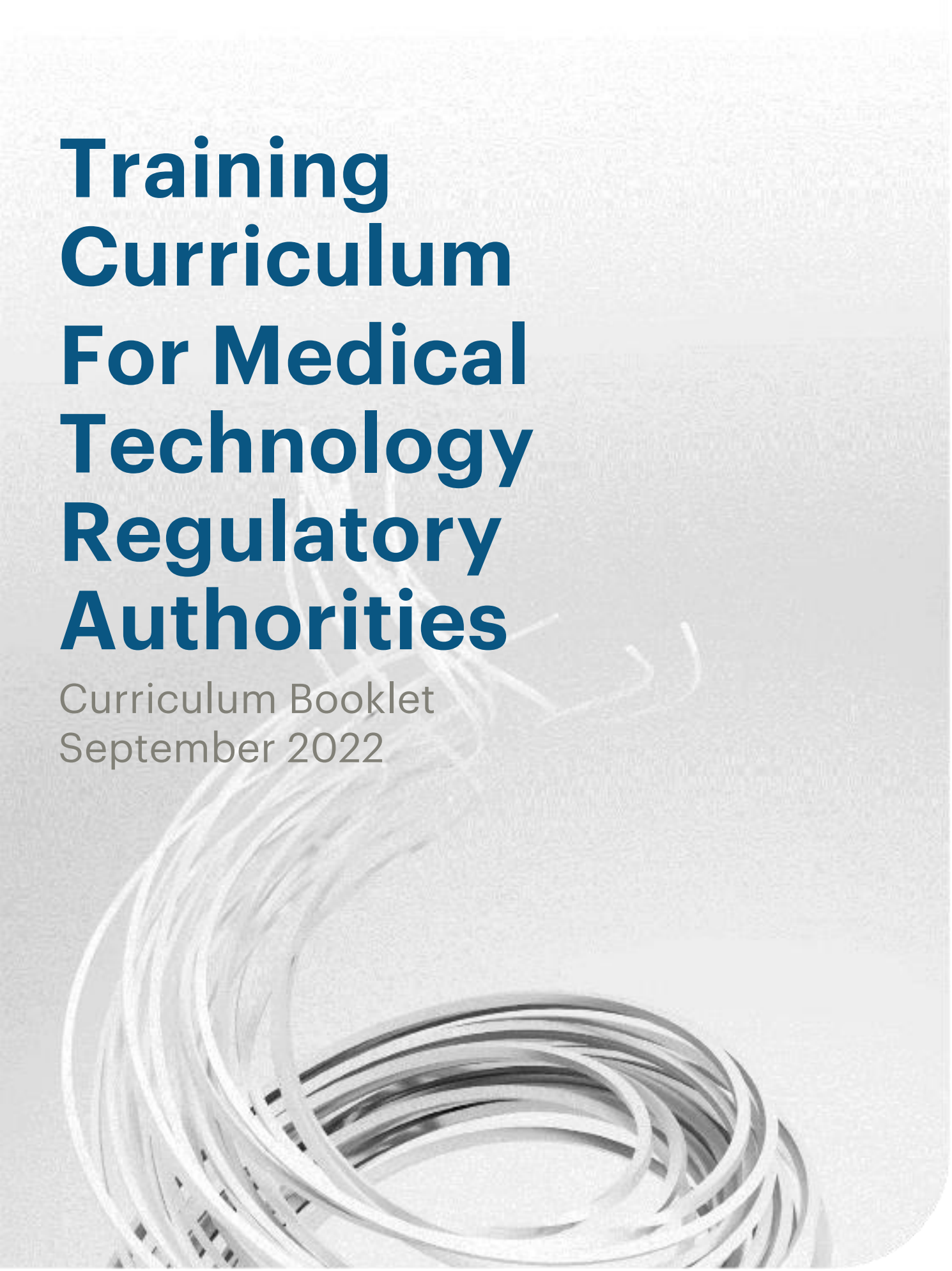
Training Curriculum For Medical Technology Regulatory Authorities

Curriculum Booklet
September 2022



Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

APACMed
The voice of MedTech

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Table of Contents

Executive Summary

The Medical Technology (MedTech) industry has always undergone constant evolution at a rapid pace driven by advancements in technology, changes in consumer and patient expectations as well as upheavals such as the recent global Covid-19 pandemic. Amidst a dynamically changing MedTech landscape, regulators play a crucial and competent role in ensuring that approved products meet the requirements of Essential Principles of safety, and performance. They also play a pivotal role in ensuring innovation that are both path breaking and safe, from the MedTech industry made available to patients swiftly. The need of the hour is to ensure effective deployment of capacity and capability building to create an effective future ready MedTech workforce comprising of both industry regulatory professionals and regulators. In Asia Pacific (APAC), to address this need, Global Harmonization Working Party [GHWP] (formerly Asian Harmonization Working Party), and Asia Pacific Medical Technology Association (APACMed) had worked with Deloitte in 2018 to launch "Competency Framework for Asia Pacific MedTech Regulators". Leveraging this framework, further, in 2021, GHWP, APACMed, and Accenture jointly initiated a study across all GHWP member jurisdictions to develop and rollout this cardinal MedTech Regulators Training Curriculum booklet to kick-start the capability development process.

This curriculum booklet was crafted based on the competency model established in 2018 and insights gathered from GHWP member jurisdictions along with a workshop, surveys and secondary research, led by GHWP and APACMed.

The research outcome revealed the fact that some jurisdictions have their own training programs in place. However, there is a growing need for a harmonized structured curriculum which also includes new and emerging technologies, thereby leading to better collaboration and best practice sharing in the arena of learning and development. This booklet leverages the existing practices and programs to create this harmonized training curriculum for all the member jurisdictions.

This booklet provides a harmonized training curriculum for MedTech regulators under the following competencies:

Foundational Competencies:
Legal, Communication, Multisector Partnership, Industry Insight, Operations, Management.

General Technical Competencies:
Scientific & Engineering Principles and Regulatory Principles.

Functional Technical Competencies: Premarket, Postmarket, Distribution Control, Manufacturing Control, Good Laboratory Testing, Clinical Oversight.

This booklet also recommends courses under the defined domains with detailed course outline, mode of delivery and duration of each course and level of expertise of the target trainees. Developed through sound fundamentals and a systematic and dynamic research process, the content in this booklet is aimed to provide structured training curriculum for regulators to equip and enable them to stay ahead of the curve especially with the fast-evolving global regulatory landscape.

Chapter 1
Introduction

It is an understatement to say that the MedTech industry has become significantly more complex and diverse with the arrival and addition of newer technologies and specializations such as biotechnology, nanotechnology, cell & gene therapy, and digital health products. This poses a serious and significant challenge to the regulatory authorities to be constantly equipped with the required skillsets and expertise to assess and regulate each of these different technologies. Moreover, regulatory systems were earlier developed to cater to the needs of a less connected world, however, there has been a paradigm shift where the present environment presents an opportunity to bridge the growing gap between quality, safety and efficacy, and access through cooperation and capacity building. We have also seen that the need for better access to innovative technologies has been best highlighted by the recent global COVID-19 pandemic which required regulatory authorities to be more agile and rely on other Regulatory Authorities to expedite the access to essential medical products to tackle the pandemic. That it is paramount and the need of the hour to employ effective capability and capacity building to create an effective future ready MedTech workforce comprising of both industry regulatory professionals and regulators.

With this objective, Asian Harmonization Working Party (now Global Harmonization Working Party -GHWP), and Asia Pacific Medical Technology Association (APACMed) along with Knowledge Partner — Deloitte had collaborated in 2018 to develop a white paper on "*Competency Framework for Asia Pacific Regulatory Professionals*".

That project was an initiative to study all GHWP member jurisdictions in order to develop a harmonized competency framework for the regulators. This framework leveraged the valuable work of the World Health Organization (WHO), the AHWP etc. and established a high-level framework for MedTech regulators across the globe by structuring and prioritizing the competencies across three dimensions: Foundational, General Technical and Functional Technical. This framework was designed to serve as a tool for developing prioritized training curricula for MedTech regulators.

Leveraging the same framework, further, in 2021, GHWP, APACMed, jointly initiated a study across all GHWP member jurisdictions which was facilitated by Accenture, to develop and rollout a much-needed MedTech Regulators Training Curriculum program to kick-start the capacity & capability development process. The objective of this booklet is to come up with standardized and harmonized training curriculum cutting across different core competencies beneficial for all regulators in Asia Pacific. The primary focus of this paper is to define the future direction of regulatory trainings for all GHWP member jurisdictions. Developed through sound fundamentals and a systematic and dynamic research process, this booklet provides a comprehensive curriculum to regulators to equip and enable them to be ahead of the curve especially with the fast-evolving global regulatory landscape.

Chapter 2
Methodology

This curriculum for regulators is built on the "Harmonized Competency Framework for Medical Technology Regulators" developed by GHWP and APACMed and categorized as follows:

Foundational Competencies:

- Legal
- Communication
- Multisector Partnership
- Industry Insight
- Operations
- Management

General Technical Competencies:

- Scientific & Engineering
- Principles and Regulatory
- Principles.

Functional Technical Competencies:

- Pre-market,
- Post-market,
- Distribution Control,
- Manufacturing Control
- Good Laboratory Testing
- Clinical Oversight.

Competency category	Domain	Modules
Foundational Competency	**Legal**	• Legal Documents (Local & International) • Technical Documents (Local & International) • Legislative Process • Legal Writing
	Communication	• Effective Communication (Verbal and Written) • Interpersonal skills • Public education • Negotiation • Public Speaking • Information Dissemination and Media Strategy
	Multi-sectoral partnership	• International Initiatives & Networks • Stakeholder Engagement • Public Health • Diplomatic & Foreign Affairs Policy • Foreign Languages and Culture • Healthcare Ecosystem
	Industry Insights	• Local Industry Landscape • Emerging Technologies and Products • International Industry Landscape • Evaluation of new technologies- Processes and regulations to facilitate access*
	Operations	• Code of Conduct • Critical Thinking and Problem Solving • Budget Planning and Management • Documentation & Filing • Customer Service • IT Skills • Technical Report Writing
	Management	• Quality Management System • Project Management • Risk Management • Crisis Management • People Management • Mentoring and Coaching • Training • Leadership • Good Regulatory Practice • Policy Analysis & Strategies

Figure 1. Structure of Competency Framework for MedTech Regulators

Competency category	Domain	Modules
General Technical Competency	**Scientific & Engineering Principles**	• Human Anatomy & Physiology • Biological Sciences • Biomaterials • Biochemistry • Nanomaterials • Biomechanics • Bioelectronics • Radiation and Nuclear Medicine • Digital Technology (mobile health, telemedicine, AI etc)
	Regulatory Principles	• Differences between Pharmaceuticals, General MDs and IVDs • Combination & Borderline Products • Risk Classification • Essential Principles of Safety & Performance • Device Nomenclature • Device Labelling & Unique Device Identifier • Conformity Assessment Concepts and Principles • Post-marketing Surveillance System • Supply Chain Integrity • Local Standards • International Standards

Figure 1. Structure of Competency Framework for MedTech Regulators (cont'd)

Competency category	Domain	Modules
Functional Technical Competency	**Pre-Market**	• International Medical Device Requirements • Device Registration Grouping Principles • Submission Dossier Format and Content • Declaration of Conformity Requirements • General Device Safety and performance
	Post-Market	• International Medical Device Requirements in post-marketing Surveillance • Risk Management Principles • Advertising and Promotional Regulation • Supervision of Reprocessing of Single-use Medical Devices (SuMDs) • Change management • Refurbished Devices
	Distribution Control	• Good Distribution Practice • Quality System Auditing Skills • Risk Management Principles • Import/Export Regulations (including customs requirements – Local & International) • Disposal of Medical Devices • Environmental considerations
	Manufacturing Control	• International Medical Device Requirements in Quality Systems • Good Manufacturing Practice (Local) • Good Manufacturing Practice (International) • Quality System Auditing Skills Design Validation and/or Verification Methods • Risk Management Principles • Manufacturing Process & Technology • Calibration and Metrology • Cleanroom Processes
	Laboratory Testing	• Good Laboratory Practice • Laboratory quality management system • Occupational health and safety standards • Relevant Test Standards (Local and International)
	Clinical Oversight	• Declaration of Helsinki & Nuremberg Code Statistics • ISO 14155 Clinical Investigation of MD for Humans • Good Clinical Practice • Clinical Evaluation (Evidence Based & Statistics)

Figure 1. Structure of Competency Framework for MedTech Regulators (cont'd)

A step-by-step approach as given below was employed in collaboration with regulators.

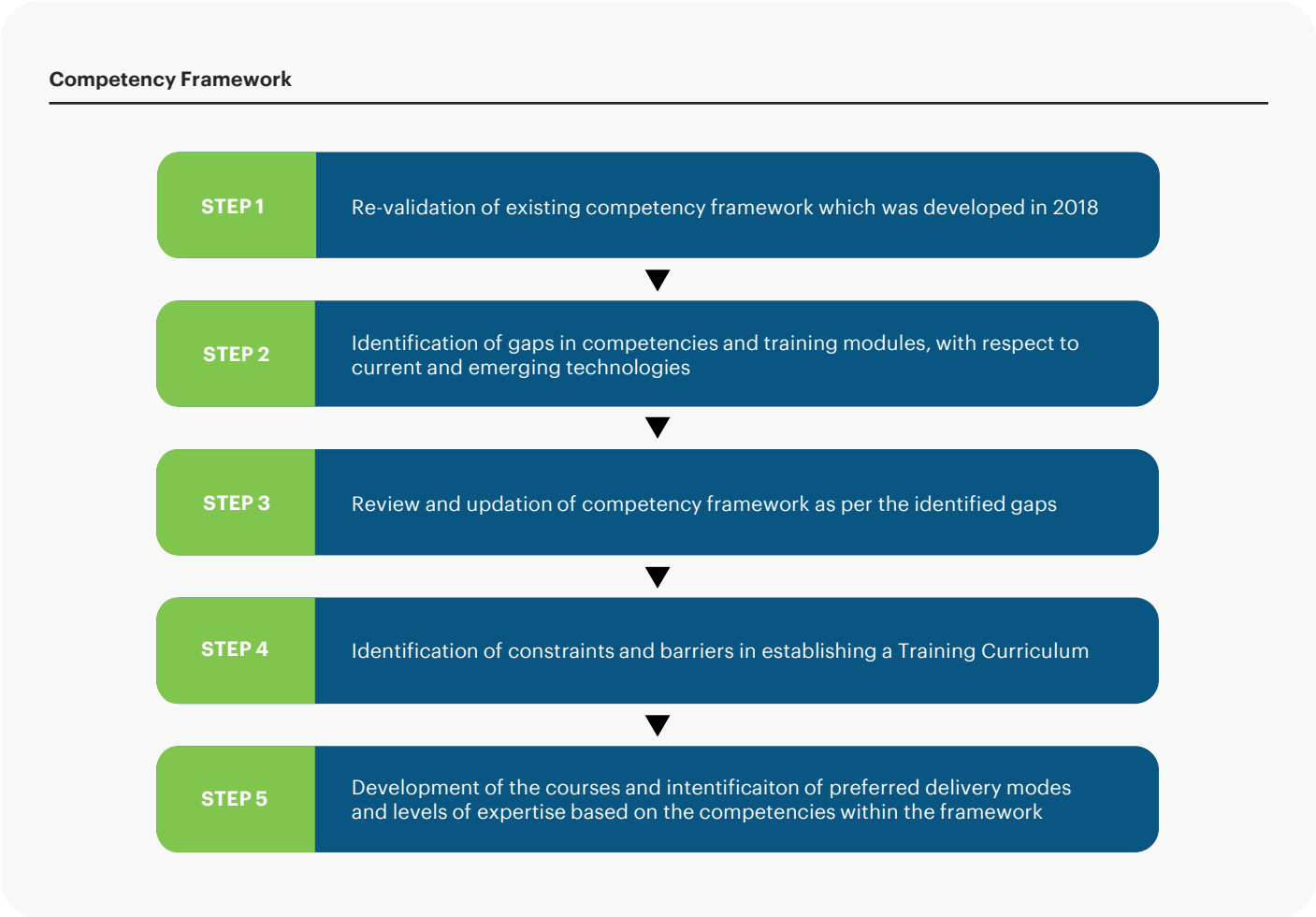


Figure 2 Illustrates the step-by-step training development approach

This training curriculum has been developed as a standardized reference program for all GHWP member jurisdictions with the option of being tailored to meet their individual training needs, specifically, around the various delivery modes, professional levels, and durations of the trainings. Hence every attempt was made to leverage existing training assets keeping member jurisdiction aspirations in mind. The white paper draws insights from the curriculum design workshop, primary and secondary research to validate the Competency Framework for Regulators which is then used to develop a Training Curriculum to deliver these competencies.

At the outset, it was imperative to validate the Harmonized MedTech Competency Framework in the light of current development on a global stage, such as the Pandemic and ongoing rapid technological advancements. There was also a need to establish a baseline of current trainings and curriculum in place across GHWP member jurisdictions.

Identifying constraints and barriers to establishing a Training Curriculum was also recognized across several parameters such as cost of training, accessibility, and language. These objectives were fulfilled through an initial Curriculum design 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.

In addition to the above primary research, the team conducted detailed secondary research to develop the training curriculum and course outline.

Chapter 3
Workshop and Survey Findings

As mentioned in Chapter 2, the Curriculum design workshop and the subsequent survey were used to validate *'Harmonized MedTech Competency Framework'* and understand the constraints and barriers while creating a training curriculum.

The below figures depicts the constraints and barriers identified during our workshop. Regulators who participated in the workshop outlined each of the following 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

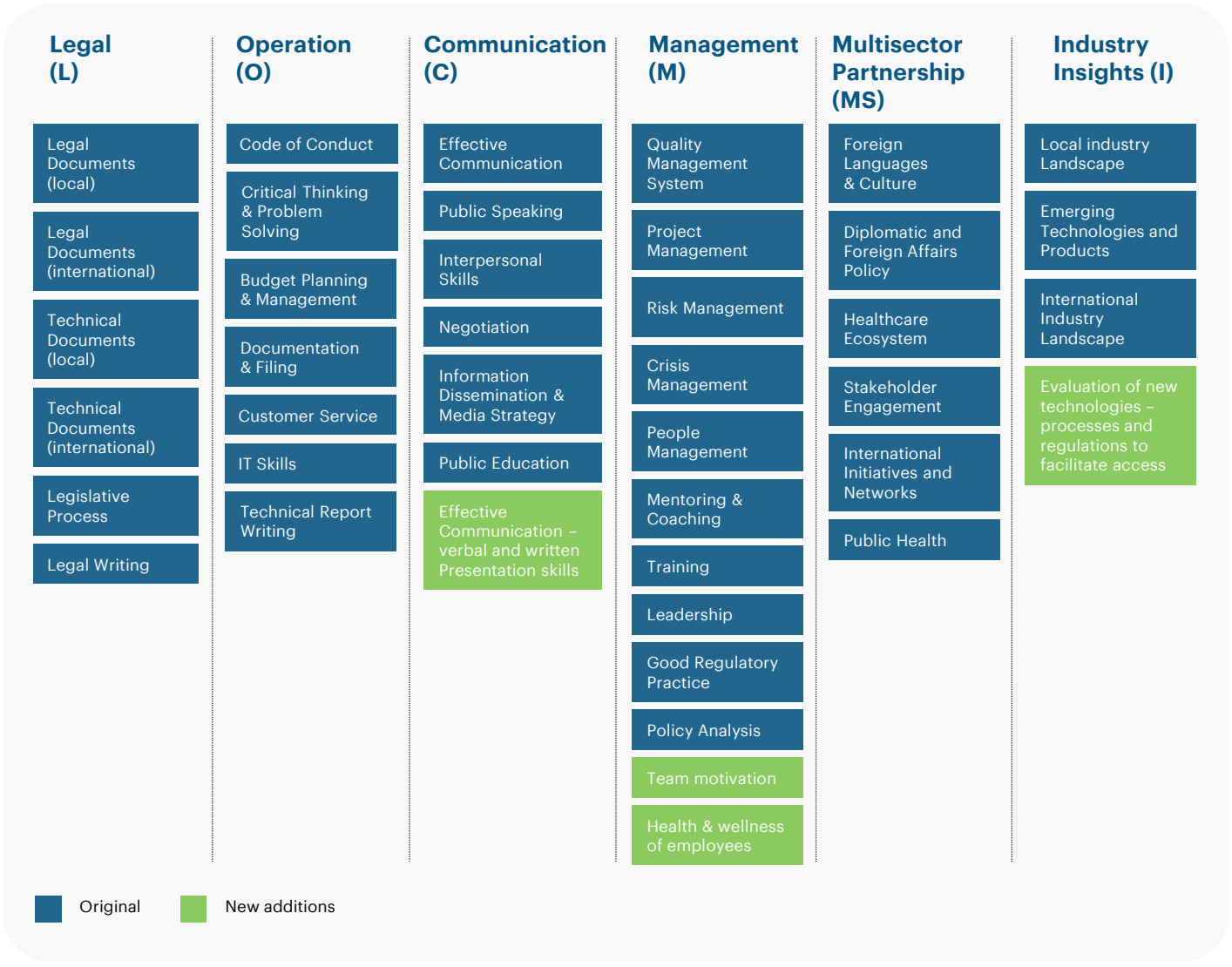
Preference for trainings delivered in local language.

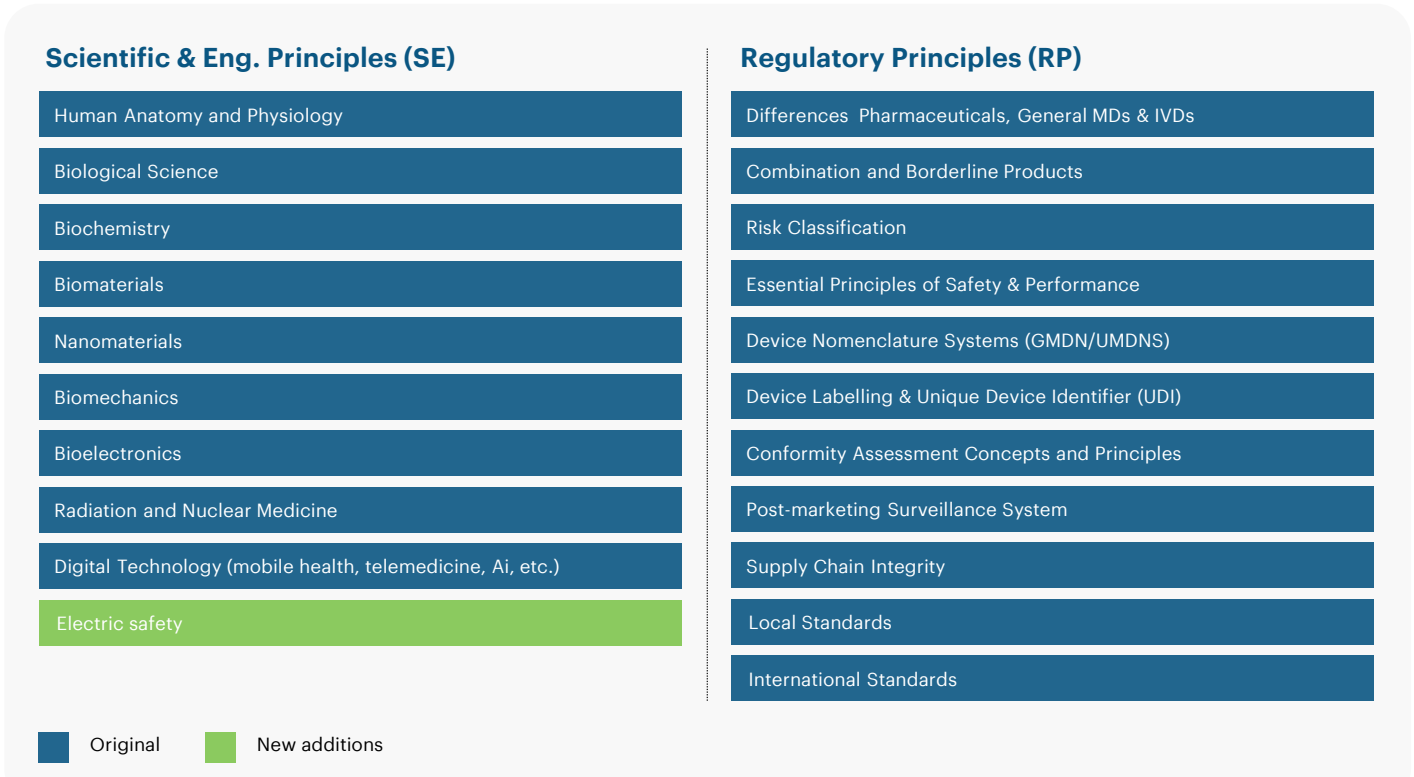
Culture

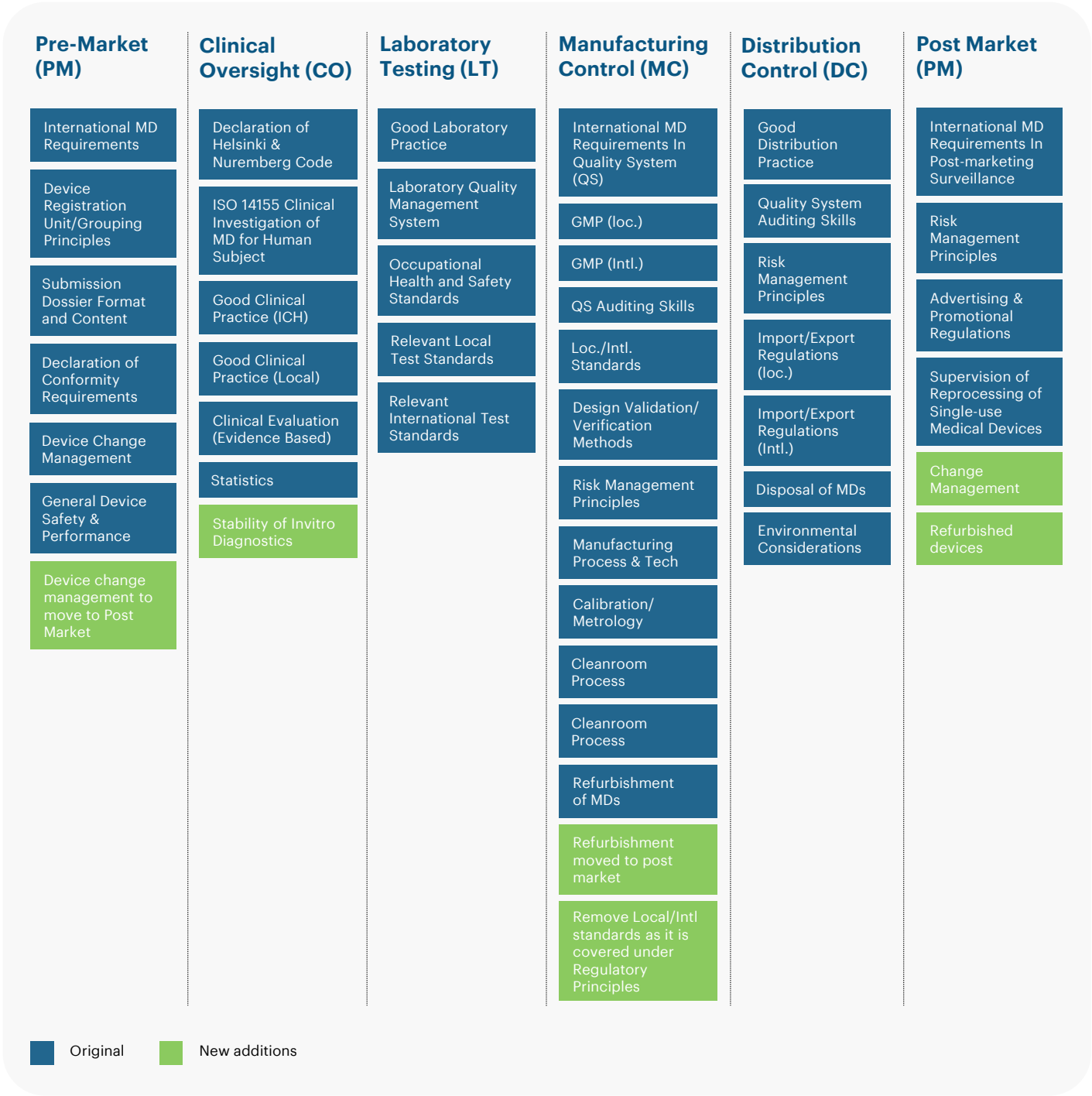
Diverse perspectives on trainings and the way of learning.

Through these exercises it was inferred that there was an overall agreement across all jurisdictions on existing competency framework. However, given the continuous evolution of technology and rapid change of regulatory environment, the need to revisit some of the predefined competencies was highlighted and changes were recommended.

The below figure illustrates the updated competency framework with the new additions highlighted in Green.







The above tables are a result of the curriculum workshop and survey findings which summarize the best practices followed by GHWP member jurisdictions to enhance regulators' capacity and capability building.

Chapter 4
Training Curriculum and Course Details

As briefed under Chapter 3, once the Curriculum design workshop and the subsequent survey validated the '*Harmonized MedTech Competency Framework*' and the team had understanding on the relevant constraints and barriers for training curriculum, the team further deep-dived to create outlines for different courses which are mapped out to the respective domain and compentencies. These training courses have been developed as a standardized reference program for all GHWP member jurisdictions with the option of being tailored to meet their individual training needs; and recommend preferred delivery mode (e.g. Interactive workshops, Interactive & Practice workshop, Webinars), and training duration for different modules under a course, mapped out to different professional levels (Beginners, intermediate and Advanced). The below figure maps the modules and courses against the respective competencies.

	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

Figure 3: Coverage of Training Curriculum on MedTech Competency Framework

Course 1: Legal Competency: Foundational

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

- Legal Documents (Local & International)
- Technical Documents (Local & International)
- Legislative Process
- Legal Writing

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
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 conformance	Webinar	8 hours	All levels
Legislative Process	Overview of legistative 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
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

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 Development of negotiation skills through exercises workshops, and feedback	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 Development of public speaking skills through exercises, workshops, and feedback	Interactive & Practice workshop	4 hours	All levels
Information Dissemination & Media Strategy	Media management Sensitivity to classified information Introduction to corporate communication strategy	Webinar	2 hours	Intermediate
Presentation skills	Introduction of best presentation practices through examples, templates and case studies Development of presentation skills through exercises workshops, and feedback	Interactive workshop	8 hours	Beginner

Course 3: Multi-sectoral partnership Competency: Foundational

Domain: Multi-sectoral partnership
Competency mapping (knowledge/skills/behaviors):

- International Initiatives & Networks
- Stakeholder Engagement
- Public Health
- Diplomatic & Foreign Affairs Policy
- Foreign Languages and Culture
- Healthcare Ecosystem

Module	Outline	Delivery Mode	Duration	Professional Level
International Initiatives & Networks	Knowledge on current affairs and real time international initiatives and programs Leverage the knowledge to participate in relevant initiatives and programs	Webinar	2 hours	Intermediate
Stakeholder Engagement	Understanding stakeholder personality Effective engagement with different stakeholders through soft skills	Webinar	2 hours	Intermediate
Public Education	Foundations of Public health Public Health Research methods Health Behaviours and communication Implemenating Public Health programs and policies Ethics in Public health practices	Webinar	4 hours	Intermediate
Diplomatic & Foreign Affairs Policy	Understanding Foreign policies Response to different policies and preferences Management of International Relations	Webinar	4 hours	Intermediate
Foreign Languages & Culture	Stages of intercultural sensitivities Perceptions, judgments, and assumptions Understanding Cross-cultural norms Managing cultural differences Develop cultural intelligence and Intercultural competence	Webinar	4 hours	Advanced
Healthcare Ecosystem	Introduction to difference/diverse healthcare ecosystems Reimbursement landscape – payors-providers relationships Hospital Infrastructure – Private-Public sectors	Interactive workshop	4 hours	Advanced

Course 4: Industry Insights Competency: Foundational

Domain: Industry Insights
Competency mapping (knowledge/skills/behaviors):

- Local Industry Landscape
- Emerging Technologies and Products
- International Industry Landscape
- Evaluation of new technologies- Processes and regulations to facilitate access (updated)

Module	Outline	Delivery Mode	Duration	Professional Level
Local Industry Landscape	Review current MedTech regulatory industry landscape Align on future requirements based on technology advancements and government policies	Webinar	2 hours	Basic
Emerging Technologies and Products	Update on emerging technologies and products for regulatory preparedness. E.g., 3D printing, AI/ML, SaMD etc	Webinar	2 hours	All levels
International Industry Landscape	Review of the global landscape of MedTech regulatory industry Respond to global technology advancements, products, and services	Webinar	4 hours	Advance
Evaluation of new technologies- Processes and regulations to facilitate access	Tools and methodologies needed to evaluate disruptive technologies and novel innovations Regulatory compliance objectives and guidelines related to disruptive technologies and novel innovations Fit for purpose regulations and processes Case studies on fit for purpose regulations	Webinar	4 hours	All levels

Course 5: Operations Competency: Foundational

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

- Code of Conduct
- Critical Thinking and Problem Solving
- Budget Planning and Management
- Documentation & Filing
- Customer Service
- IT Skills
- Technical Report Writing

Module	Outline	Delivery Mode	Duration	Professional Level
Code of Conduct	Compliance with local rules and regulations Avoiding violation of local code of conduct	Guidance document	2 hours	Beginner
Critical Thinking and Problem Solving	Fundamental concepts of critical thinking – • Observation • Analysis • Inference • Communication process • Problem solving	Interactive workshop	4 hours	All levels
Budget Planning and Management	Cost analysis Resource analysis and allocation Designing a budget Monitoring and control of the cost	Webinar	4 hours	Advanced
Documentation & Filing	Good documentation practice Case study on writing and archiving document and files	Interactive workshop	2 hours	Beginner
Customer Service	Overview of customer service Value of customer service Customer identification	Webinar	2 hours	All levels
IT Skills	Understanding IT systems and networks Overview of working software (MS Word, MS Excel, MS PPT etc) Overview of formulas and pivoting in MS Excel	Interactive workshop	4 hours	Beginner
Technical Report Writing	Process to write a professional technical report Discuss drafting, structure, language, layout, design, and production Share templates and best practices	Webinar	2 hours	Beginner

Course 6: Management Competency: Foundational

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

- Quality Management System
- Project Management
- Risk Management
- Crisis Management
- People Management
- Mentoring and Coaching
- Training
- Leadership
- Good Regulatory Practice
- Policy Analysis & Strategies
- Team Motivation*
- Health and wellness of employees*

Module	Outline	Delivery Mode	Duration	Professional Level
Quality Management System	Introduction to Quality management principles and standards ISO 9001 & ISO 13485	Webinar	4 hours	All levels
Project Management	Project management principles and tools to proactively plan for evolving timelines and requirements, engage stakeholders and combat resistance to change, streamline documentation requirements	Webinar	4 hours	Intermediate
Risk Management	Application of risk management frameworks to identify, minimize or eliminate risk Methodology and guidelines for risk mitigation	Webinar	4 hours	Advanced
Crisis Management	Crisis management principles in the management of global health crises Scenario based crisis management with examples and case studies Steps to create crisis management plan and its execution	Interactive workshop	4 hours	All levels
People Management	Building an optimal work culture to improve productivity Management of inter-personal conflicts, Conflict resolution Advanced EQ Listening and problem-solving skills Communication Technical competency Coaching and mentoring	Webinar + Interactive Workshop	2 days	Intermediate & Advanced
Mentoring and Coaching	Mentoring and coaching basics Role of Mentor/ Coach vs Mentee, Coachee Common coaching challenges Best Practices on coaching and mentoring	Interactive workshop	4 hours	Advanced
Training	Overview of basic elements of good training program Best training practices	Webinar	2 hours	Advanced

Module	Outline	Delivery Mode	Duration	Professional Level
Leadership	Leadership principles such as relationship building, agility and adaptability, innovation and creativity, employee motivation, empathy, EQ and decision making	Webinar	2 hours	Advanced
Good Regulatory Practice (GRP)	The Importance of High-Level Political Commitment to GRP Transparency, clarity, and predictability of regulations The use of stakeholder management tools such as regulatory reviews Oversight mechanisms to ensure compliance with GRP Regulatory coherence and consistency The importance of International regulatory co-operation Discussions on best practices and case studies of GRP	Interactive workshop	8 hours	All levels
Policy Analysis & Strategies	Identifying potential policy options Prioritization of policies Analysis of important and critical policies Policy analytical framework Policy research and stakeholder mapping Strategic plans and implementation programs	Webinar	2 hours	Intermediate & Advanced
Team Motivation	Informal team events and team building activities Create a favourable workplace environment Opportunities for self-development Learning & development programs	Webinar	2 hours	Advanced
Health and wellness of employees	Team building activities and Team retreats Optimized & flexible work hours Consistent assessment of work-related stress and injuries Safe and trustworthy work environment Emotional support system at workplace	Webinar	2 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	Webinar	4 hours	Beginner
	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			
Biological Sciences	Introductory Biology	Webinar	2 hours	Beginner
	Biophysical Chemistry			
	Organic Chemistry			
	Principles of Genetics			
	Molecular & Cell Biology			
	Microbiology			
	Biostatistics			
Biomaterials	History of biomaterials General Properties of Bio–materials	Webinar	2 hours	Beginner
	Classes of materials used in medicine			
	Metallic and Ceramic biomaterials			
	Polymeric Biomaterials			
	Testing of biomaterials			
	Standards for Biomaterials			
Biochemistry	Introductory Biology	Webinar	4 hours	Beginner
	Principles of Organic Chemistry			
	Principles of Analytical Chemistry			
	Molecular Structure in Biochemistry			
	Genetics			
	Metabolic Biochemistry			
	Human Molecular and Cellular Biology or Cell Biology			

Module	Outline	Delivery Mode	Duration	Professional Level
Nanomaterials	Introducing Natural Sciences	Webinar	2 hours	Beginner
	Spectroscopy			
	Organic Synthesis			
	Colloid Science			
	Mechanics of nanomaterials			
	Modelling and Simulation			
	Soft Condensed Matter Theory			
Biomechanics	Introduction to Biomechanics Mechanics and Circulation	Webinar	4 hours	Beginner
	Mechanics of Biological System			
	Bio -Solid Mechanics of Hard Tissues			
	Bio-Solid Mechanics of Soft Tissues			
	Biomechanics of Implants			
	Soft Computing in Biomechanics			
Bioelectronics	Bioelectrodes	Webinar	4 hours	Beginner
	Physiological Transducers			
	Fundamentals of Bioelectric Signals			
	Bio Potential Recording			
	Biosignal Processing			
	Bioamplifiers			
	Interface Standards and PC Buses			
	Medical Image Processing			
Radiation & Nuclear Medicine	Basic physics and radiation biology	Webinar	2 hours	Beginner
	Dosimetry			
	Safety rules and regulations			
	Administrative and regulatory aspects of nuclear medicine			
	Quality control and regulatory issues of radiopharmaceuticals			
Digital Health and Wearable Technology	Introduction to digital health and different types of digital health technologies – Interconnected domains, health information systems, telehealth, artificial intelligence, machine learning and deep learning	Webinar	4 hours	All levels
	Introduction to mobile heath – wearables and extracorporeal implants			
Electrical Safety	Compliance	Webinar	2 hours	Beginner
	Standards for safety			
	Quality Control			

Course 8: Regulatory Principles Competency: General Technical

Domain: Regulatory Principles
Competency mapping (knowledge/skills/behaviors):

- Differences between Pharmaceuticals, General MDs and IVDs
- Combination & Borderline Products
- Risk Classification
- Essential Principles of Safety & Performance
- Device Nomenclature
- Device Labelling & Unique Device Identifier
- Conformity Assessment Concepts and Principles
- Post-marketing Surveillance System
- Supply Chain Integrity
- Local Standards
- International Standards

Module	Outline	Delivery Mode	Duration	Professional Level
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
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
Risk Classification	General classification system (IMDRF and AMDD) Risk based classification scheme Classification Rules Case Studies	Interactive workshop	2 hours	Beginner & Intermediate
Risk Classification IVD Medical Devices	General IVD classification system (IMDRF and AMDD) Risk based IVD classification scheme Classification Rules Research use only products Case Studies	interactive workshop	2 hours	Beginner & Intermediate
Conformity Assessment & Essential Principles (Medical Devices)	Conformity Assessment Elements MDs Conformity Assessment System MDs Declaration of Conformity General Essential Principals MDs Case Studies	Interactive workshop	2 hours	Beginner & Intermediate

Module	Outline	Delivery Mode	Duration	Professional Level
Conformity Assessment & Essential Principles (In Vitro Diagnostic Devices)	Conformity Assessment Elements IVDs Conformity Assessment System IVDs Declaration of Conformity General Essential Principals IVDs Case Studies	Interactive workshop	2 hours	Beginner & Intermediate
Global Device Nomenclature Systems (GMDN/ UMDNS)	History of Device Nomenclature Systems Role of Nomenclature Systems in ensuring compliance Examples of GMDN/ UMDNS	Webinar	2 hours	All levels
Device labelling and UDI	UDI System-Understand UDI attribution processes and GTIN allocation rules for healthcare UDI (Device Identifier and Production Identifier) UDI Label UDI Databases (GUDID, EUDAMED and others) UDI Trends	Webinar	2 hours	All levels
Post market surveillance	Post-market Surveillance, Vigilance definitions Adverse Event Reporting Field Safety Corrective Actions (FSCA) Reporting Case studies	Interactive Workshop	2 hours	All levels
Supply Chain Integrity and Security	Supply chain principles Policies, procedures, and technologies used to provide visibility and traceability of products within the supply chain Importation and exportation management (general requirements, product knowledge and global sourcing knowledge)	Webinar	2 hours	Intermediate & Advanced
Local Standards	Role of local standards Definition and purpose of standards Introduction to commonly used local standards Role to Essential Principles using Standards	Webinar	2 hours	Beginner & Intermediate
International Standards	Role of international standards Definition and purpose of standards Standard organizations Introduction to commonly used standards (MD and IVDs) Role to Essential Principles using Standards	Webinar	2 hours	Beginner & Intermediate

Course 9: Pre-Market Competency: Functional Technical

Domain: Pre-Market
Competency mapping (knowledge/skills/behaviors):

- International Medical Device Requirements
- Device Registration Grouping Principles
- Submission Dossier Format and Content
- Declaration of Conformity Requirements
- General Device Safety and performance

Module	Outline	Delivery Mode	Duration	Professional Level
International Medical Device Requirements	IMDRF Regulatory Framework IMDRF Risk based Classification System IMDRF Conformity Assessment System IMDRF Dossier requirement – Regulatory Product Submission (RPS) structure	Webinar	2 hours	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
Submission Dossier Format and Content	Understand submission template (IMDRF RPS & CSDT) for all products classes for both MDD & IVDD	Webinar	2 hours	Beginner
Declaration of Conformity Requirements	Role of Declaration of conformity requirements and template	Webinar	1 hour	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

Course 10: Post-Market Competency: Functional Technical

Domain: Post-Market
Competency mapping (knowledge/skills/behaviors):

- International Medical Device Requirements in post-marketing Surveillance
- Risk Management Principles
- Advertising and Promotional Regulation
- Supervision of Reprocessing of Single-use Medical Devices (SuMDs)
- Change management
- Refurbished Devices

Module	Outline	Delivery Mode	Duration	Professional Level
International Medical Device Requirements in post-marketing Surveillance	Understand Post Market Surveillance; Decision Tree; AE's, SAE's SUSAR Understand the role of a post market surveillance program on device safety, efficacy, risk management and product development Describe the sources of post market surveillance data and their relative strengths and weaknesses Identify the various actions that can result from the collection and analysis of post market surveillance data	Webinar	4 hours	Beginner
Risk Management Principles	ISO1471: Medical Devices-Application of risk management of medical devices	Webinar	4 hours	Beginner & Intermediate
Advertising and Promotional Regulation	Good promotion practices Different types of promotional materials Competition laws Best practices on product claims Code of conduct Case studies	Interactive Workshop	2 hours	Intermediate
Supervision of reprocessing of Single-use Medical Devices (SuMDs)	Definition of Single Use Devices International perspective on Single use devices	Webinar	1 hour	Advanced
Post market Change Management	Change management principles Change categories Reporting of changes Change application Case studies	Interactive workshop	1 Hour	All levels
Good Refurbishment practice	Definition of Refurbished Devices Best practices for Refurbished Devices Refurbishment processes Case studies	Interactive workshop/ Webinar	2 hours	Intermediate & Advanced

Course 11: Distribution Control Competency: Functional Technical

Domain: Distribution Control
Competency mapping (knowledge/skills/behaviors):

- Good Distribution Practice
- Quality System Auditing Skills
- Risk Management Principles
- Import/Export Regulations (including customs requirements — Local & International)
- Disposal of Medical Devices
- Environmental considerations

Module	Outline	Delivery Mode	Duration	Professional Level
Good Distribution Practice (GDP)	Understanding of GDP requirements. GMP vs. GDP Principles of Good Distribution Practices Roles and Responsibilities	Webinar	2 hours	All levels
Quality System Auditing Skills and Risk Management	Introduction to Quality Management system requirements for Good Distribution Practices for Medical Devices, and its application to meet the regulatory requirement Conformance audit principles and methods Risk based assessment approach	Webinar	4 hours	All levels
Risk Management Principles	Type of different risks and best mitigation strategies for the distribution of devices	Webinar	2 hours	Intermediate
Import/Export Regulations (including customs requirements – Local & International)	Understand Import and export rules and regulations in different jurisdictions	Webinar	4 hour	Beginner
Disposal of Medical Devices	Overview of the issue with improper disposal of medical devices Best Practices of Medical Waste management	Webinar	1 Hour	Intermediate
Environmental considerations	Environmental sustainability Environmental health and safety & International best practices of regulating environmental aspects of medical devices	Webinar	2 hours	Intermediate

Course 12: Manufacturing Control Competency: Functional Technical

Domain: Manufacturing Control
Competency mapping (knowledge/skills/behaviors):

- International Medical Device Requirements in Quality Systems
- Good Manufacturing Practice (Local)
- Good Manufacturing Practice (International)
- Quality System Auditing Skills Design Validation and/or Verification Methods
- Risk Management Principles
- Manufacturing Process & Technology
- Calibration and Metrology
- Cleanroom Processes

Module	Outline	Delivery Mode	Duration	Professional Level
International Medical Device Requirements in Quality Systems	Quality management for manufacturing systems Overview of manufacturing defects Managing Calibration of devices and understanding of Metrology during device design	Webinar	4 hours	Beginner
Understanding Good Manufacturing Practices (GMP)	Understand medical device Good Manufacturing Practices (GMP) requirement Understand the 'Quality-by-design' concept and how it's embodied in GMP regulations Understand, how GMP regulations go beyond product 'manufacture' and impacts all levels of an organization Understand difference between medical device verification and validation Recognize the different documentation requirements, including Design History File, Device Master Records and Device History Records Awareness of Management Responsibilities Differentiate between medical device and Pharmaceuticals GMP requirements Understand the most significant GMP regulations and guidance documents affecting device manufacturing	Interactive Workshop	8 hours	Beginner
Quality System Auditing Skills	Auditing principles, tools and techniques Understanding the details of Quality metrics and auditing requirements	Webinar	4 hours	Intermediate
Design Validation and/or Verification Methods	Design Verification Design validation Design V&V, supporting Essential Principles Case studies	Interactive Workshop	8 hours	Intermediate & Advanced
Risk Management Principles	Risk management process from manufacturing perspective (ISO 13485)	Webinar	2 Hour	Intermediate

Module	Outline	Delivery Mode	Duration	Professional Level
Manufacturing Process & Technology	Basic manufacturing process for Medical Devices Environmental control requirements Processes used to manufacture medical devices Design transfer to manufacturing-process and requirements Best practices in designing and manufacturing medical devices	Webinar	4 hours	Intermediate
Calibration and Metrology	Measuring equipments and instruments, involved in device manufacturing and quality control Procedure requirements on medical device equipments calibration and control- as per ISO 13485	Webinar	4 hours	Intermediate
Cleanroom Processes	Controlled manufacturing environment requirements and it's classification level with respect to risk class of medical device Set-up and validation of controlled area as per ISO 14644 requirements	Webinar	3 hours	Intermediate

Course 13: Laboratory Testing Competency: Functional Technical

Domain: Laboratory Testing
Competency mapping (knowledge/skills/behaviors):

- Good Laboratory Practice and Laboratory quality management system
- Occupational health and safety standards
- Relevant Test Standards (Local and International)

Module	Outline	Delivery Mode	Duration	Professional Level
Good Laboratory Practices (GLP) program and Laboratory quality management system (ISO 17025)	Overview of regulations and guidelines related to GLP-Good Laboratory Practices requirements Knowledge about QMS and certification processes for Laboratory as per ISO 17025	Webinar	4 hours	All levels
Occupational health and Safety standards	Understanding of the Medical Device Laboratory test standards as applicable internationally and locally Introduction to laboratory hazards and how to control them based on standards internationally	Interactive workshop	4 hours	Beginner & Intermediate
Relevant Test Standards (Local and International)	Overview of horizontal and vertical International standards Examples of test standards (Internal and/or international) Use of product standards, supporting conforamnce and essential principles	Interactive workshop	8 hours	All levels

Course 14: Clinical Oversight Competency: Functional Technical

Domain: Clinical Oversight
Competency mapping (knowledge/skills/behaviors):

- Declaration of Helsinki & Nuremberg Code Statistics
- ISO 14155 Clinical Investigation of MD for Humans
- Good Clinical Practice
- Clinical Evaluation (Evidence Based & Statistics)
- ISO 23640 Specific trainings for IVD (updated)

Module	Outline	Delivery Mode	Duration	Professional Level
Declaration of Helsinki & Nuremberg Code	Understanding the importance of the Nuremberg Code and the focuses on the human rights of research subjects Understanding the Declaration of Helsinki focusing on the obligations of physician-investigators to research subjects.	Document	2 hours	Beginner
ISO 14155 - Clinical investigation of medical devices for human subjects	Understanding of good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.	Webinar	4 hours	Beginner
Good Clinical Practice (GCP) course	GCP Principles for clinical research trials in the respective jurisdiction. GCP Principles, Research protocol, Research Misconduct, Recruitment & Retention, Misconduct, Recruitment & Retention,	Webinar	1 day	Intermediate
Clinical Evaluation	Clinical evaluation process, clinical investigations, and post market clinical follow up studies and data collection (Referring to ISO 14155, ISO 20916)	Webinar	4 hours	Beginner
ISO 23640 - stability of in-vitro diagnostic reagent	General and specific requirements for stability evaluation; The definition of an IVD shelf life • The establishment of the stability of IVD reagents in use after the opening of the primary packaging • The monitoring of IVD reagents already placed on the market • The monitoring and verification of stability specifications after modifications of the IVD reagents that might affect the stability	Webinar	4 hours	Beginner

Chapter 5
Conclusion

This Regulators Curriculum Booklet was spearheaded by GHWP, steered by APACMed and facilitated by Accenture. GHWP and APACMed employed a staggered approach to collect feedback through a workshop from several GHWP member jurisdictions and through additional surveys with jurisdictions that could not participate in the workshop.

The following steps were carried out methodically that culminated in this curriculum booklet;

a) Re-validation of existing competency;
b) Identification of gaps in competencies and training modules;
c) Review and updation of competency framework;
d) Identification of constraints and barriers &
e) Development of the courses.

One of the important outcomes of our research is the identification of the following constraints and barriers that act as an impediment to the creation of a training curriculum such as:

a) Lack of structured and harmonized curriculum;
b) Resource and capacity;
c) Cost incurred in consistent training;
d) Lack of high quality trainings and subject matter experts (SME) &
e) Barriers.

Developed through the above sound fundamentals and a systematic and dynamic research process, this booklet provides a comprehensive curriculum to provide training for regulators in order to equip them and make them stay ahead of the curve especially during an evolving global regulatory landscape. Along with detailed course outline, the booklet also provides the mode of delivery and duration of each course to cater to different levels of expertise of the target trainees. APACMed's vision is to follow up with a subsequent project to build a comprehensive Learning & Development platform for harmonized training programs based on the curriculum proposed in this paper, with the most optimized delivery of these training programs for regulators.

About Us

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Global Harmonization Working Party (GHWP) is established as a non-profit organization. Its goals are to study and recommend ways to harmonize global medical device regulations and to work in coordination with the International Medical Device Regulators Forum, APEC and other related international organizations aiming at establishing harmonized requirements, procedures, and standards.

The Working Party is a group of experts from the medical device regulatory authorities and the medical device industry. Membership is open to those representatives from the globe that support the above stated goals.

APACMed

The voice of MedTech

Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific.

Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, APACMed works proactively with bilateral, regional, and local government bodies to shape policies, demonstrate the value of medical technology, and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific. APACMed is also host to the annual Asia Pacific MedTech Forum.

accenture

Leading global professional services company, providing a broad range of services in strategy and consulting, interactive, technology and operations, with digital capabilities across all these services. We combine unmatched experience and specialized capabilities across more than 40 industries — powered by the world's largest network of Advanced Technology and Intelligent Operations centers. With 505,000 people serving clients in more than 120 countries, Accenture brings continuous innovation to help clients improve their performance and create lasting value across their enterprises.

Accenture Life Sciences offers a full range of services in Strategy, Consulting, Accenture Song, Operations and Technology that help deliver more personalized healthcare and better patient outcomes. We work with our pharmaceutical, biotech, medical technology, distributor, and consumer health clients globally to redefine the future of the life sciences industry: combining the latest technology with scientific breakthroughs to revolutionize how medical treatments are discovered, developed, and delivered to patients around the world.

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